STOP!

CASE NO. 06-5630 CI

Volume No. 1

☒ This is not the last volume of this file, and no documents are to be added. Add new papers to the last volume only.

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☐ This case has been consolidated. Add new papers to File No. _____ only.

☐ Venue has been changed to _____. All new filings should be forwarded to the Clerk of Court at that location.

☐ This case has been removed to U.S. District Court, File No. _____. All new filings should be forwarded to U.S. District Court.

☐ Other: _____

_____

_____

TF-320 (7/95) (pink cdsk)
STOP CARD

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CIV

PLAINTIFF'S MOTION FOR RULE OF LAW CONCERNING ITS CLAIMS AND PROOFS

The State of Alaska moves for a ruling of law concerning its ability to establish liability, causation and damages through the testimony of expert witnesses who will rely on statistical and epidemiological evidence rather than through the testimony of each physician who prescribed Zyprexa and each Medicaid recipient who was injured by the drug. This motion is supported by the Plaintiff's Memorandum Describing Its Claims and Proofs submitted to the Court on March 1, 2007. The State of Alaska is also filing a proposed Order for the Court's consideration.

/

/

/

LAW OFFICES
FELDMAN ORLANSKY
& SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
TEL: 907.272.3538

000001

DATED this 30 day of April, 2007.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
Counsel for Plaintiff

RICHARDSON, PATRICK, WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of Plaintiff's Motion for Rule of Law Concerning Its Claims and Proofs was served by (messenger) (facsimile) on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy S Crowe
Date 5/1/07

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

APR 25 2007

ORDER GRANTING EXTENSION

This Court having considered the parties' Stipulation for Extension of Time,

IT IS HEREBY ORDERED that the Defendant Eli Lilly and Company shall have an extension of time until May 4, 2007, to file its response to Plaintiff's Memorandum Describing Its Claims and Proofs.

DATED this 27th day of April, 2007.

The Honorable Mark Rindner

I certify that on April 27, 2007 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

LAW OFFICES
FELDMAN ORLANSKY
& SANDERS
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

STIPULATION FOR EXTENSION OF TIME

COME NOW the parties, by and through counsel, and stipulate that defendant shall have an extension of time until May 4, 2007, to file its response to Plaintiff's Memorandum Describing Its Claims and Proofs.

4/25/07
Date

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

4/25/07
Date

LANE POWELL LLC
Attorneys for Defendant

BY _____
Brewster H. Jamieson
AK Bar No. 8411122

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Filed in the Trial Courts
STATE OF ALASKA, THIRD DISTRICT
APR 03 2007
By Clerk of the Trial Courts Deputy

Case No. 3AN-06-05630 CI

ERRATA TO LILLY'S MEMORANDUM IN ADVANCE OF STATUS HEARING (APRIL, 6, 2007, 2:00 P.M.)

Defendant Eli Lilly and Company, through its counsel of record, and files this errata to Lilly's Memorandum in Advance of Status Hearing (April 6, 2007, 2:00 pm), which was filed with the Court on March 29, 2007. Exhibits A, B, C and D were inadvertently not attached to the Memorandum. Attached hereto are those exhibits.

DATED this 3rd day of April, 2007.

LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 8411122

I certify that on April 3, 2007, a copy of the foregoing was served by ~~mail~~ hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

009867.0038/159496.1

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A B C D

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

STIPULATED SUPPLEMENTAL SCHEDULING ORDER

The parties agree, and this Court orders, that the Order of January 10, 2007, is supplemented and revised as follows:

I. NATURE OF THIS CASE

This case shall be characterized as non-routine. Accordingly, this case is exempt from the Initial Disclosure requirements of Rule 26(a) (1) and from the thirty-interrogatory limit of Rule 33 (a). The following pretrial deadlines listed in this Court's Order of January 10, 2007, are rescinded, subject to a future order of this Court: preliminary witness lists; retained and supplemental expert witness identification; service of written discovery; other expert opinion testimony summary; retained expert reports; deposition of lay witnesses; dispositive motions; motions re expert opinion evidence; deposition of expert witnesses; and discovery motions.

II. MOTION FOR RULE OF LAW

A. On March 1, 2007, plaintiff filed a motion for rule of law setting forth a summary of its burden of proof for each element (including damages) of each count in its

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Complaint; a summary of the general types of facts that it intends to establish to satisfy its burden on each count; and a general description of the witnesses through which it will prove such facts. Defendant shall respond to the motion no later than April 25, 2007. Plaintiff may file a reply no later than May 10, 2007.

B. The purposes of this motion include:

1. Determining whether plaintiff's definition of its burden of proof and its summary of the evidence are sufficient to satisfy the legal requirements of each count of the Complaint; and

2. Assisting the Court in determining the scope of discovery.

III. DISCOVERY

A. Defendant has produced more than 15 million pages of documents in discovery in *In re Zyprexa Products Liability Litigation*, MDL No. 1596 (E.D.N.Y.) ("Zyprexa MDL"). Plaintiff may serve requests for the production of documents in addition to, but not duplicative of, those already produced in the Zyprexa MDL. Lilly may object to such requests on any grounds, including that such discovery would be duplicative of discovery already taken in the Zyprexa MDL and available to plaintiff in the repository of Lilly documents established by the Plaintiffs' Steering Committee in the Zyprexa MDL, subject to the terms of Case Management Order No. 3 ("CMO-3") (copy attached) in the Zyprexa MDL. To the extent that documents are produced in this action that are not duplicative of

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documents produced in the Zyprexa MDL, the terms of the attached protective order shall control. Upon motion of any party, the Court may amend the terms of this protective order.

B. Several depositions of Lilly employees and former Lilly employees have been taken in the Zyprexa MDL. Zyprexa MDL Case Management Order No. 15 ("CMO-15") (copy attached) requires counsel for Zyprexa MDL plaintiffs to coordinate with counsel in state court actions against Lilly. The Court notes that plaintiff in this action is represented by counsel who is a member of the Plaintiffs' Steering Committee ("PSC") in the Zyprexa MDL. For purposes of this action, plaintiff may, without leave of court, take ten depositions of employees or former employees of defendant, subject to Lilly's rights to object to any deposition under the Alaska Rules of Civil Procedure.

C. The following guidelines shall govern depositions in this case:

1. Who May Be Present. Unless otherwise ordered by this Court, depositions may be attended by counsel of record, members and employees of their firms, attorneys specially engaged by a party for purposes of the deposition, court reporters, videographers, the deponent, and counsel for the deponent. Upon application, and for good cause shown, the Court may permit attendance by a person who does not fall within any of the categories set forth in the preceding sentence. While the deponent is being examined about any stamped confidential document or the confidential information contained therein, persons to whom disclosure is not authorized under the protective order governing this litigation shall be excluded from the deposition. Any portion of the deposition transcript

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containing confidential information shall be sealed so as not to waive confidentiality when the transcript or video medium is placed in the document depository.

2. Duration. Counsel should consult prior to a deposition to agree upon the time required to depose a particular witness. Absent agreement of the parties or order of the Court or the Discovery Master, based on a showing of good cause, the length of depositions shall be controlled by the Alaska Rules of Civil Procedure.

3. Scheduling. Absent extraordinary circumstances, counsel should consult in advance with opposing counsel and counsel for proposed deponents in an effort to schedule depositions at mutually convenient times and locations. Counsel are expected to cooperate and coordinate the scheduling of depositions.

4. Coordination with Other Actions. Counsel for plaintiff shall use their best efforts to coordinate the scheduling of depositions with counsel for other plaintiffs in other state or federal courts in order to minimize the number of times that a witness shall appear for a deposition. Any deposition in this action may be cross-noticed by any party in any Zyprexa-related action pending in any state or federal court, and any deposition in any Zyprexa-related action pending in any state or federal court may be cross-noticed by any party in this action. Each deposition notice shall include the name, address and telephone number of the primary examiner(s) designated by the party noticing the deposition; and the date, time and place of the deposition. If a deposition has been cross-noticed in this action,

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then the plaintiff may not take a subsequent deposition of that witness except for good cause shown.

5. Depositions Taken in Other Proceedings. Plaintiff is aware of all depositions of present or former employees of defendant that have been taken by the Plaintiffs' Steering Committee in the Zyprexa MDL. The plaintiff in this proceeding shall not, without good cause, re-notice the depositions of witnesses who have already been deposed in the Zyprexa MDL. In the event that a party re-notices the deposition of a witness who has already been deposed, should a party object, then such objection must be made within ten days of the notice, and counsel shall meet and confer within five days of the objection to attempt to resolve the dispute. If no agreement can be reached, the matter shall be brought to the Court for resolution at the earliest possible time and without undue delay to avoid postponement of the deposition.

6. Documents Used in Connection with Depositions.

a. Production of Documents. Non-party witnesses subpoenaed to produce documents shall, to the extent possible, be served with the document subpoena at least thirty calendar days before a scheduled deposition.

b. Copies. Extra copies of documents about which deposing counsel expects to examine a deponent should be provided to primary counsel for the parties and the deponent during the course of the deposition.

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c. Marking of Deposition Exhibits. All documents previously produced and used as deposition exhibits shall be referred to by the unique alpha-numeric identifiers appearing on the documents.

d. Objections to Documents. Objections to the relevance or admissibility of documents used as deposition exhibits are not waived, and are reserved for later ruling by the Court or by the trial judge.

D. Pursuant to Alaska R. Civ. P. 53, the Court hereby appoints Dan Hensley, Esquire, as the discovery master ("DM"). Subject to the procedures set forth in this Order, the DM is authorized to decide all issues arising under Alaska R. Civ. P. 26-37 in this action. Notwithstanding his appointment, the DM's authority shall not extend to the first set of discovery requests served by defendant nor to the ten depositions of employees and former employees of Lilly that are referenced in paragraph III(B). The following procedures and guidelines shall be followed in submitting disputes to the DM for consideration:

1. Before submitting a discovery dispute to the DM for resolution, the parties shall make a good faith effort to resolve any such dispute. Any motion filed with the DM must include the certification required by Civil Rule 37(a) (2) (A) stating that the parties attempted to resolve the dispute prior to seeking the DM's assistance.

2. If the parties are unable to resolve the dispute, motions may be filed with the DM. The party or parties to whom the motion is directed shall file an opposition within seven days from the date the motion is served by hand or electronically (10 days if mailed).

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Any motion and any opposition shall be limited to 10 pages of argument and 30 pages of exhibits, unless the filing party can make a good cause showing why additional pages are needed. The party filing the motion may file a reply memorandum. Any reply shall be filed within three days from the date the opposition is served by hand or electronically (six days if mailed). Any reply shall be limited to five pages of argument and 10 pages of exhibits, unless the party filing the reply memorandum can make a good cause showing why additional pages are needed. Each side shall submit a proposed order for the DM's signature.

3. In the event that a discovery issue arises which requires immediate resolution in order to prevent undue expense or delay (e.g., an issue arising over an instruction to a deponent not to answer a deposition question at an out-of-state deposition attended by multiple counsel), one or more parties may attempt to contact the DM by telephone for his expedited ruling on the discovery issue. If the DM cannot be reached, the party(ies) seeking immediate resolution of the discovery issue may attempt to contact the trial judge for his similar resolution of the issue.

4. Except as otherwise noted herein, all discovery disputes must first be submitted to the DM for resolution. In his discretion, the DM may schedule oral argument on any dispute presented to him for resolution. The DM is authorized to communicate on matters related to coordination of state and federal court Zyprexa actions with Peter H. Woodin, Special Master in the Zyprexa MDL.

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5. The DM shall decide the motions in the order they are received, unless a party can make a good cause showing why they should be taken out of order. The DM shall endeavor to decide the motions promptly. The DM will issue a written decision on each dispute presented to him for resolution.

6. The parties shall give telephonic notice to the DM's secretary that a motion is ripe for decision.

7. Once the DM issues a decision, a party has a right to appeal the decision to the Court. An appeal shall be filed with the Court within three days of service by hand or electronically (six days if mailed) of the DM's decision and will consist of a notice of appeal indicating which motion is being appealed, the DM's decision, and the papers filed with the DM. The DM will decide if his ruling will be stayed pending the Court's decision on appeal. If the Court affirms the DM's decision in its entirety, the Court may award the prevailing party costs and fees. The Court shall have the discretion to make any award of costs and fees against an appealing party if it determines that the appealing party did not substantially improve its position from the DM's order or if there was not a good faith basis to file the appeal. In support of the appeal to the court, the party appealing may file supplemental pleadings addressing the perceived error of the DM's order of not more than five pages. A single response shall be allowed, with no reply, within five days of service by hand or electronically (eight days if mailed) of the supplemental pleading in support of the appeal.

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8. The DM shall schedule status conferences with the parties when necessary. Any party may request a status conference with the DM to promptly resolve discovery disputes.

9. The DM's fee is $_____ per hour. All parties shall pay an equal share of the fees and costs of the DM unless he orders that the fees be allocated in some other fashion.

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

_____ By: _____
Date Eric T. Sanders, ASBA No. 75100085

LANE POWELL LLC
Attorneys for Defendant

_____ By: _____
Date Brewster H. Jamieson, ASBA No. 8411122

ORDERED this ____ day of April, 2007.

_____
The Honorable Mark Rindner
Judge of the Superior Court

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

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 Alaska 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 this action ("Action").

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 Action and that have been designated confidential shall be used by the receiving party solely for the prosecution or defense of this Action, to the extent reasonably necessary to accomplish the purpose for which disclosure is

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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

a. 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 Alaska 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 material 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

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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:

State of Alaska v. Eli Lilly and Company: 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 non-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.

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6. Permissible Disclosures of Confidential Discovery Material

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

a. counsel of record for the parties in this Action and to his/her partners, associates, secretaries, legal assistants, and employees to the extent considered reasonably necessary to render professional services in the Action;

b. inside counsel of the parties, to the extent reasonably necessary to render professional services in the Action;

c. court officials involved in this Action (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, 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 Action, 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.

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;

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g. 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;

h. outside consultants or outside experts retained for the purpose of assisting counsel in the Action;

i. 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;

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

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

l. any individual to whom disclosure is to be made under subparagraphs (d) through (k) 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 therefore 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.

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Before disclosing Confidential discovery materials to any person listed in subparagraphs (d) through (k) 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 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 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 manufacturers prescription medical products in the neuroscience area.

7. Production of Confidential Materials by Non-Parties

An non-party who is producing discovery materials in the Action 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 on paragraph .

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 as the discovery materials; provided, however, that the party returning such discovery material 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 factor 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.

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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 Alaska Rules of Civil Procedure and/this Order, provided that such motion is made within forty five days from the date the challenger of the confidential designation challenges the designation or such other time period and the parties may agree. The designating party shall have the, burden of proof on such motion to establish the propriety of its Confidential designation.

If the time for filing a motion as provided in paragraph 9(c) has expired without the filing of any such motion, or ten business days (or such longer time as, ordered by this Court) have elapsed alter the appeal period for an order of this Court that the discovery materials 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 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 days prior to the deposition if it has been unable to obtain that 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 the 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 potential 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 days after receiving a deposition, designate pages of the transcript (and exhibits thereto) as Confidential. Until expiration of such thirty-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 a Confidential in accordance with the Alaska Rules of Evidence or rulings in the Action 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 flied 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

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

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 as 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 Consultant

Nothing in this Order shall prevent or otherwise restrict counsel from rendering advice to their clients in this Action 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

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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 Action. Within ninety days after final conclusion of all aspects of this Action, 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 mere than one hundred, twenty days after final termination of this Action. 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

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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 Right 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.

ORDERED this ____ day of April, 2007.

The Honorable Mark Rindner
Judge of the Superior Court

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-05630 CI

ENDORSEMENT OF PROTECTIVE ORDER

I hereby attest to my understanding that information or documents designated Confidential are provided to me subject to the Protective Order ("Order") dated _____, 2007, (the "Protective Order"), in the above-captioned litigation ("Action"); that I have been given a copy of and have read the Order; and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Order, is a prerequisite to my review of any information or documents designated as Confidential pursuant to the Order.

I further agree that I shall not disclose to others, except in accord with the Order, any Confidential Discovery Materials, in any form whatsoever, and that such Confidential Discovery Materials and the information contained therein maybe used only for the purposes authorized by the Order.

I further agree to return all copies of any Confidential Discovery Materials I have received to counsel who provided them to me upon completion of the purpose for which they were provided and no later than the conclusion of this Action.

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EXHIBIT B
PAGE 13 OF 14

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material will continue even after this Action concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the Superior Court for the State of Alaska, Third Judicial District at Anchorage, for the purposes of any proceedings relating to enforcement of the Order.

I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by, the Court.

Date: _____

By: _____

009867.0038/159080.1

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DOCKET & FILE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------x

In re: ZYPREXA
PRODUCTS LIABILITY LITIGATION

MDL No. 1596

----------x

THIS DOCUMENT RELATES TO:
ALL ACTIONS

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

----------x

CASE MANAGEMENT
~~PRETRIAL~~ 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 manufacturers 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 Chrein
United States Magistrate Judge

Dated: August 13, 2004
Brooklyn, New York

SO ORDERED as approving act of magistrate judge and parties. No objections having been received.

Hon. Jack B. Weinstein
Senior District Judge

Dated: 8/23, 2004
Brooklyn, New York

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------x

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION

MDL No. 1596

----------x

THIS DOCUMENT RELATES TO:

ALL ACTIONS

----------x

ENDORSEMENT OF PROTECTIVE ORDER

I hereby attest to my understanding that information or documents designated Confidential are provided to me subject to the Protective Order ("Order") dated _____ ___, 2004 (the "Protective Order"), in the above-captioned litigation ("Litigation"); that I have been given a copy of and have read the Order; and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Order, is a prerequisite to my review of any information or documents designated as Confidential pursuant to the Order.

I further agree that I shall not disclose to others, except in accord with the Order, any Confidential Discovery Materials, in any form whatsoever, and that such Confidential Discovery Materials and the information contained therein may be used only for the purposes authorized by the Order.

I further agree to return all copies of any Confidential Discovery Materials I have received to counsel who provided them to me upon completion of the purpose for which they were provided and no later than the conclusion of this Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United Stated District Court, Eastern District of New York, for the purposes of any proceedings relating to enforcement of the Order.

I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: _____

By: _____

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------x

In re: ZYPREXA
PRODUCTS LIABILITY LITIGATION
----------x

THIS DOCUMENT RELATES TO:

ALL ACTIONS
----------x

ORDER
04-MD-1596

Jack B. Weinstein, Senior United States District Judge:

The following communication shall be sent to each state court judge who has a case related to Zyprexa (see Appendix A, attached):

My dear Judge [Judge's name],

Following up on my order of January 26, 2006, I have issued two further orders in *In re Zyprexa Product Liability Litigation*, 04-MD-1596:

1. An order setting a fee schedule for attorneys involved in the partial settlement.

2. An order setting a date for a summary judgment hearing and a trial date for cases filed in the Eastern District of New York.

Copies of these orders, as well as of the January 26, 2006 order, are attached to this letter.

As always, I would be pleased to cooperate with you in any way you think useful.

Very respectfully,
Jack B. Weinstein

SO ORDERED.

Jack B. Weinstein

Dated: April 18, 2006
Brooklyn, New York

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------x

In re: ZYPREXA
PRODUCTS LIABILITY LITIGATION
----------x

MEMORANDUM ON
COOPERATION BETWEEN
FEDERAL AND STATE
JUDGES

THIS DOCUMENT RELATES TO:

ALL ACTIONS

04-MD-1596 (JBW)

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JACK B. WEINSTEIN, Senior United States District Judge:

To: All state judges handling "Zyprexa-diabetes" cases
Re: Plaintiffs' Attorneys' Fees in "Zyprexa-diabetes" Cases

1. Before me are hundreds of cases against Eli Lilly & Company involving claims of diabetes-related injuries allegedly arising from the use of the antipsychotic drug Zyprexa. These cases were transferred to my court for discovery and other pretrial purposes by the federal Judicial Panel on Multidistrict Litigation from federal district courts in all of the states. Some of those cases were removed from state courts. There are motions to remand pending in this court. A number of "Zyprexa-diabetes" cases are pending in state courts.

2. Federal MDL plaintiffs' steering committees have assembled large collections of documents produced by Eli Lilly and conducted many depositions. These documents, deposition exhibits, and deposition transcripts are maintained by the current plaintiffs' steering committee in a depository in Mount Pleasant, South Carolina. In order to reduce transactional costs and the burdens on state courts, I have ruled that these materials shall be made available free of charge to litigants in state cases . *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 3495667 *3 (E.D.N.Y. Dec. 5, 2006) ("All materials obtained by PSC I and PSC II in pretrial discovery . . . . have been available free of charge to state and federal plaintiffs who agree to adhere to the terms of the protective, case management, and other orders that have been issued by

this court"). Many of the state plaintiffs' attorneys have taken advantage of the federal depository in preparing their state cases.

3. Plaintiffs' steering committees are presently being compensated for their work in assembling documents and conducting depositions through mechanisms that to date do not impose any costs for this work on state plaintiffs or their attorneys. *See id.* at *8 ("The issue of assessing state cases with the costs of a discovery process that benefits all cases, state and federal, should, in the first instance, be left to state court judges.").

4. Some twenty thousand federal cases have been settled. The settlement agreements that have been reached by Eli Lilly & Company and the federal plaintiffs' steering committees include all or most of the state "Zyprexa-diabetes" cases.

5. Because of the enormous savings in transaction costs due to work by the plaintiffs' steering committees, and for other reasons, I have limited the fees available to plaintiffs' attorneys in federal MDL cases. *See In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488 (E.D.N.Y. 2006) ("Limiting fees is particularly appropriate in the instant litigation since much of the discovery work the attorneys would normally have done on a retail basis in individual cases has been done at a reduced cost on a wholesale basis by the plaintiffs' steering committee."). I believe that those fee limits should, if possible, be applied in the state cases for a number of reasons:

A) Much of the preparatory work in state cases has already been done on a national basis, by the federal plaintiffs' steering committees, leaving less justification for high fees in individual state cases.

B) As part of the process of settlement, extensive liens from Medicare and Medicaid have been limited and controlled through national negotiations in this court involving the cooperation of all fifty states and the federal

government. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 3501263 (E.D.N.Y. Dec. 4, 2006) ("In compliance with this court's instructions . . . all fifty states as well as the federal government have resolved their Medicare and Medicaid liens."); *In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458 (E.D.N.Y. 2006) (Memorandum Order & Judgment Regarding Liens and Disbursement Procedures). These negotiated lien settlements will probably accrue to the benefit of the state plaintiffs without the need for individual negotiations by state attorneys.

C) The nature of the plaintiffs in these state and federal cases, who allegedly are schizophrenics suffering from diabetes, places them in sad and difficult situations. It is desirable that as much of the recovery as practicable go to the plaintiffs themselves.

6. Despite my strong sense that similar fee limitations in state and federal cases is a fair and equitable result for all Zyprexa-diabetes plaintiffs and their attorneys, I have decided not to impose any fee limitations in state cases. I leave this question to your esteemed discretion.

7. I believe that the relevant fee decisions have been furnished to you, but in case you do not have copies on hand I am attaching them to this memorandum. You will note that in the Memorandum & Order on Common Benefit Fund and Continuing Applicability of Orders of Court and Special Masters of December 5, 2006, the suggestion is made that the MDL court in this case can limit fees in some, if not all, cases pending in state courts. *In re Zyprexa*, 2006 WL 3495667 at *13-15. A cooperative arrangement among state and federal judges limiting fees would be desirable.

8. Fees have been capped at 35%, though they can be varied upward to a maximum of 37.5% and downward to 30% in individual cases on the basis of special circumstances. *In re Zyprexa*, 424 F. Supp. 2d at 491. When individual matrices were provided by type of case, fees

were limited to 20% in certain small, lump-sum claims. *Id.*

9. I believe that a reasonable solution to the fee problem can be arranged for cases that have been and will be settled by negotiation among counsel with the supervision and consent of the concerned state and federal judges.

10. Evidentiary hearings at the state and national level may be desirable.

11. I should very much appreciate your views. I would be happy to visit with you by a telephone conference, at your convenience.

12. This memorandum is being filed and docketed so that judges, parties, and attorneys can respond.

Jack B. Weinstein

Hon. Jack B. Weinstein

Dated: January 18, 2007
Brooklyn, New York

EXHIBIT D
PAGE 5 OF 5

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

This Court having considered the parties' Stipulation for Extension of Time,

IT IS HEREBY ORDERED that Defendant Eli Lilly and Company shall have an extension of time until April 25, 2007, to file its response to Plaintiff's Memorandum Describing Its Claims and Proofs.

ORDERED this 30 day of March/~~April~~, 2007.

The Honorable Mark Rindner

I certify that on March 23, 2007, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

809867.0038/158004.1

I certify that on March 30, 2007 of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

000049

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.	)	Case No. 3AN-06-5630 CIV

ORDER GRANTING PERMISSION FOR NON-RESIDENT ATTORNEY MATTHEW LEE GARRETSON TO APPEAR AND PARTICIPATE

IT IS HEREBY ORDERED that the Motion and Application of Non-Resident Attorney Matthew Lee Garretson for Permission to Appear and Participate as co-counsel for plaintiff State of Alaska in the above-referenced case is GRANTED.

DATED this 30 day of March, 2007.

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on March 30, 2007 a copy of this above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

000050

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER GRANTING PERMISSION FOR NON-RESIDENT ATTORNEY JOSEPH W. STEELE TO APPEAR AND PARTICIPATE

IT IS HEREBY ORDERED that the Motion and Application of Non-Resident Attorney Joseph W. Steele for Permission to Appear and Participate as co-counsel for plaintiff State of Alaska in the above-referenced case is GRANTED.

DATED this 30 day of March, 2007.

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on March 30, 2007 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

000051

MAR 28 2007

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER GRANTING PERMISSION FOR NON-RESIDENT ATTORNEY MITCHELL R. JENSEN TO APPEAR AND PARTICIPATE

IT IS HEREBY ORDERED that the Motion and Application of Non-Resident Attorney Mitchell R. Jensen for Permission to Appear and Participate as co-counsel for plaintiff State of Alaska in the above-referenced case is GRANTED.

DATED this 30 day of March, 2007.

BY THE COURT

Mark Rindner
Superior Court Judge

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

I certify that on March 30, 2007 of the above was mailed to each of the following their addresses of record:
Sanders Jamieson

Administrative Assistant

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

LILLY'S MEMORANDUM IN ADVANCE OF STATUS HEARING (APRIL, 6, 2007, 2:00 P.M.)

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

COMES NOW, Eli Lilly and Company ("Lilly"), and provides this Memorandum in advance of the Status Hearing currently scheduled for April 6, 2007 at 2 p.m. This Memorandum is intended to assist the Court in understanding the issues to be addressed at that Status Hearing.

I. BACKGROUND

Following the Scheduling Hearing with Court on January 8, 2007, the parties conferred in good faith regarding a supplemental scheduling order and, to a large extent, agreed on the terms of that order. Attached hereto as Exhibit A is a draft Stipulated Supplemental Scheduling Order prepared by Lilly; attached as Exhibit B is Lilly's proposed draft Protective Order. Although plaintiff and Lilly agree on most of the terms of the Supplemental Scheduling Order, what follows is a list of the disputed items. Lilly urges the Court to place a high value on the importance of federal-state coordination, which is critical to conserving the resources of the Court and the parties. Such coordination is a guiding principle of the federal multidistrict litigation, *In re Zyprexa Product Liability Litigation*, MDL 1596 (E.D.N.Y.) ("Zyprexa MDL"). Coordination among the federal and state courts has enabled the parties to conduct a staggering amount of discovery—with nearly 15 million pages of documents produced by Lilly alone—and to resolve more than 28,000 individual claims before trial.

A B C

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

Accordingly, Lilly urges this Court to use many of the same tools employed by the Honorable Jack B. Weinstein in the Zyprexa MDL to assist in the resolution of this litigation.

II.. SPECIFIC AREAS OF DISPUTE

A. Paragraph III(A). The parties disagree only over one question: whether Case Management Order No. 3 ("CMO-3") of the Zyprexa MDL or an Alaska-specific protective order modeled on CMO-3 should govern. Lilly understands that plaintiff prefers that CMO-3 cover this case. Attached as Exhibit C is a copy of CMO-3. A review of this order, as well as the draft Alaska-specific order, demonstrates why CMO-3 cannot and should not function as the protective order in this case. CMO-3 governs documents produced in the MDL, not state court. Moreover, Lilly will be producing documents in this litigation that were not produced in the MDL and have no relevance there. Lilly does not believe that those documents should come under the umbrella of CMO-3 and generally be available to all plaintiffs in all cases.

B. Paragraph III(C)(4). This paragraph encourages coordination between state and federal courts, and plaintiff objects to its inclusion. We urge the court to coordinate discovery in this case with the many other Zyprexa cases that are pending around the country. Judge Weinstein has set the standard for this. Attached as exhibit D are two of his orders in which he encourages federal-state coordination. The results, summarized above, support continued coordination.

C. Paragraph III(C)(5). Plaintiff objects to this paragraph, which Lilly considers essential to continued coordination and avoidance of duplication in these cases.

D. Paragraph III(D)(4). Plaintiff objects to the sentence authorizing communications between the Alaska Discovery Master and Peter H. Woodin, who has been appointed as Special Master by Judge Weinstein in the Zyprexa MDL. Special Master Woodin has been instrumental in assisting Judge Weinstein in coordinating state and federal

discovery. The draft submitted by Lilly simply authorizes the Discovery Master to communicate with Mr. Woodin, again to ensure continued federal-state coordination.

Lilly looks forward to addressing and resolving these issues at the upcoming Status Hearing.

DATED this 29th day of March, 2007.

LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122

I certify that on March 29, 2007, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

_____
Marci L. Biggerstaff, CPS, PLS
009867.0038/159273.1

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

FILED
STATE OF ALASKA
THIRD DISTRICT
07 MAR 28 PM 4:27
CLERK, TRIAL COURTS
BY _____ DEPUTY

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

STIPULATION FOR EXTENSION OF TIME

COME NOW the parties, by and through counsel, and stipulate that defendant shall have an extension of time until April 25, 2007, to file its response to Plaintiff's Memorandum Describing Its Claims and Proofs.

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

3/28/07
Date

By _____
Eric T. Sanders, ASBA No. 75100085

LANE POWELL LLC
Attorneys for Defendant

3/23/07
Date

By _____
Brewster H. Jamieson, ASBA No. 8411122

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

D

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

MOTION AND APPLICATION OF NON-RESIDENT ATTORNEY MATTHEW LEE GARRETSON FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska Rule of Civil Procedure 81(a)(2), attorney Matthew Lee Garretson of the law firm of Garretson & Steele, LLC, whose mailing address is 9545 Kenwood Road, Suite 304, Cincinnati, Ohio 45242 (Telephone: (513) 794-0400), applies for permission to appear and participate as co-counsel for plaintiff State of Alaska in this action.

Mr. Garretson will associate with the undersigned, Eric T. Sanders, a member of the Bar of this Court, who maintains an office at a place within the district, with whom the Court and opposing counsel may readily communicate regarding this case. My Consent of Local Counsel in support of this motion is filed herein.

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

Mr. Garretson is a member in good standing of the Bar of the State of Ohio. A copy of his Certificate of Good Standing with the Bar of the State of Ohio is attached as Exhibit A. Proof of payment of the required fee to the Alaska Bar Association is also attached as Exhibit B.

DATED this 27 day of March, 2007.

FELDMAN ORLANSKY & SANDERS
Attorneys for State of Alaska

By_____
Eric T. Sanders
Alaska Bar No. 7510085

CONSENT OF LOCAL COUNSEL

The undersigned consents and moves for the granting of the application of Matthew Lee Garretson to appear and participate as co-counsel in this action on behalf of plaintiff State of Alaska. The undersigned is authorized to practice law in the State of Alaska and is admitted to the Superior Court for the Third Judicial District at Anchorage.

Dated this 27 day of March, 2007.

FELDMAN ORLANSKY & SANDERS

By:_____
Eric T. Sanders
Alaska Bar No. 7510085
500 L Street, Suite 400
Anchorage, Alaska 99501
Telephone: (907) 272-3538
Facsimile: (907) 274-0819

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

Certificate of Service

I hereby certify that a true and correct copy of the foregoing Motion and Application of Non-Resident Attorney Matthew Lee Garretson for Permission to Appear and Participate was served by mail / messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy S Crowe
Date 3/28/07

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

The Supreme Court of Ohio

CERTIFICATE

I, RICHARD A. DOVE, Director of the Attorney Services Division of the Supreme Court of Ohio, do hereby certify that I am the custodian of the records of the Office of Attorney Registration & CLE of the Supreme Court and that the Attorney Services Division is responsible for reviewing Court records to determine the status of Ohio attorneys. I further certify that, having fulfilled all of the requirements for admission to the practice of law in Ohio,

Matthew Lee Garretson

was admitted to the practice of law in Ohio on November 09, 1998; has registered as an active attorney pursuant to the Supreme Court Rules for the Government of the Bar of Ohio; is in good standing with the Supreme Court of Ohio; and is entitled to practice law in this state.

IN TESTIMONY WHEREOF, I have subscribed my name and affixed the seal of the Supreme Court, this 12th day of March, 2007.

RICHARD A. DOVE
Director, Attorney Services Division

Sue Moore
Attorney Registration Assistant

000060

Exhibit A, Motion to Participate – Garretson
Case No. 3AN-06-5630 Civ

A B C

ALASKA BAR ASSOCIATION

P.O. Box 100279, Anchorage, Alaska 99510-0279

(907) 272-7469

Customer's Order No.	Phone No.	Date 3-27-07

Sold to Garretson Law Firm

Address 9545 Kenwood Rd. Ste 304

City Cincinnati, OH 45242

Sold By	Cash	C.O.D.	Charge	On Acct.	Mdse. Retd.	Paid Out	

Qty.	Description	Price	Amount
	Rule 81		550.00
	Matthew Garretson NA		
	assoc. w/ Eric Sanders 7510085		
	Case # 3AN-06-5630		
	check # 2027		
	2007		
	All claims and returned goods MUST be accompanied by this bill.	Tax	
	Rec'd. By Devon Richardson	Total	550.00

029104 *Thank You!*

Item# G3R
To Reorder,
Please Call Toll Free: 1-800-558-0220

000061

Exhibit B, Motion to Participate – Garretson
Case No. 3AN-06-5630 Civ

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

MOTION AND APPLICATION OF NON-RESIDENT ATTORNEY MITCHELL R. JENSEN FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska Rule of Civil Procedure 81(a)(2), attorney Mitchell R. Jensen of the law firm of Siegfried & Jensen, whose mailing address is 5664 South Green Street, Murray, Utah 84123 (Telephone: (801) 266-0999), applies for permission to appear and participate as co-counsel for plaintiff State of Alaska in this action.

Mr. Jensen will associate with the undersigned, Eric T. Sanders, a member of the Bar of this Court, who maintains an office at a place within the district, with whom the Court and opposing counsel may readily communicate regarding this case. My Consent of Local Counsel in support of this motion is filed herein.

Mr. Jensen is a member in good standing of the Bar of the State of Utah. A copy of his Certificate of Good Standing with the Bar of the State of Utah is attached as

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

Exhibit A. Proof of payment of the required fee to the Alaska Bar Association is also attached as Exhibit B.

DATED this 27 day of March, 2007.

FELDMAN ORLANSKY & SANDERS
Attorneys for State of Alaska

By _____
Eric T. Sanders
Alaska Bar No. 7510085

CONSENT OF LOCAL COUNSEL

The undersigned consents and moves for the granting of the application of Mitchell R. Jensen to appear and participate as co-counsel in this action on behalf of plaintiff State of Alaska. The undersigned is authorized to practice law in the State of Alaska and is admitted to the Superior Court for the Third Judicial District at Anchorage.

Dated this 27 day of March, 2007.

FELDMAN ORLANSKY & SANDERS

By: _____
Eric T. Sanders
Alaska Bar No. 7510085
500 L Street, Suite 400
Anchorage, Alaska 99501
Telephone: (907) 272-3538
Facsimile: (907) 274-0819

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

Certificate of Service
I hereby certify that a true and correct copy of the foregoing Motion and Application of Non-Resident Attorney Mitchell R. Jensen for Permission to Appear and Participate was served by mail/ messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy S Crowe
Date 3/28/07

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

Utah State Bar

645 South 200 East, Suite 310 • Salt Lake City, Utah 84111-3834
Telephone: 801-531-9077 • Fax: 801-531-0660

John C. Baldwin
Executive Director

March 16, 2007

To Whom It May Concern:

This is to certify that **Mitchell R. Jensen**, Utah State Bar **No. 03724**, was admitted to practice law in Utah on **October 6, 1982** and is an active member of the Utah State Bar in good standing. "Good standing" is defined as a lawyer who is current in the payment of all Bar licensing fees, has met mandatory continuing legal education requirements, if applicable, and is not disbarred, presently on probation, suspended, or has not resigned with discipline pending, from the practice of law in this state.

No public disciplinary action involving professional misconduct has been taken against the license of **Mitchell R. Jensen** to practice law.

Katherine A. Fox
General Counsel
Utah State Bar

000065

Exhibit A
Motion to Participate-Jensen
Case No. 3AN-06-5630 Civ

A B C

ALASKA BAR ASSOCIATION
P.O. Box 100279, Anchorage, Alaska 99510-0279
(907) 272-7469

Customer's Order No.	Phone No.	Date
		3-27-07

Sold to: Siegfried a Jensen
Address: 5664 South Green Street
City: Murray UT 84123

Sold By	Cash	C.O.D.	Charge	On Acct.	Mdse. Retd.	Paid Out

Qty.	Description	Price	Amount
	Rule 81		550. 00
	Mitchell Jensen NA —		
	assoc. w/ Eric Sanders 7510085		
	case # 3AN-06-5630		
	check # 092711		
	2007		
	All claims and returned goods MUST be accompanied by this bill.	Tax	
	Rec'd. By Devon Richardson	Total	550. 00

029103 *Thank You!*

Item# GSR
To Reorder,
Please Call Toll Free: 1-800-558-0220

Exhibit B
Motion to Participate-Jensen
Case No. 3AN-06-5630 Civ

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CIV

MOTION AND APPLICATION OF NON-RESIDENT ATTORNEY JOSEPH W. STEELE FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska Rule of Civil Procedure 81(a)(2), attorney Joseph W. Steele of the law firm of Siegfried & Jensen, whose mailing address is 5664 South Green Street, Murray, Utah 84123 (Telephone: (801) 266-0999), applies for permission to appear and participate as co-counsel for plaintiff State of Alaska in this action.

Mr. Steele will associate with the undersigned, Eric T. Sanders, a member of the Bar of this Court, who maintains an office at a place within the district, with whom the Court and opposing counsel may readily communicate regarding this case. My Consent of Local Counsel in support of this motion is filed herein.

Mr. Steele is a member in good standing of the Bar of the State of Utah. A copy of his Certificate of Good Standing with the Bar of the State of Utah is attached as

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

Exhibit A. Proof of payment of the required fee to the Alaska Bar Association is also attached as Exhibit B.

DATED this 21 day of March, 2007.

FELDMAN ORLANSKY & SANDERS
Attorneys for State of Alaska

By _____
Eric T. Sanders
Alaska Bar No. 7510085

CONSENT OF LOCAL COUNSEL

The undersigned consents and moves for the granting of the application of Joseph W. Steele to appear and participate as co-counsel in this action on behalf of plaintiff State of Alaska. The undersigned is authorized to practice law in the State of Alaska and is admitted to the Superior Court for the Third Judicial District at Anchorage.

Dated this 21 day of March, 2007.

FELDMAN ORLANSKY & SANDERS

By: _____
Eric T. Sanders
Alaska Bar No. 7510085
500 L Street, Suite 400
Anchorage, Alaska 99501
Telephone: (907) 272-3538
Facsimile: (907) 274-0819

LAW OFFICES
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FAX: 907.274.0819

Certificate of Service

I hereby certify that a true and correct copy of the foregoing Motion and Application of Non-Resident Attorney Joseph W. Steele for Permission to Appear and Participate was served by mail/ messenger on:

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Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy J. Crowe
Date 3/28/07

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
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Utah State Bar

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Telephone: 801-531-9077 • Fax: 801-531-0660

John C. Baldwin
Executive Director

March 16, 2007

To Whom It May Concern:

This is to certify that **Joseph W. Steele V**, Utah State Bar **No. 09697**, was admitted to practice law in Utah on **May 19, 2003** and is an active member of the Utah State Bar in good standing. "Good standing" is defined as a lawyer who is current in the payment of all Bar licensing fees, has met mandatory continuing legal education requirements, if applicable, and is not disbarred, presently on probation, suspended, or has not resigned with discipline pending, from the practice of law in this state.

No public disciplinary action involving professional misconduct has been taken against the license of **Joseph W. Steele V** to practice law.

Katherine A. Fox
General Counsel
Utah State Bar

000070

Exhibit A
Motion to Participate – Steele
Case No. 3AN-06-5630 Civ

A B C

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Exhibit B
Motion to Participate – Steele
Case No. 3AN-06-5630 Civ

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

MOTION AND APPLICATION OF NON-RESIDENT ATTORNEY H. BLAIR HAHN FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska Rule of Civil Procedure 81(a)(2), attorney H. Blair Hahn of the law firm of Richardson, Patrick, Westbrook & Brickman, LLC, whose mailing address is P.O. Box 1007, Mt. Pleasant, South Carolina 29465 (Telephone: (843) 727-6500), applies for permission to appear and participate as co-counsel for plaintiff State of Alaska in this action.

Mr. Hahn will associate with the undersigned, Eric T. Sanders, a member of the Bar of this Court, who maintains an office at a place within the district, with whom the Court and opposing counsel may readily communicate regarding this case. My Consent of Local Counsel in support of this motion is filed herein.

Mr. Hahn is a member in good standing of the Bar of the State of South Carolina. A copy of his Certificate of Good Standing with the Bar of the State of South Carolina is

LAW OFFICES
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TEL: 907.272.3538
FAX: 907.274.0819

attached as Exhibit A. Proof of payment of the required fee to the Alaska Bar Association is also attached as Exhibit B.

DATED this 8 day of March, 2007.

FELDMAN ORLANSKY & SANDERS
Attorneys for State of Alaska

By _____
Eric T. Sanders
Alaska Bar No. 7510085

CONSENT OF LOCAL COUNSEL

The undersigned consents and moves for the granting of the application of H. Blair Hahn to appear and participate as co-counsel in this action on behalf of plaintiff State of Alaska. The undersigned is authorized to practice law in the State of Alaska and is admitted to the Superior Court for the Third Judicial District at Anchorage.

Dated this 8 day of March, 2007.

FELDMAN ORLANSKY & SANDERS

By: _____
Eric T. Sanders
Alaska Bar No. 7510085
500 L Street, Suite 400
Anchorage, Alaska 99501
Telephone: (907) 272-3538
Facsimile: (907) 274-0819

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FAX: 907.274.0819

Certificate of Service

I hereby certify that a true and correct copy of the foregoing Motion and Application of Non-Resident Attorney H. Blair Hahn for Permission to Appear and Participate was served by mail / messenger on:

Brewster H. Jamieson - msg
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

Andrew R. Rogoff - mail
Pepper Hamilton LLP
3000 Two Logan Square
Philadelphia, Pennsylvania 19103-2799

By Peggy S Crowe
Date 3/9/07

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AO 136
(Rev. 6/82)

CERTIFICATE OF GOOD STANDING

UNITED STATES OF AMERICA

DISTRICT OF SOUTH CAROLINA

I, Larry W. Propes, Clerk of the United States District Court, District of South Carolina,

DO HEREBY CERTIFY That H. Blair Hahn, ID# 5717, was duly admitted to practice in said Court on December 23, 1992, and is in good standing as a member of the bar of said Court.

Dated at Charleston, South Carolina
on February 8, 2007.

Larry W. Propes, Clerk

By _____, Deputy Clerk

000075

Exhibit A
Motion to Participate – Hahn
Case No. 3AN-06-5630 Civ

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Case No. 3AN-06-5630 Civ

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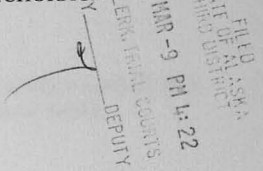
A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE



STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

MOTION AND APPLICATION OF NON-RESIDENT ATTORNEY DAVID L. SUGGS FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska Rule of Civil Procedure 81(a)(2), attorney David L. Suggs of the law firm of Richardson, Patrick, Westbrook & Brickman, LLC, whose mailing address is 27995 Boulder Circle, Shorewood, Minnesota 55331 (Telephone: (952) 401-4377), applies for permission to appear and participate as co-counsel for plaintiff State of Alaska in this action.

Mr. Suggs will associate with the undersigned, Eric T. Sanders, a member of the Bar of this Court, who maintains an office at a place within the district, with whom the Court and opposing counsel may readily communicate regarding this case. My Consent of Local Counsel in support of this motion is filed herein.

Mr. Suggs is a member in good standing of the Bar of the State of Minnesota. A copy of his Certificate of Good Standing with the Bar of the State of Minnesota is

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attached as Exhibit A. Proof of payment of the requ[illegible] Association is also attached as Exhibit B.

DATED this 8 day of March, 2007.

FELDMAN ORLANSKY & SANDERS
Attorneys for State of Alaska

By _____
Eric T. Sanders
Alaska Bar No. 7510085

CONSENT OF LOCAL COUNSEL

The undersigned consents and moves for the granting of the application of David L. Suggs to appear and participate as co-counsel in this action on behalf of plaintiff State of Alaska. The undersigned is authorized to practice law in the State of Alaska and is admitted to the Superior Court for the Third Judicial District at Anchorage.

Dated this 8 day of March, 2007.

FELDMAN ORLANSKY & SANDERS

By: _____
Eric T. Sanders
Alaska Bar No. 7510085
500 L Street, Suite 400
Anchorage, Alaska 99501
Telephone: (907) 272-3538
Facsimile: (907) 274-0819

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Certificate of Service

I hereby certify that a true and correct copy of the foregoing Motion and Application of Non-Resident Attorney David L. Suggs for Permission to Appear and Participate was served by mail / messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

Andrew R. Rogoff - mail
Pepper Hamilton LLP
3000 Two Logan Square
Philadelphia, Pennsylvania 19103-2799

By Peggy S Crowe
Date 3/9/07

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FAX: 907.274.0819

UNITED STATES DISTRICT COURT

District of Minnesota

CERTIFICATE OF GOOD STANDING

I, Richard D. Sletten, Clerk of this Court, certify that David L. Suggs, Bar # 147485, was duly admitted to practice in this Court on March 7, 1984, and is in good standing as a member of the Bar of this Court.

Dated at Minneapolis, Minnesota, on February 12, 2007.

RICHARD D. SLETTEN, CLERK

(By) Deborah D. Bell, Deputy Clerk

000080

Exhibit A
Motion to Participate – Suggs
Case No. 3AN-06-5630 Civ

Form Modified 12/30/03

A B C

UNITED STATES DISTRICT COURT

District of Minnesota

CERTIFICATE OF GOOD STANDING

I, Richard D. Sletten, Clerk of this Court, certify that David L. Suggs, Bar # 147485, was duly admitted to practice in this Court on March 7, 1984, and is in good standing as a member of the Bar of this Court.

Dated at Minneapolis, Minnesota, on February 12, 2007.

RICHARD D. SLETTEN, CLERK

(By) Deborah D. Bell, Deputy Clerk

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Exhibit A
Motion to Participate – Suggs
Case No. 3AN-06-5630 Civ

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Motion to Participate - Suggs
Case No. 3AN-06-5630 Civ

000081

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	
Plaintiff,	
vs.	
ELI LILLY AND COMPANY,	Case No. 3AN-06-5630 CIV
Defendant.	

MOTION AND APPLICATION OF NON-RESIDENT ATTORNEY CHRISTIAAN MARCUM FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska Rule of Civil Procedure 81(a)(2), attorney Christiaan Marcum of the law firm of Richardson, Patrick, Westbrook & Brickman, LLC, whose mailing address is P.O. Box 1007, Mt. Pleasant, South Carolina 29465 (Telephone: (843) 727-6500), applies for permission to appear and participate as co-counsel for plaintiff State of Alaska in this action.

Mr. Marcum will associate with the undersigned, Eric T. Sanders, a member of the Bar of this Court, who maintains an office at a place within the district, with whom the Court and opposing counsel may readily communicate regarding this case. My Consent of Local Counsel in support of this motion is filed herein.

Mr. Marcum is a member in good standing of the Bar of the State of South Carolina. A copy of his Certificate of Good Standing with the Bar of the State of South

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ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

Carolina is attached as Exhibit A. Proof of payment of the required fee to the Alaska Bar Association is also attached as Exhibit B.

DATED this 8 day of March, 2007.

FELDMAN ORLANSKY & SANDERS
Attorneys for State of Alaska

By _____
Eric T. Sanders
Alaska Bar No. 7510085

CONSENT OF LOCAL COUNSEL

The undersigned consents and moves for the granting of the application of Christiaan Marcum to appear and participate as co-counsel in this action on behalf of plaintiff State of Alaska. The undersigned is authorized to practice law in the State of Alaska and is admitted to the Superior Court for the Third Judicial District at Anchorage.

Dated this 8 day of March, 2007.

FELDMAN ORLANSKY & SANDERS

By: _____
Eric T. Sanders
Alaska Bar No. 7510085
500 L Street, Suite 400
Anchorage, Alaska 99501
Telephone: (907) 272-3538
Facsimile: (907) 274-0819

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Certificate of Service

I hereby certify that a true and correct copy of the foregoing Motion and Application of Non-Resident Attorney Christiaan Marcum for Permission to Appear and Participate was served by mail / messenger on:

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Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

Andrew R. Rogoff - mail
Pepper Hamilton LLP
3000 Two Logan Square
Philadelphia, Pennsylvania 19103-2799

By Peggy S. Crowe
Date 3/9/07

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AO 136
(Rev. 6/82)

CERTIFICATE OF GOOD STANDING

UNITED STATES OF AMERICA

DISTRICT OF SOUTH CAROLINA

I, Larry W. Propes, Clerk of the United States District Court, District of South Carolina,

DO HEREBY CERTIFY That Christiaan Marcum, ID# 7556, was duly admitted to practice in said Court on October 16, 2000, and is in good standing as a member of the bar of said Court.

Dated at Charleston, South Carolina
on February 8, 2007.

Larry W. Propes, Clerk

By Melissa Deuman, Deputy Clerk

000085

Exhibit A
Motion to Participate – Marcum
Case No. 3AN-06-5630 Civ

A B C

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	assoc. w/ Eric Sanders 7510085		
	case # 3AN-06-5630		
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Exhibit B
Motion to Participate - Marcum
Case No. 3AN-06-5630 Civ

A B C

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CIV

PLAINTIFF'S MEMORANDUM DESCRIBING ITS CLAIMS AND PROOFS

I. INTRODUCTION

The State of Alaska ("the State") filed this civil action on its own behalf against drug manufacturer Eli Lilly & Co. ("Lilly") for damages proximately caused to the State by Lilly's introduction of the defective drug Zyprexa into the State's Medicaid population. The State alleges that it has been and in the future will pay additional expenses for the medical care of Alaska's Medicaid population because Medicaid recipients developed diabetes and diabetes-related illnesses as a direct result of ingesting Zyprexa. The State also seeks civil penalties for Lilly's deceptive Zyprexa marketing practices.

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The State's complaint asserts five claims for relief: (1) violations of Alaska's Unfair Trade Practices and Consumer Protection Act (AS 45.50.471 *et seq.*); (2) strict products liability (failure to warn); (3) strict products liability (design defect); (4) negligence; and (5) fraud and negligent misrepresentation.

The court requested a brief recitation of the State's *prima facie* causes of action, and an outline of the proof that the State expects to produce to satisfy each element. Lilly has argued that, in order to prove its case, the State must present a large number of the affected Medicaid recipients and their prescribing physicians. This memorandum demonstrates that such proof is not necessary, and that the State may prove its claims using aggregate data and statistical, epidemiological, and endocrinological analyses.

The State did not file this action on behalf of a class of individuals or as an action in subrogation; it filed this lawsuit to recover its own monetary damages. Thus, the State need not rely upon evidence of injury to specific persons. Rather, the State can and will prove its own case through expert testimony based on scientifically derived statistical evidence of Zyprexa's effect upon the State's Medicaid population and the damages the State has sustained as a result of Lilly's actions.

II. BACKGROUND

In 1996, Lilly began marketing the prescription pharmaceutical drug Zyprexa as a supposedly safer alternative to older, conventional antipsychotic drugs such as

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haloperidol and thorazine. Other companies developed similar drugs, and as a group these newer medications are often referred to as "atypical antipsychotics." During clinical trials it became apparent that Zyprexa (more so than the other atypical antipsychotics) caused patients to experience significant weight gain, which led to hyperglycemia and diabetes. When Lilly sought approval of Zyprexa from the FDA, Lilly failed to disclose fully the hyperglycemic and diabetic side effects it had observed. Ignorant of these dangerous side effects, the FDA approved Zyprexa for the treatment of schizophrenia, and later also approved it for the treatment of bipolar disorder. These are the only two indications for which Zyprexa ever received FDA approval.

Lilly initially marketed Zyprexa with no warnings or precautions regarding hyperglycemia or diabetes, choosing instead to bury any reference to those side effects by inaccurately characterizing them as "infrequent" events observed in clinical trials. Once on the market, however, many patients taking Zyprexa experienced significant weight gain and then developed diabetes and diabetes-related conditions, causing death in extreme cases. Though post-marketing adverse event reports of these conditions mounted, at no time did Lilly choose to warn physicians of them, or even mention them in the post-marketing events section of Zyprexa's label.

While outwardly denying any connection between Zyprexa and diabetes, Lilly's own doctors and executives internally acknowledged the link. Lilly's documents show

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that, rather than warning physicians of the problem, Lilly instead focused on devising ways to broaden the market for Zyprexa and to evade any safety concerns the medical or regulatory community might have.

In 2000, Lilly launched a marketing campaign for the drug entitled "Viva Zyprexa." "Viva Zyprexa" revolved around marketing Zyprexa to primary care physicians and family doctors who generally do not treat the serious psychiatric conditions for which Zyprexa is approved. Thus, instead of marketing Zyprexa to these physicians as a treatment for schizophrenia and bipolar disorder (the only conditions for which Zyprexa legally could be marketed), Lilly falsely touted the drug as "safe" and "efficacious" for a variety of symptoms and disorders, such as geriatric dementia and general malaise, the kind of symptoms that primary care physicians are more likely to see in their patients. As part of its marketing campaign, Lilly developed a number of fictional patient exemplars to illustrate to primary care physicians the type of nebulous and ill-defined off-label conditions it claimed Zyprexa could treat effectively. "Donna" was one such patient:

> Donna is a single mom in her mid-30s, appearing in your office in drab clothing and seeming somewhat ill at ease. Her chief complaint is, "I feel so anxious and irritable lately." Today, she says she's been sleeping more than usual and has trouble concentrating at work and at home.[1]

[1] Taken from Lilly's promotional materials.

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Regarding Zyprexa's safety profile, Lilly told physicians that weight gain on Zyprexa was a "therapeutic benefit." (The FDA later cited Lilly for misleading physicians and ordered Lilly to delete the claim that weight gain is a benefit.) Lilly also referred to weight gain on Zyprexa as "manageable" when it knew it was not. With regard to diabetes, Lilly avoided the issue altogether with physicians if possible. Lilly instructed its drug representatives that, if asked a direct question, they should provide answers that Lilly knew were false and tell physicians that there is no link between Zyprexa and diabetes, that diabetes occurs at comparable rates among all atypical antipsychotics, and that diabetes occurred at rates comparable to placebo in clinical trials.

As a result of Lilly's aggressive overpromotion of Zyprexa, prescriptions rose, along with Lilly's revenues. As the number of persons taking Zyprexa went up, so did the number of patients who suffered extreme weight gain, hyperglycemia, diabetes, and diabetes-related conditions. In September 2003, the FDA mandated that Zyprexa and all other atypical antipsychotic drugs include warnings regarding hyperglycemia and diabetes and recommendations for baseline and periodic blood glucose testing. Lilly finally communicated these warnings and recommendations to physicians in March 2004.

III. PROVING THE STATE'S DIRECT CLAIMS AGAINST LILLY: AN OVERVIEW

A significant portion of the Alaska residents who took Zyprexa for both approved and non-approved uses are recipients of the State's Medicaid program; thus, the State

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paid for thousands of prescriptions of a defective drug. Moreover, as a result of Zyprexa's defect, namely that it causes people to develop diabetes and diabetes-related conditions, the State must now provide life-long care to many Medicaid recipients who suffer these problems because they took Zyprexa. Thus, Lilly's misleading marketing proximately caused the State significant monetary damages. Under state law, the State of Alaska is authorized -- and indeed required -- to bring suit to recover its damages, and accordingly the State filed this action on its own behalf.

In order to prove its case and recover its damages, the State must prove only Lilly's liability for the State's own damages, not those of individual Medicaid recipients. The State's claim does not rest in the experience of the many individual Zyprexa users, but in the aggregate effect upon the State's Medicaid program. This effect can most easily and accurately be seen and measured through examination of the State's Medicaid data.

The State of Alaska maintains an immense database of information on the benefits it provides through its Medicaid program. This database contains basic information concerning the diagnosis and treatment of all recipients, consisting of reports made by doctors under state and federal law. Each doctor is required to indicate by code (International Classification of Diseases, Ninth Revision, or ICD-9) the reason for each

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patient visit for which Medicaid is billed. The records in the database establish each recipient's diagnoses, what treatment was provided, and how much Medicaid paid.

By examining the database, the State can identify every Medicaid recipient who took Zyprexa, whether it was prescribed to treat an approved or off-label condition, and how much was paid to treat each condition. By comparing the group of Medicaid recipients who took Zyprexa against similar, properly controlled groups who did not take Zyprexa, the State can measure the increased incidence of diabetes in users of the drug, and thereby prove the number of diabetes cases within the Medicaid population that are directly attributable to Zyprexa. From its records, the State also can accurately calculate the increased costs it already has incurred to provide care for Zyprexa-related diabetes, and it can project the extra costs it will incur in the future to provide care for Medicaid recipients who developed diabetes and diabetic complications as a result of consuming Zyprexa.

Lilly may argue that the State must prove which specific cases of diabetes were caused by Zyprexa, but this is incorrect. For example, the State expects analysis of Alaska's Medicaid database to demonstrate that Zyprexa users are more than three times more likely to develop diabetes than a control group of non-users. This would be comparable to the scientifically and statistically sound data from other states that establish that Zyprexa use was directly responsible for a 370 percent increase in diabetes

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cases in patients taking Zyprexa within those states' Medicaid populations.[2] In this case, because individual patients are not seeking reimbursement, there is no need to prove which individuals within the Medicaid population comprise those who would not have developed diabetes without taking Zyprexa, as distinct from those who would have developed diabetes even without taking the drug. The State is responsible for all Medicaid patients who developed diabetes; it paid the extra costs for those whose diabetes is Zyprexa-related, and it can recover those costs by proving the total extra costs it incurred as a result of Lilly's marketing a defective drug.

A key point in this case, from the State's perspective, is understanding the difference between generic and specific causation. Generic causation refers to proof that an agent, for example a pharmaceutical drug, can or does cause a particular injury or condition in a population of individuals. Specific causation refers to proof that the agent proximately caused an injury or condition in a specific individual. As pointed out above, because the State seeks compensation for increased costs incurred within a population, the State's burden in this case is to establish generic causation in that population (i.e., the rate by which Alaska Medicaid recipients who took Zyprexa show an increased incidence

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[2] *See* Exhibit A, *Risk of Diabetes Mellitus Associated with Atypical Antipsychotic Use among Medicaid Patients with Bipolar Disorder: A Nested Case-Control Study,* PHARMACOTHERAPY (Vol. 27 No. 1 January 2007) at page 1, Measurements and Main Results.

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of diabetes compared to the background rate of the disease in matched controls); the State does not need to prove specific causation in any particular individual in this population.

Use of statistical data to study the incidence and progression of disease within a particular population is known as epidemiology. Epidemiological data are routinely used to prove generic causation of injuries in tort litigation. In fact, there is likely no more widely used science in the courtroom than epidemiology, particular in toxic tort and products liability cases.[3] Epidemiologic evidence is often relied upon to establish or dispute whether exposure to a particular agent causes harm or disease.[4] Generally,

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[3] *See* Exhibit B, MICHAEL D. GREEN, D. MICHAEL FREEDMAN, & LEON GORDIS, REFERENCE GUIDE ON EPIDEMIOLOGY, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (2000) [hereafter "REFERENCE GUIDE"] at 335.

[4] *See, e.g., Siharath v. Sandoz Pharm. Corp.,* 131 F. Supp. 2d 1347, 1356 (N.D. Ga. 2001) ("epidemiological studies provide the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or disease" (internal quotation omitted)); *see generally* Exhibit B, REFERENCE GUIDE at 335 n.5 (citing additional cases). In a case involving the ingestion of aspirin in the development of Reye's Syndrome, the Court in *Tyler v. Sterling Drug, Inc.,* 19 F. Supp. 2d 1239, 1242-43 (N.D. Okla. 1998), relied upon six factors set out in *General Electric Co. v. Joiner,* 522 U.S. 136, (1997), for determining when reliance on epidemiological evidence is sufficient to prove causation: (1) the studies must be relevant and reliable; (2) the subject of the studies must be similar to the case on trial; (3) the authors of the study must be able to draw conclusions from the statistics; (4) the studies should suggest a link between the increase of the incidence of illness and exposure to the product at issue; (5) the studies should involve the product at issue; and (6) the studies should not show exposure to more than one potentially toxic product as a cause of the illness. Further, "the studies should not have too great an analytical gap between the data and the expert opinion proffered." Applying these standards, the Court found that the epidemiological studies relied upon demonstrated a connection between aspirin and Reye's Syndrome.

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epidemiology that proves a relative risk of 2.0 or greater is acceptable evidence of generic causation and, even in some cases, specific causation.[5]

The use of epidemiology to analyze a state's Medicaid data to determine an increase in the incidence of diabetes in Zyprexa users is not novel. The methodology that the State will use in this case is comparable to that reported in a recently published study, *Risk of Diabetes Mellitus Associated with Atypical Antipsychotic Use Among Medicaid Patients with Bipolar Disorder: A Nested Case-Control Study,* PHARMACOTHERAPY (Vol. 27 No. 1 January 2007).[6] The authors analyzed a database of 45 million individuals from the Medicaid populations of seven states, compiling the ICD-9 codes of those recipients who took Zyprexa. Using the ICD-9 diagnosis codes, the authors identified patients who were prescribed atypical antipsychotics such as Zyprexa and who subsequently developed diabetes, and a control group that did not receive these drugs. The authors refined the data by controlling for confounding variables such as age, sex, psychiatric and medical comorbidities, and concomitant drugs that increase a patient's risk for diabetes. Based on

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The State's evidence will satisfy these standards.

[5] *See* Exhibit B, REFERENCE GUIDE at 384 (stating that a "relative risk greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent" and that a "substantial number of courts" accept this reasoning); *see also id.* at nn.39-40 (citing cases).

[6] A copy of this study is provided as Exhibit A.

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standard statistical analyses, the authors demonstrated that there is a statistically significant increased risk of diabetes in patients treated with Zyprexa.[7] Similar studies involving other drugs have been conducted upon the Medicaid population of California.[8]

The State has retained the necessary experts to examine the Medicaid database and to conduct a similar, Alaskan study, using the same epidemiological methods to determine Zyprexa's effect on Alaska's Medicaid population. This study will show the extent to which diabetes and diabetes-related illnesses increased among Zyprexa users in Alaska's Medicaid population. It is expected that the results of this study will be similar to all previous studies -- a marked increase in diabetes among Zyprexa users.

To quantify its damages, the State will use the science of endocrinology, which studies the long-term effects of diabetes and its related diseases. The progression of diabetes is well-studied. For example, based upon numerous studies of diabetes, if a population of 1000 diabetics is tracked statistically, it is a medical fact that a certain percentage of that group will eventually suffer from blindness as a consequence of the diabetes, a certain percentage will suffer a heart attack as a result of diabetes, etc.

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[7] The authors determined a "Hazard Ratio" of 3.7, meaning a Zyprexa user is 3.7 times more likely to develop treatment emergent diabetic complications. *See* Exhibit A.

[8] *See* B.L. Lambert, C.H. Chou, K.Y. Chang, E. Tafese, & W. Carson, *Antipsychotic exposure and type 2 diabetes among patients with schizophrenia: a matched case-control study of California Medicaid claims,* PHARMACOEPIDEMIOL DRUG SAF 2005, 14:417-25.

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Endocrinological analysis will assist the State in quantifying these effects in the Zyprexa-diabetic population.[9]

Finally, the State will rely upon an economic model, scientifically derived, which calculates the increase in costs related to diabetes and diabetic complications for the given population. Together, the endocrinological and economic analyses will prove the State's monetary damages due to the increase in diabetes among Medicaid patients who took Zyprexa.

IV. PROVING THE STATE'S CLAIMS AGAINST LILLY: A CLAIM-BY-CLAIM ANALYSIS

The State's complaint alleges claims for strict products liability for design defect; strict liability for failure to warn; violations of the Alaska Unfair Trade Practices Act; negligence; and fraud. These causes of action and the State's intended proof are addressed in turn in the following sections.

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[9] Some examples of epidemiological studies involving endocrinology include T.L. Gary, L.R. Bone, M.N. Hill, D.M. Levine, M. McGuire, C. Saudek, & F.L. Brancati, *Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans,* PMID:12799126; A. Adeniyi, A.R. Folsom, F.L. Brancati, M. Desvorieux, J.S. Pankow, & H. Taylor, *Incidence and risk factors for cardiovascular disease in African Americans with diabetes: the Atherosclerosis Risk in Communities (ARIC) study,* J. NAT'L MED. ASSOC. 94(12):1025-35 (Dec. 2002). Plaintiff will use the same methods relied upon by these peer-reviewed articles.

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A. Strict Products Liability -- Design Defect

Under Alaska law, if Lilly marketed a defectively designed drug, it may be held strictly liable for the damages suffered by the State, regardless of Lilly's intent or the source of the drug's defects.

> The focus of attention in strict liability cases is not on the conduct of the defendant, but rather on the existence of the defective product which causes injuries. Liability is attached, as a matter of policy, on the basis of the existence of a defect rather than on the basis of the defendant's negligent conduct.[10]

"A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being."[11] Thus, upon a demonstration that Zyprexa was defective in design and that the defect is the proximate cause of the State's damages, Lilly must be held strictly liable for those damages.

In its case, the State will prove that Zyprexa is defective in design, in that it causes serious injuries when used for its intended purpose. In other words, when Zyprexa is prescribed and ingested as recommended by Lilly, Zyprexa causes significant side effects that imperil the health of users and increase the State's costs for these patients' treatment. As a result of the design defect, the State has suffered damages and will continue to

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10 *Shanks v. The Upjohn Co.*, 835 P.2d 1189, 1199 (Alaska 1992).

11 *Clary v. Fifth Ave. Chrysler Center,* 454 P.2d 244, 247 (Alaska 1969).

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suffer damages stemming from the extra cost of medical care required by Alaska Medicaid recipients who used Zyprexa.

The preceding section of this memorandum outlined the way the State will prove causation and damages. The following sections outline the two ways in which the State will prove that Zyprexa was defectively designed. The Alaska Supreme Court has recognized two ways to establish a design defect in a drug.[12] These prongs are independent; only one need be proved to establish design defect. The State is prepared to prove both.

1. Zyprexa failed to perform as safely as an ordinary doctor would expect when used by patients in an intended and reasonably foreseeable manner.

Under Alaska law, if a prescription drug does not perform as safely as an ordinary doctor[13] would expect it to perform when used by his patients in the intended manner, the drug is by law "defective," and the manufacturer of the drug is strictly liable for any damages proximately caused by such use of the drug.[14] The "ordinary doctor's expectation" is an objective standard. Just as courts do not expect testimony from the

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12 *See Shanks,* 835 P.2d at 1194-95.

13 The *Shanks* Court explained that when dealing with prescription drugs, it is the expectation of the prescribing physician -- and not the patient -- that must be considered in this test. *See id.*

14 *See id.* at 1195.

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man on the street to discover the views of a "reasonable man," so the State will not offer (and the court should not allow defendants to offer) testimony from individual "ordinary physicians." Rather, the State will rely on expert testimony and documentary evidence to prove that the "ordinary doctor" would expect a drug that was marketed for the safe treatment of an illness to treat that illness safely (both for approved conditions and for off-label conditions for which the drug was promoted). In this case, the evidence will establish that ordinary doctors did not expect that Zyprexa had side effects that placed patients at risk of developing lifelong debilitating illnesses. Documentary evidence will corroborate the expert testimony by showing that, when Zyprexa's problems were revealed, fewer doctors prescribed it.

The State's evidence that Zyprexa did not perform as safely as expected when used by patients in the intended and reasonably foreseeable manner will include:

1) Scientific, epidemiological evidence that Zyprexa carries a significant risk of diabetes, several times that of the normal population, which was unexpected by the ordinary doctor;

2) Statistical evidence from Japan showing that new prescriptions went down by approximately 75 percent after Lilly was forced to issue full warnings of the drug's risk;

3) Epidemiological evidence showing that once adequate warnings were given in the United States regarding Zyprexa's risks, physicians' prescribing practices changed and the number of prescriptions went down;

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4) Evidence from Lilly's own documents demonstrating that when the link between Zyprexa and diabetes became known, or when adequate warnings were given, the number of prescriptions decreased;

5) Internal Lilly documents discussing the fact that, if the connection between Zyprexa and diabetes were known, physicians would generally not prescribe the drug off-label, because they would be required to subject their patients to regular blood-glucose monitoring;

6) Lilly marketing materials instructing the sales force to avoid the diabetes issue, thereby actively seeking to eliminate the risk of diabetes from the "ordinary doctor's" risk-benefit analysis; and

7) Expert testimony about the reasonable expectation of the ordinary doctor with regard to safe performance of a drug that is unaccompanied by adequate warnings.

This evidence will be more than ample to establish that the medical community did not expect Zyprexa's side effects, and will more than adequately satisfy the standard of proving a defective drug as set forth by the Alaska Supreme Court in the first test in *Shanks*.

2. Zyprexa's defect, the increased risk of diabetes, proximately caused the State's damages, and on balance the benefits of Zyprexa's design do not outweigh its inherent risk of danger.

The second method of proving pharmaceutical design defect under *Shanks* is to show that the design of the drug proximately caused the plaintiff's damages, and the

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defendant fails to prove that the benefits of the drug outweigh the inherent risks of its design.[15]

In *Shanks,* the Alaska Supreme Court articulated a multi-factored test for the trier of fact to consider when deciding whether a drug's benefits outweigh its risks. Those factors are:

- The seriousness of the side effect;
- The likelihood that the side effect will occur;
- The feasibility of an alternative design that would eliminate or reduce the side effect without reducing efficacy;
- The harm of an alternative design in reduced efficacy or new side effects; and
- The seriousness of the condition for which the drug is indicated.[16]

The State's evidence, much of it already developed in the Multi-District Litigation ("MDL"), will be sufficient to refute any evidence that Lilly presents on the risk/benefit balance. The evidence will include:

1) Epidemiological and endocrinological evidence addressing the seriousness of Zyprexa's side effects, including that the use of Zyprexa requires constant monitoring and carries significant risks of hyperglycemia, diabetes, and diabetic complications such as blindness, amputation, and death;

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15 *See id.* at 1196-97.

16 *See id.*

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2) Epidemiological evidence showing that the likelihood of the side effect -- developing diabetes as a result of taking Zyprexa -- is high, with studies indicating that Zyprexa users are three to four times more likely to develop the disease than non-users;

3) Expert testimony that alternative drugs effectively treat schizophrenia and bipolar disorder and do not carry risks similar to Zyprexa; and

4) Expert testimony that alternative drugs effectively treat the off-label uses for which Zyprexa was marketed and do not carry the same serious side effects.

That the risk/benefit balance did not justify marketing Zyprexa will be particularly easy for the State to show with respect to the off-label uses for which Lilly promoted Zyprexa. For the many individuals who were prescribed Zyprexa for treatment of depression, anxiety, geriatric dementia, general malaise, and countless other maladies as a result of Lilly's "Viva Zyprexa" marketing campaign, the drug carried no benefit whatsoever. There are many other efficacious alternative drugs that have been approved for these conditions and they do not carry the serious diabetes-related side effects.

As the above sections show, under either prong of the *Shanks* test, the State's proof of Lilly's liability for damages caused by a design defect does not require the testimony of numerous patients or physicians.

B. Strict Products Liability -- Failure to Warn

The Alaska Supreme Court explained the basis for a strict liability claim for failure to warn as follows:

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> Under a strict liability failure to warn theory, if the plaintiff proves the product as marketed posed a risk of injury to one who uses the product in a reasonable and foreseeable manner and the product is marketed without adequate warnings of the risk, the product is defective. If such a defect is the proximate cause of the plaintiff's injuries, the manufacturer is strictly liable unless the defendant manufacturer can prove the risk was scientifically unknowable at the time the product was distributed to the plaintiff.[17]

In evaluating the effectiveness of a warning, adequacy is generally evaluated with the following factors in mind: (1) whether the scope of risk or danger posed by the product is clearly indicated; (2) whether the extent or seriousness of harm resulting from the risk or danger is reasonably communicated; and (3) whether the warning is conveyed in a manner likely to alert a reasonably prudent physician.[18] In the context of prescription drugs, the warning should be sufficient to put an ordinary physician on notice of the nature and extent of any scientifically knowable risks or dangers inherent in the use of the drug.[19] The State will present evidence that clearly demonstrates Lilly was well aware of Zyprexa's association with hyperglycemia and diabetes and its related complications before the drug was introduced to the market, and thus Lilly should have warned about the risk of that serious hazard from day one. It should be undisputed that Lilly did not provide these warnings until forced to do so by the FDA.

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17 *Id.* at 1200.

18 *See id.*

19 *See id.* (citing *Polley v. Ciba-Geigy Corp.*, 658 F. Supp. 420 (D. Alaska 1987)).

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The State's proof for this cause of action is much the same as already outlined above for other claims:

1) The State will prove the product poses a risk of severe harm by using Lilly's own documents that establish Lilly knew that, when used as recommended by Lilly, Zyprexa causes weight gain and is associated with diabetes and diabetic conditions;

2) The State will show the lack of adequate warning through expert testimony and by demonstrating the 75 percent drop in new prescriptions when proper warnings were given in Japan, as well as the drop-off in prescriptions in the United States after warnings were provided;

3) The State will prove that the defects in Zyprexa proximately caused the State's injuries using epidemiological data for Alaska's Medicaid population, which should align with other studies that establish a three- to four-fold increase in diabetes among Zyprexa users as compared to a control group;

4) The State will show that the risk of diabetes was not only scientifically knowable but was actually known by Lilly, using internal documents in which Lilly executives discussed the diabetes problem; and

5) The State will quantify its damages through endocrinological and economic models, as discussed above.

Again, the State can meet its burden of proof on all elements of a *prima facie* case without relying on testimony from individual physicians or patients.

C. Violation of Alaska's Unfair Trade Practices Act

The State must prove two primary elements to establish a *prima facie* case of unfair or deceptive acts or practices under the Act: (1) that the defendant is engaged in

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trade or commerce; and (2) that in the conduct of trade or commerce, the defendant committed an unfair or deceptive act.[20] Neither intent to deceive nor actual injury is required: "All that is required is a showing that the acts and practices were capable of being interpreted in a misleading way."[21] Further, the act or practice need not necessarily be deceptive to be "unfair" for purposes of this Act. A defendant's conduct may be unfair and violative of the Act if it offends public policy as it has been established by statutes, the common law, or otherwise; it is immoral, unethical, oppressive, or unscrupulous; or it causes substantial injury to consumers or competitors or other businesses.[22]

Here, there should be no dispute that Lilly was engaged in trade or commerce. The State intends to prove that Lilly's conduct violated at least five different provisions of the Unfair Trade Practices Act.[23] Specifically, the State alleges that Lilly committed the following acts in violation of the statute:

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[20] *State v. Grogan*, 628 P.2d 570, 573 (Alaska 1981); *State v. O'Neill Investigations, Inc.*, 609 P.2d 520, 534 (Alaska 1980).

[21] *O'Neill Investigations,* 609 P.2d at 535.

[22] *See id.*

[23] AS 45.50.471(b) provides that the specifically enumerated acts are examples of "unfair and deceptive acts," but conduct may violate the Unfair Trade Practices Act even if it does not fit precisely within one of the listed categories.

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1) Lilly represented Zyprexa to have characteristics, uses, benefits and/or qualities that it did not have, violating AS 45.50.471(b)(4). The State will prove this violation with evidence that Lilly through its representatives marketed Zyprexa as safe and effective, both for uses for which it was approved by the FDA and for many uses that were not approved. Lilly knew that the drug was not safe for any of these uses.

2) Lilly represented that Zyprexa was of a particular standard, quality, and grade suitable for consumption when in fact it was not, violating AS 45.50.471(b)(6). The proof of this violation is essentially the same as in the previous paragraph.

3) Lilly engaged in conduct creating a likelihood of confusion or misunderstanding, which misled or damaged purchasers of Zyprexa, violating AS 45.50.471(b)(11). With a prescription drug, the focus is on whether the prescribing physician was misled. The discussion above outlines how the State will prove through expert testimony that Lilly's campaign to promote the drug for unapproved uses would mislead doctors.

4) Lilly used misrepresentations or omissions of material facts with the intent that others rely on them in connection with the sale of Zyprexa, violating AS 45.50.471(b)(12). Lilly's own documents will prove that Lilly made intentional misrepresentations and omissions of fact with respect to weight gain and diabetes, with the intent that physicians rely on these misstatements.

5) Lilly violated the labeling and advertising provisions of AS 17.20, which is a violation of AS 45.50.471(b)(48). The evidence for this violation is that Lilly marketed Zyprexa for uses for which it was not approved.

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If successful in proving any of these violations, the State may collect three times its actual damages.[24] As discussed in preceding sections, the State will prove its actual damages by showing that, due to Lilly's misrepresentations and other unfair acts, physicians prescribed Zyprexa in situations where they otherwise would not have prescribed the drug, and, without the misrepresentations, the incidence of diabetes in Medicaid patients would have been much less. Further, there would have been less direct cost to the State, as the drug would have been used only for the very limited indications for which it is approved. Through epidemiological and endocrinoligical studies, and statistical and aggregate data about the Medicaid population, the State can quantify its actual damages. Once again, testimony about any individual consumer of the drug is not required to meet any portion of the State's burden of proof under this cause of action.

D. Negligence

The tort of negligence consists of four distinct elements: (1) duty, (2) breach of duty, (3) causation, and (4) damages.[25] The existence and extent of a duty is a question of law.[26] "The concept of 'duty' in negligence encompasses a broad range of policy

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[24] *See* AS 45.50.531(a).

[25] *See, e.g., Lyons v. Midnight Sun Transp. Servs., Inc.,* 928 P.2d 1202, 1204 (Alaska 1996).

[26] *See, e.g., Mulvihill v. Union Oil Co.,* 859 P.2d 1310, 1314 n.4 (Alaska 1993).

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considerations underlying the determination when, and to what extent, an individual should bear the costs of a given activity."[27] In general, the duty of care runs to all who might foreseeably be injured by an actor's conduct.[28]

The State's negligence claim is based on the unremarkable proposition that Lilly had a duty to manufacture and distribute only drugs that would perform as intended, and that, if marketed as safe, would in fact be safe when ingested in a reasonably foreseeable manner. This duty was owed not only to consumers but to the State, whom Lilly recognized as the financially responsible party.

The State will show with documentary evidence and testimony that Lilly marketed a drug that it knew causes significant weight gain and increased risk of hyperglycemia and diabetes, and that Lilly deliberately marketed the drug without adequate warnings of the known risks and for uses well beyond its approved indications. By this conduct, Lilly breached its duty to the State because it knew or should have known Zyprexa would cause serious health injuries to Medicaid patients and knew or should have known that the State would be injured by having to bear the financial costs of treating those illnesses.

A defendant's negligent conduct "may be the legal or proximate cause of the plaintiff's injury if the negligent act was more likely than not a substantial factor in

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[27] *Maddox v. River & Sea Marine, Inc.*, 925 P.2d 1033, 1036 (Alaska 1996).

[28] *See Lynden Inc. v. Walker*, 30 P.3d 609, 614 (Alaska 2001).

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bringing about the injury."[29] As discussed above, the State will prove that Lilly's negligence was the proximate cause of its injuries through expert testimony and epidemiological evidence. For the reasons discussed above, the State only needs to prove the extent of damages caused by Zyprexa to the group of Alaska Medicaid patients as a whole, and need not identify each individual patient who developed diabetes as a result of taking Zyprexa. The State will prove its claim by showing that, as a direct result of Lilly's failure to include warnings of Zyprexa's side effects in the United States, Alaska Medicaid recipients suffered numerous injuries for which the State has been and will be financially responsible. The expert testimony and epidemiological evidence are more than sufficient to demonstrate that Lilly's conduct was a substantial contributing factor in bringing about the State's damages. The State's damages, as discussed above, are the past, present and future costs of treating Medicaid recipients with diabetes and diabetic conditions who would not have developed these conditions had they not been prescribed Zyprexa.

E. Fraud

In Alaska, "[t]he elements for a cause of action for knowing misrepresentation or deceit include: a false representation of fact, scienter, intention to induce reliance,

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29 *P.G. v. State,* 4 P.3d 326, 334 (Alaska 2000).

justifiable reliance, and damages."[30] Scienter means that the defendant knows the falsity of the representation.[31] Specific intent to deceive is not required; rather, it is sufficient that the defendant have reason to expect that its false statement will influence the other's conduct.[32]

To prove its fraud claim, the State will present evidence to show that Lilly represented Zyprexa as safe and effective for a variety of conditions, knowing that it was not safe and expecting and intending that others would rely on that false representation. As outlined above, the State will show that Lilly's fraudulent misrepresentations about Zyprexa and its side effects were the proximate cause of damages to the State and its Medicaid program. Key evidence on the fraud claim will include:

1) Lilly's own internal documents and marketing materials showing that its marketing campaign to doctors -- including Alaska doctors -- contained false representations about Zyprexa's design, risks, and side effects;

2) Lilly's internal documents showing that Lilly was aware of Zyprexa's risks and side effects at the time it was issuing misleading marketing materials to physicians, and knew that the marketing materials were misleading in nature, thus satisfying the scienter requirement;

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30 *Barber v. National Bank of Alaska*, 815 P.2d 857, 862 (Alaska 1991).

31 *See City of Fairbanks v. Amoco*, 952 P.2d 1173, 1176 n.4 (Alaska 1998).

32 *See Lightle v. State Real Estate Comm'n,* 146 P.3d 980, 984 (Alaska 2006).

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3) Lilly's internal documents and marketing materials that instructed its sales representatives to shun discussion of Zyprexa's diabetes-related side effects and to misrepresent that connection so as to induce physicians to rely on Lilly's positive promotions and to prescribe Zyprexa to their patients, demonstrating the intent to induce reliance;

4) Expert testimony that physicians justifiably relied upon Lilly's misrepresentations as the drug manufacturer;

5) Statistical evidence, including Lilly's own internal documents, showing that when the misrepresentations were made, prescriptions went up, yet when Lilly began to issue adequate warnings, prescriptions decreased, demonstrating that physicians as a whole relied upon the misrepresentations, and altered their prescribing practices once those misrepresentations were revealed; and

6) Damages in the form of increased costs of medical care for the affected Medicaid population, as described throughout this brief.

Lilly well knew, when it instructed its drug representatives to make fraudulent misrepresentations to Alaska physicians, that the State was by far the largest purchaser of Zyprexa, as well as the purchaser of much of the medical care that would be required by patients who developed diabetes after using Zyprexa. Lilly also knew that its misrepresentations were inevitably going to damage the State's Medicaid department through the purchase of Zyprexa for Medicaid patients. These facts establish that Lilly foresaw the harm to the State and that Lilly's fraudulent misrepresentations are the proximate cause of the State's monetary damages.

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As with each other cause of action, the State does not need testimony from individual physicians or patients to prove any element of this claim. The statistical, expert, and documentary evidence that the State will present amply addresses the question of justifiable reliance on Lilly's misrepresentations within the medical community. Statistical and expert testimony will prove the State's damages.

V. NATURE AND EXTENT OF THE STATE'S DAMAGES AND INJURIES

The preceding sections of this brief touch frequently on the nature of the State's damages, and how it intends to prove these damages; this section offers a few comments specifically focused on proving damages.

As plaintiff, the State must prove it damages by a preponderance of the evidence.[33] It must establish with "reasonable probability" the nature and extent of any future damages, which it can do by producing evidence that gives the jury "some reasonable basis upon which . . . [to] estimate with a fair degree of certainty the probable loss which plaintiff will sustain in order to enable it to make an intelligent determination of the extent of the loss."[34] That there may be some uncertainty or difficulty in measuring the damage does not bar plaintiff's damage claim. It is necessary for the State to prove the *fact* of damages. However, "[o]nce the fact of damages has been proven to a reasonable

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33 *See Pluid v. B.K.*, 948 P.2d 981, 985 (Alaska 1997).

34 *See Lyndon Inc. v. Walker*, 30 P.3d 609 (Alaska 2001).

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probability, the *amount* of such damages, on the other hand, need only be proven to such a degree as to allow the finder of fact to reasonably estimate the amount to be allowed for the item of damage."[35]

After demonstrating through epidemiological studies an increase in the incidence of diabetes related to Zyprexa use, the State will rely upon endocrinology, clinical literature, and treatment guidelines (introduced through expert witnesses) to demonstrate the amount of care occasioned by the increase in diabetes. Through the use of expert endocrinolgical testimony, the State will demonstrate the medical sequelae which may be expected once a patient develops diabetes. The State will prove through clinical literature and expert testimony the percentage of diabetics who go on to develop specific complications. Diabetes is a progressive disease. Experts will describe the care that is needed as a patient progresses from diabetic complication to diabetic complication.

Thus, the State will specify the annual and recurring resources associated with good medical practice to diagnose, treat, and manage patients with type-2 diabetes mellitus, pancreatitis, and other serious acute diabetic events as well as secondary injuries such as heart attack, stroke, blindness, and amputation. While medical experts may identify the complete "standard of care" for each type of complication, Medicaid only covers a portion of the tests, procedures, and resources needed in the standard continuum

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35 *Pluid*, 948 P.2d at 985.

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of care. The State will seek compensation only for its actual costs. Billing and coding experts, therefore, will testify about the codes that identify procedures covered under Alaska's Medicaid program, and they will identify the rates that Medicaid pays to health care providers for the covered medical services.

Proving past damages is relatively straightforward. To prove future damages, actuaries and statisticians will testify from the State's records about the amount of time the average Medicaid recipient with the specific complications remains on the Medicaid rolls. Thus, the State will be able to calculate with reasonable certainty the amount of damages the State will suffer in the future as a result of the introduction of Zyprexa into the State Medicaid population. Once the State proves by a preponderance of the evidence that it has suffered and will suffer damages as a result of Zyprexa's introduction into Alaska's Medicaid population, it need only prove the amount of damages to such a degree as to allow the jury to reasonably estimate the amount to award. Yet again, the proof will be through expert witnesses and aggregate data. The State can prove its damages claim without presenting testimony by individual physicians or patients.

VI. CONCLUSION

The evidence produced in the MDL proves the defectiveness of Zyprexa. Similar and additional evidence will be developed through discovery in this case. Epidemiological evidence proves the relationship between the established defect and the

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damages suffered. Endocrinological evidence provides an explanation for the causal relationship between Zyprexa and weight gain, diabetes, and diabetic-related conditions. Further, experts in endocrinology explain the course and treatment of persons who contract diabetes as a result of taking Zyprexa. Thus, Alaska has more than ample evidence to prove its case in chief, and there is no need to take testimony from numerous doctors or Medicaid Recipients.

DATED this 1st day of March, 2007.

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Reprinted from
Volume 27, Number 1

Jan 2007

PHARMACOTHERAPY

Risk of Diabetes Mellitus Associated with Atypical Antipsychotic Use Among Medicaid Patients with Bipolar Disorder: A Nested Case-Control Study

Jeff J. Guo, Ph.D., Paul E. Keck, Jr., M.D., Patricia K. Corey-Lisle, Ph.D., Hong Li, Ph.D., Dongming Jiang, Ph.D., Raymond Jang, Ph.D., and Gilbert J. L Italien, Sc.D.

The Official Journal of the accp American College of Clinical Pharmacy

Risk of Diabetes Mellitus Associated with Atypical Antipsychotic Use Among Medicaid Patients with Bipolar Disorder: A Nested Case-Control Study

Jeff J. Guo, Ph.D., Paul E. Keck, Jr., M.D., Patricia K. Corey-Lisle, Ph.D., Hong Li, Ph.D., Dongming Jiang, Ph.D., Raymond Jang, Ph.D., and Gilbert J. L'Italien, Sc.D.

Study Objective. To quantify the risk of diabetes mellitus associated with atypical antipsychotics compared with conventional antipsychotics in managed care Medicaid patients with bipolar disorder.

Design. Retrospective nested case-control study.

Data Source. Integrated seven-state Medicaid managed care claims database from January 1, 1998–December 31, 2002.

Patients. Two hundred eighty-three patients with diabetes (cases) and 1134 controls matched by age, sex, and the index date on which bipolar disorder was diagnosed.

Measurements and Main Results. Cases were defined as those having an *International Classification of Diseases, Ninth Revision* diagnosis of diabetes or those receiving treatment with antidiabetic drugs. Both case and control patients had at least a 3-month exposure to either conventional or atypical antipsychotic agents or three filled prescriptions related to treatment for bipolar disorder. Of the 283 cases, 139 (49%) received atypical antipsychotics (olanzapine, risperidone, quetiapine, ziprasidone, and clozapine) and 133 (47%) were prescribed conventional antipsychotics. To compare the risk for new-onset diabetes associated with atypical versus conventional antipsychotics, we conducted a Cox proportional hazard regression, in which we controlled for age; sex; duration of bipolar disorder follow-up; use of lithium, anticonvulsants, antidepressants, and other drugs; and psychiatric and medical comorbidities. Compared with patients receiving conventional antipsychotics, the risk of diabetes was greatest among patients taking risperidone (hazard ratio [HR] 3.8, 95% confidence interval [CI] 2.7–5.3), olanzapine (3.7, 95% CI 2.5–5.3), and quetiapine (2.5, 95% CI 1.4–4.3). The risk for developing diabetes was also associated with weight gain (HR 2.5, 95% CI 1.9–3.4), hypertension (HR 1.6, 95% CI 1.2–2.2), and substance abuse (HR 1.5, 95% CI 1.0–2.2).

Conclusion. Olanzapine, risperidone, and quetiapine are all associated with development or exacerbation of diabetes mellitus in patients with bipolar disorder. When prescribing therapy for this patient population, metabolic complications such as diabetes, weight gain, and hypertension need to be considered.

Key Words: diabetes, bipolar disorder, atypical antipsychotics, managed care, Medicaid.

(Pharmacotherapy 2007;27(1):27–35)

Traditionally, mood stabilizers such as lithium, divalproex, and carbamazepine have been the primary agents used to treat bipolar disorder. Although conventional antipsychotics also have

been prescribed to treat acute mania, long-term maintenance use of these agents is limited due to their intolerable adverse events, including akathisia, extrapyramidal symptoms, and tardive dyskinesia. Atypical antipsychotics (aripiprazole, clozapine, olanzapine, quetiapine, risperidone, and ziprasidone) are generally regarded as having lower risk for causing extrapyramidal symptoms than conventional antipsychotics; they have been used with increasing frequency in the treatment of bipolar disorder since the mid-1990s.[1–4] This trend may reflect the antimanic or mood-stabilizing properties of atypical antipsychotics and their favorable tolerability profiles compared with conventional agents.[5–7] Recent clinical trials suggest that antipsychotic augmentation might be efficacious for treatment of bipolar depression.[7–9] Unfortunately, atypical antipsychotics are associated with metabolic complications that place patients at risk for weight gain, altered glucose metabolism, dyslipidemia, myocarditis, and cardiomyopathy.[10–13]

The increased risk for diabetes associated with atypical antipsychotics may reflect direct effects of these drugs on β-cell function and insulin action.[10, 11] Several published studies, including a number of retrospective cohort studies, have shown associations between the development of diabetes or glucose intolerance and the atypical antipsychotics clozapine, olanzapine, and risperidone in patients with schizophrenia.[14–23] A research group reported hazard ratios (HRs) for diabetes risk of 1.1–1.2 in Veterans Affairs patients who received atypical antipsychotics.[24] Two groups in the United Kingdom found that atypical antipsychotics were associated with HRs for diabetes of 4.7–5.8.[24, 25] An analysis based on the World Health Organization's adverse drug reaction database found that these agents had an HR for diabetes as high as 10.22.[26] Several cases of diabetic ketoacidosis and diabetes associated with atypical antipsychotics have been reported among adult[27] and pediatric[28, 29] patients with bipolar disorder. Although atypical antipsychotics are widely used to treat mania, their association with diabetes onset has not been adequately quantified in patients with bipolar disorder.[30]

Not only is the Medicaid program the dominant payer for mental health services in the United States,[31] but the number of Medicaid enrollees in managed care organizations has increased since the mid-1990s.[32] Studies using Iowa and California Medicaid claims databases have found that patients with schizophrenia exposed to clozapine or olanzapine were at increased risk for type 2 diabetes.[33, 34] Yet, very little information exists about the risk of diabetes associated with antipsychotic drug use among patients with bipolar disorder in the managed care Medicaid population.

We hypothesized that atypical antipsychotics would present a different risk for diabetes than conventional antipsychotics. Our objectives were to investigate the association between atypical antipsychotics and diabetes mellitus in patients with bipolar disorder in the managed care Medicaid population and compare it with the association between conventional antipsychotics and diabetes in the same patient population. In assessing the risk for diabetes, we controlled for key covariates such as age, sex, and psychiatric and medical comorbidities, as well as concomitant drugs that affect patients' risk for hyperglycemia.

Methods

Data Source

Our data source was a multistate managed care claims database (PharMetrics, Watertown, MA). The database covered over 45 million individuals enrolled in managed care organizations with 70 health plans, including seven state Medicaid managed care programs, in four U.S. regions: Midwest (34.1%), East (15.6%), South (23.9%), and West (26.4%).[35] The database included each patient's date of enrollment and pharmacy, medical, and institutional claims. Each medical claim was recorded with accompanying diagnostic codes from the *International Classification of Diseases, Ninth Revision* (ICD-9) that justified

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Presented at the International Conference of Pharmacoepidemiology, Bordeaux, France, August 20–25, 2004.

Supported by a grant from the Bristol-Myers Squibb Pharmaceutical Research Institute, Wallingford, Connecticut.

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the medical service. This geographically diversified claims database provides a large quantity of health information pertaining to the Medicaid population. The use of Medicaid or managed care claims databases for pharmacoepidemiologic studies has been well documented.[14, 23, 24, 33, 34]

Study Design

We used a retrospective nested case-control (population-based case-control) design. Claims data from January 1, 1998–December 31, 2002 (5 calendar years) were reviewed. To protect patient confidentiality, we deleted patient names, insurance plan identification numbers, and other patient identifiers from the claims database. Randomized patient numbers and patients' birth years were used for identification and calculation of age. The research project was approved by the University of Cincinnati Medical Center's institutional review board.

Study Cohort Identification

As shown in Figure 1, from 1998–2002 a total of 48,965 managed care Medicaid patients had at least one diagnosis of an affective disorder (ICD-9 code 296.xx) or cyclothymia (ICD-9 code 301.13). We excluded 4841 patients with schizophrenia (295.xx), 30,624 patients with depression only (296.2x and/or 296.3x), and 29 patients aged 65 years or greater during the study period. These exclusions enabled us to assess patients with bipolar disorder while avoiding confounding due to patients who had schizophrenia and/or depression or who were eligible for both Medicare and Medicaid. The final cohort consisted of 13,471 patients with bipolar disorder indicated by any of the following ICD-9 codes: 296.0, 296.1, and 296.4–296.8. Because less than 0.1% of the study group had cyclothymia, patients with that disorder were not categorized separately.

In keeping with other published retrospective cohort studies,[15–25] we selected a cohort of patients who had a minimum of 3 months of exposure to atypical or conventional antipsychotics or at least three filled prescriptions related to treatment of bipolar disorder during the study period. Incident cases of diabetes were identified by either the earliest diagnosis of ICD-9 code 250.xx or treatment for diabetes after the first identified use of antipsychotics. The date for the first diabetes diagnosis or first use of antidiabetic drugs was defined as the diabetes index date. To ensure that we were identifying incident cases of diabetes, we checked medical and prescription claim records for any diagnosis or treatment of diabetes before the diabetes index date. Patients were rejected as cases if they had a prescription for oral antidiabetic agents before the diabetes index date. The oral antidiabetic agents identified were sulfonylurea drugs (acetohexamide, glipizide, glyburide), a biguanide (metformin), thiazolidinediones (pioglitazone, rosiglitazone), α-glucosidase inhibitors (acarbose, miglitol), and the new drugs repaglinide and nateglinide.

The index date of bipolar diagnosis was the first date of diagnosis indicated by designated ICD-9 codes for bipolar disorder during the study period. For each case we matched five controls according to age at bipolar diagnosis index date (standard deviation of 5 yrs), sex, and the month and year of diagnosis of bipolar disorder. Controls meeting the matching criteria were selected at random using SAS, version 8.0 (SAS Institute Inc., Cary, NC), software. Controls were selected from a population of patients who had been diagnosed with bipolar disorder but were not diagnosed with or treated for diabetes at any time during the study period. Because the

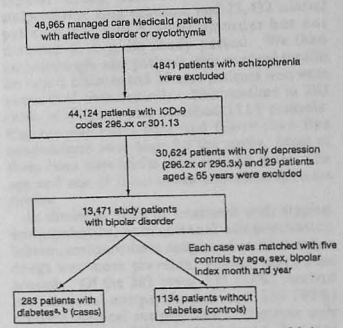

Figure 1. Patient flow diagram of incident cases of diabetes mellitus and controls from patients with bipolar disorder in the United States managed care Medicaid population, 1998–2002. [a]Incident cases of diabetes were identified by either earliest diagnosis of *International Classification of Diseases, Ninth Revision* (ICD-9) code 250.xx or treatment for diabetes. [b]Eighty-nine case patients with fewer than five matched controls were included in the analysis.

month and year of bipolar diagnosis were part of the matching criteria, the calendar time distributions of the bipolar index date were the same for both cases and controls.

Drug Use and Covariates

We classified antipsychotics as either conventional or atypical. The atypical antipsychotics were olanzapine, risperidone, quetiapine, ziprasidone, and clozapine. Aripiprazole was not included in this analysis as it was not available during the study period. The conventional antipsychotics were haloperidol, chlorpromazine, fluphenazine, loxapine, molindone, perphenazine, thioridazine, trifluoperazine, thiothixene, and pimozide. Other antipsychotics, such as thioxanthenes (flupenthixol, zuclopenthixol), pipotiazine, and methotrimeprazine were not included in this study because they were not available in the United States.

Published reports indicate that some drugs elevate blood glucose levels in some patients. Thus, our analysis incorporated data on administration of any of the following drugs during the study period: α-blockers (e.g., doxazosin, prazosin, terazosin), β-blockers (e.g., atenolol, betaxolol, bisoprolol), thiazide diuretics (e.g., chlorothiazide, chlorthalidone, polythiazide), corticosteroids (e.g., methylprednisolone, hydrocortisone), phenytoin, oral contraceptives containing norgesterol, and valproic acid.[30,36,37]

For both cases and controls, all prescription drug claims for treatment of bipolar disorder and diabetes were abstracted and reviewed. The follow-up period began with each patient's first bipolar diagnosis date and ended with the index date of diabetes, the end of the study period, or the end of the patient's enrollment in the managed care Medicaid program, whichever came first. We used dichotomous variables to indicate whether a patient had received concomitant drugs known to be associated with diabetes or hyperglycemia. All drug claims were identified by national drug codes.

In addition to drugs known to affect the risk of diabetes, we adjusted the analysis for psychiatric comorbidities (alcohol abuse, substance abuse disorder, personality disorder, anxiety disorder, and impulse-control disorder) and medical comorbidities (hypertension, weight gain, arthritis, cerebral vascular disease, chronic obstructive pulmonary disease, dyslipidemia, and coronary heart disease. The ICD-9 codes were used to identify comorbid conditions from either hospital or clinical encounters.

Statistical Analysis

All analyses were performed with SAS, version 8.0. Descriptive statistics were used to explore patient demographics and drug use categories. The age of each patient was simply the age at bipolar diagnosis. We conducted the Cox proportional hazard regression to assess the risk for diabetes associated with antipsychotic drugs due to the consideration of time-to-event with censoring and covariates. We determined hazard ratios for each risk factor with 95% confidence intervals. Patients taking conventional antipsychotics were the referent group in our comparison of diabetes risk among patients.

Results

Table 1 summarizes the characteristics of the study population. During the 5-year study period (1998–2002), of the 13,471 managed care Medicaid patients with bipolar disorder, 1730 (13%) had at least one prescription for atypical antipsychotics, 1918 (14%) had prescriptions for conventional antipsychotics, 1048 (8%) for lithium, 3013 (22%) for anticonvulsants, and 4011 (30%) for antidepressants.

The first cohorts we selected consisted of 323 case patients who developed diabetes after the bipolar index date and after their first antipsychotic drug exposure and 12,432 control patients who had bipolar disorder but not diabetes during the study period. We then excluded eight case patients who received insulin for type 1 diabetes and 32 case patients who were unmatched with controls. This resulted in 283 cases of diabetes and matched 1134 controls. Eighty-nine cases that had fewer than five controls/case were kept for the study. Most of those cases were adults older than 50 years. The age and sex of these cases and controls were similar.

As shown in Table 1, treatment with atypical antipsychotics, conventional antipsychotics, lithium, anticonvulsant drugs, and antidepressant drugs was more prevalent among cases than controls. Of the 283 cases, 133 (47%) received conventional antipsychotics, and 139 (49%) received atypical antipsychotics. Because only five patients (< 2%) received more than one atypical antipsychotic during the study period, we did not categorize this patient group.

Compared with patients receiving conventional antipsychotics, the risk for diabetes was greatest among patients taking risperidone (HR 3.8, 95% CI 2.7–5.3), olanzapine (HR 3.7, 95% CI

Table 1. Characteristics of the Study Patients

Characteristic	No. (%) of Patients	
	Cases (n=283)	Controls (n=1134)
Age (yrs)		
≤ 12	5 (1.77)	25 (2.20)
13–17	10 (3.53)	50 (4.41)
18–34	70 (24.73)	329 (29.01)
35–49	129 (45.58)	562 (49.56)
50–64	69 (24.38)	168 (14.81)
Sex		
Female	227 (80.21)	916 (80.78)
Male	56 (19.79)	218 (19.22)
Psychotherapeutic drugs[a]		
Lithium	153 (54.06)	119 (10.49)
Anticonvulsants[b]	164 (57.95)	289 (25.48)
Atypical antipsychotics	139 (49.12)	164 (14.46)
Olanzapine	51 (18.02)	79 (6.97)
Quetiapine	18 (6.36)	20 (1.76)
Risperidone	65 (22.97)	61 (5.38)
Ziprasidone	2 (0.71)	3 (0.26)
Clozapine	3 (1.06)	2 (0.18)
Antidepressants	174 (61.48)	374 (32.98)
Conventional antipsychotics	133 (47.00)	213 (18.78)
Other concomitant drugs[a]		
β-Blockers	63 (22.26)	86 (7.58)
α-Blockers	4 (1.41)	7 (0.62)
Corticosteroids	78 (27.56)	171 (15.08)
Thiazide diuretics	30 (10.60)	38 (3.35)
Oral contraceptives	9 (3.18)	17 (1.50)
Valproic acid	1 (0.35)	8 (0.71)
Phenytoin	5 (1.76)	18 (1.59)
Psychiatric comorbidities[c]		
Alcohol abuse	22 (7.77)	147 (12.96)
Substance abuse	41 (14.48)	146 (12.87)
Anxiety disorder	150 (53.00)	445 (39.24)
Impulse-control disorder	5 (1.76)	22 (1.94)
Personality disorder	21 (7.42)	65 (5.73)
Medical comorbidities[c]		
Hypertension	130 (45.94)	194 (17.11)
Weight gain	79 (27.92)	90 (7.94)
Arthritis	16 (5.65)	30 (2.65)
Chronic obstructive pulmonary disease	41 (14.49)	71 (6.26)
Cerebral vascular disease	15 (5.30)	27 (2.38)
Coronary heart disease	11 (3.88)	5 (0.44)
Dyslipidemia	8 (2.83)	5 (0.44)

[a]Some patients received more than one drug.
[b]Anticonvulsants were divalproex and carbamazepine.
[c]Some patients were diagnosed with more than one comorbid condition.

2.5–5.3), quetiapine (HR 2.5, 95% CI 1.4–4.3), and the anticonvulsants divalproex and carbamazepine (HR 1.6, 95% CI 1.2–2.1; Table 2). These data were obtained in a process that controlled for the covariates of age, sex, and duration of follow-up; use of lithium, anticonvulsants, and antidepressants; concomitant drugs (not related to bipolar disorder); and psychiatric and medical comorbidities. In addition, patients whose bipolar disorder was coupled with substance abuse, hypertension, and/or weight gain had a significantly higher risk for diabetes than their counterparts.

Discussion

This multistate, population-based, nested case-control study examined the risk of diabetes

associated with use of antipsychotics in Medicaid patients with bipolar disorder. After controlling for personal risk factors and concomitant drug use, we found that patients receiving atypical antipsychotics for bipolar disorder are at increased risk for diabetes. Our findings add to the body of observational evidence indicating that certain atypical antipsychotics may be associated with an increased risk for diabetes among patients with bipolar disorder.[27–29] It is unclear, however, whether the diabetes in the study population is due to the use of atypical antipsychotics versus the underlying condition of bipolar disorder versus characteristics of the Medicaid population, such as low socioeconomic status, poor overall physical health, unhealthy lifestyles, and poor access to health care services.

Atypical antipsychotics are generally regarded as having less potential for causing extrapyramidal symptoms and a higher serotonin:dopamine receptor affinity compared with conventional antipsychotics.[11, 12] Recent literature indicates that clozapine, olanzapine, and risperidone are more likely to be associated with diabetes (indicated by diabetic ketoacidosis and an atherogenic lipid profile) than other atypical agents.[14, 28, 29, 38, 39] One possible mechanism for hyperglycemia is impairment of insulin resistance, which may occur because of weight gain or a change in body fat distribution or by a direct effect on insulin-sensitive target tissues.[2, 10, 11]

Our findings are comparable to data from published pharmacoepidemiologic studies of patients with schizophrenia.[14, 23–25] For example, reported HRs for diabetes in patients with schizophrenia were 1.2–5.8 for olanzapine and 1.1–2.2 for risperidone.[14, 23–25, 33] These values can be compared with the HRs we obtained for the same drugs in patients with bipolar disorder: HR 3.7 (95% CI 2.5–5.3) for olanzapine and 3.8 (95% CI 2.7–5.3) for risperidone (Table 2). After controlling for comorbidities, personal risk factors, and concomitant drugs, we also found that quetiapine increases the risk for diabetes in patients with bipolar disorder (HR 2.5, 95% CI 1.4–4.4). Although quetiapine has been linked to diabetes in case reports,[40–43] earlier studies have failed to confirm this association.[33] This may be due to their small sample sizes or lack of control for confounding variables.[44] The HRs associated with clozapine (HR 2.9, 95% CI 0.9–9.6) and ziprasidone (HR 4.3, 95% CI 1.0–18.9) in our study were large, but they were not statistically significant. This might be due to the small number of patients in our study who received either clozapine or ziprasidone. Long-term data from large, randomized, controlled trials are needed to more explicitly examine the association between diabetes and various atypical antipsychotic drugs.

As shown in Table 2, in addition to antipsychotic use, diabetes risk is also associated with weight gain and hypertension. As the literature indicates, olanzapine, clozapine, and risperidone are associated with weight gain,[13, 45, 46] hyperlipidemia, and hypertriglyceridemia, all of which are independent risk factors for heart disease.[14, 47, 48] Our findings of elevated HRs for weight gain and hypertension make it likely that the incident cases of diabetes we identified were associated with metabolic syndrome. Our data also show that patients with substance abuse have a heightened risk for diabetes. It is possible that these patients might have less healthy lifestyles, poorer drug compliance, or poorer access to health care services than patients without substance abuse.[49, 50] Poor drug compliance might lead to drug overdose, which could increase the risk for diabetes in this population.[33]

Our study had several limitations. Children, women, and low-income populations are overrepresented in the Medicaid population. Thus, our findings might not be indicative of the general population. We inferred drug use from automated pharmacy claims data. Although baseline drug use differed between cases and controls, we tried to adjust for these differences with the Cox proportional hazard model. Because of the retrospective nature of a claims database review, we could not assess individual patients with regard to severity of bipolar disorder, socioeconomic class, lipid profiles, fasting glucose concentrations, or changes in body mass index related to weight gain.

Moreover, data on patients' ethnicity were missing when PharMetrics (data vendor) collected medical claims information from participating managed care organizations. Another concern is that clinicians may have prescribed one drug versus another based on patients' specific symptoms. We attempted to reduce this potential confounding bias by adjusting for known concomitant drugs and comorbidities. We also included dyslipidemia and coronary heart disease as comorbidities, as these provide a rough proxy for patients at high risk for diabetes. It is possible that we underestimated the prevalence of diabetes due to our study's limited time window, changes in

Table 2. Hazard Ratios for Diabetes Risk

Variable	Hazard Ratio[a]	95% CI
Pyschotherapeutic drugs		
Conventional antipsychotic	1.000	1.000
Olanzapine	3.664	2.542–5.281
Quetiapine	2.476	1.427–4.296
Risperidone	3.771	2.699–5.269
Ziprasidone	4.297	0.976–18.923
Clozapine	2.872	0.862–9.575
Lithium	1.016	0.729–1.416
Anticonvulsant[b]	1.571	1.153–2.140
Antidepressant	1.138	0.842–1.538
Other concomitant drugs		
β-Blocker	1.329	0.960–1.839
α-Blocker	0.669	0.235–1.907
Corticosteroid	1.048	0.775–1.417
Thiazide diuretic	1.254	0.807–1.947
Oral contraceptive	1.766	0.829–3.761
Valproic acid	0.359	0.049–2.640
Phenytoin	0.428	0.167–1.098
Psychiatric comorbidities		
Alcohol abuse	0.623	0.390–0.996
Substance abuse	1.491	1.033–2.152
Anxiety disorder	1.257	0.963–1.640
Impulse-control disorder	0.499	0.183–1.360
Personality disorder	1.096	0.673–1.783
Medical comorbidities		
Hypertension	1.636	1.208–2.216
Weight gain	2.516	1.876–3.375
Arthritis	0.920	0.535–1.582
Chronic obstructive pulmonary disease	1.289	0.865–1.921
Cerebral vascular disease	1.223	0.702–2.129
Coronary heart disease	1.134	0.588–2.188
Dyslipidemia	1.844	0.813–4.182

CI = confidence interval.
[a]Model for age, sex, bipolar follow-up months, use of drugs, psychiatric and medical comorbidities.
[b]Anticonvulsants were divalproex and carbamazepine.

managed care enrollment, and the fact that some mental services may not have been billed to patients' managed care organizations. Finally, we identified comorbid conditions by diagnostic codes without considering the contribution of drugs to weight gain, hypertension, cerebral vascular disease, and other disorders.

Despite the above limitations, our study adds to the limited literature about diabetes risk in patients with bipolar disorder in managed care Medicaid programs. It provides useful information on disease management strategies in terms of selection of mood stabilizers and consideration of relevant comorbidities for patients with bipolar disorder, especially the managed care Medicaid population. Atypical antipsychotics provide great benefit to a wide variety of individuals with psychiatric disorders; nevertheless, they have a constellation of adverse effects related to increased risk for weight gain, diabetes, and dyslipidemia.[10,11]

Conclusion

The atypical antipsychotics olanzapine, risperidone, and quetiapine are consistently associated with increased risk for diabetes in patients with bipolar disorder after adjustment for relevant risk factors. Metabolic complications are a clinically important issue for patients receiving antipsychotic therapy. The choice of olanzapine, risperidone, or quetiapine for a specific patient with bipolar disorder should involve consideration of each agent's risks and benefits, with attention to comorbid conditions relevant to the patient's risk for diabetes. Thus,

the propensity of an antipsychotic agent to induce or exacerbate diabetes is a critical consideration in the selection of an agent to treat bipolar disorder.

Acknowledgment

The authors would like to thank Sharmane Guo for her technical support and language edits.

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Exhibit A
Plaintiff's Memorandum Describing
Its Claims and Proofs
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Reference Manual on Scientific Evidence

Second Edition

WEST GROUP
ST. PAUL, MN
2000

Reference Guide on Epidemiology

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CONTENTS

I. Introduction

Epidemiology is the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations. The purpose of epidemiology is to better understand disease causation and to prevent disease in groups of individuals. Epidemiology assumes that disease is not distributed randomly in a group of individuals and that identifiable subgroups, including those exposed to certain agents, are at increased risk of contracting particular diseases.[1]

Judges and juries increasingly are presented with epidemiologic evidence as the basis of an expert's opinion on causation.[2] In the courtroom, epidemiologic research findings[3] are offered to establish or dispute whether exposure to an agent[4] caused a harmful effect or disease.[5] Epidemiologic evidence identifies

1. Although epidemiologists may conduct studies of beneficial agents that prevent or cure disease or other medical conditions, this reference guide refers exclusively to outcomes as diseases, because they are the relevant outcomes in most judicial proceedings in which epidemiology is involved.

2. Epidemiologic studies have been well received by courts trying mass tort suits. Well-conducted studies are uniformly admitted. 2 Modern Scientific Evidence: The Law and Science of Expert Testimony § 28–1.1, at 302–03 (David L. Faigman et al. eds., 1997) [hereinafter Modern Scientific Evidence]. It is important to note that often the expert testifying before the court is not the scientist who conducted the study or series of studies. *See, e.g.*, DeLuca v. Merrell Dow Pharms., Inc., 911 F.2d 941, 953 (3d Cir. 1990) (pediatric pharmacologist expert's credentials sufficient pursuant to Fed. R. Evid. 702 to interpret epidemiologic studies and render an opinion based thereon); *cf.* Landrigan v. Celotex Corp., 605 A.2d 1079, 1088 (N.J. 1992) (epidemiologist permitted to testify to both general causation and specific causation); Loudermill v. Dow Chem. Co., 863 F.2d 566, 569 (8th Cir. 1988) (toxicologist permitted to testify that chemical caused decedent's death).

3. An epidemiologic study, which often is published in a medical journal or other scientific journal, is hearsay. An epidemiologic study that is performed by the government, such as one performed by the Centers for Disease Control (CDC), may be admissible based on the hearsay exception for government records contained in Fed. R. Evid. 803(8)(C). *See* Ellis v. International Playtex, Inc., 745 F.2d 292, 300–01 (4th Cir. 1984); Kehm v. Procter & Gamble Co., 580 F. Supp. 890, 899 (N.D. Iowa 1982), *aff'd sub nom.* Kehm v. Procter & Gamble Mfg. Co., 724 F.2d 613 (8th Cir. 1983). A study that is not conducted by the government might qualify for the learned treatise exception to the hearsay rule, Fed. R. Evid. 803(18), or possibly the catchall exceptions, Fed. R. Evid. 803(24) & 804(5). *See Ellis*, 745 F.2d at 305, 306 & n.18.

In any case, an epidemiologic study might be part of the basis of an expert's opinion and need not be independently admissible pursuant to Fed. R. Evid. 703. *See In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1240 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied*, 487 U.S. 1234 (1988); *cf.* Grassis v. Johns-Manville Corp., 591 A.2d 671, 676 (N.J. Super. Ct. App. Div. 1991) (epidemiologic study offered in evidence to support expert's opinion under New Jersey evidentiary rule equivalent to Fed. R. Evid. 703).

4. We use *agent* to refer to any substance external to the human body that potentially causes disease or other health effects. Thus, drugs, devices, chemicals, radiation, and minerals (e.g., asbestos) are all agents whose toxicity an epidemiologist might explore. A single agent or a number of independent agents may cause disease, or the combined presence of two or more agents may be necessary for the development of the disease. Epidemiologists also conduct studies of individual characteristics, such as blood pressure and diet, which might pose risks, but those studies are rarely of interest in judicial proceedings. Epidemiologists may also conduct studies of drugs and other pharmaceutical products to assess their efficacy and safety.

5. DeLuca v. Merrell Dow Pharms., Inc., 911 F.2d 941, 945–48, 953–59 (3d Cir. 1990) (litigation

agents that are associated with an increased risk of disease in groups of individuals, quantifies the amount of excess disease that is associated with an agent, and provides a profile of the type of individual who is likely to contract a disease after being exposed to an agent. Epidemiology focuses on the question of general causation (i.e., is the agent capable of causing disease?) rather than that of specific causation (i.e., did it cause disease in a particular individual?).[6] For example, in the 1950s Doll and Hill and others published articles about the increased risk of lung cancer in cigarette smokers. Doll and Hill's studies showed that smokers who smoked ten to twenty cigarettes a day had a lung cancer mortality rate that was about ten times higher than that for nonsmokers.[7] These studies identified an association between smoking cigarettes and death from lung cancer, which contributed to the determination that smoking causes lung cancer.

However, it should be emphasized that *an association is not equivalent to causation*.[8] An association identified in an epidemiologic study may or may not be causal.[9] Assessing whether an association is causal requires an understanding of

over morning sickness drug, Bendectin); Cook v. United States, 545 F. Supp. 306, 307–16 (N.D. Cal. 1982) (swine flu vaccine alleged to have caused plaintiff's Guillain-Barré disease); Allen v. United States, 588 F. Supp. 247, 416–25 (D. Utah 1984) (residents near atomic test site claimed exposure to radiation caused leukemia and other cancers), *rev'd on other grounds*, 816 F.2d 1417 (10th Cir. 1987), *cert. denied*, 484 U.S. 1004 (1988); *In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 780–90 (E.D.N.Y. 1984) (Vietnam veterans exposed to Agent Orange and dioxin contaminant brought suit for various diseases and birth defects in their offspring), *aff'd*, 818 F.2d 145 (2d Cir. 1987); Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1115 (5th Cir. 1991) (cancer alleged to have resulted from exposure to nickel-cadmium fumes), *cert. denied*, 503 U.S. 912 (1992); Kehm v. Procter & Gamble Co., 580 F. Supp. 890, 898–902 (N.D. Iowa 1982) (toxic shock syndrome alleged to result from use of Rely tampons), *aff'd sub nom.* Kehm v. Procter & Gamble Mfg. Co., 724 F.2d 613 (8th Cir. 1983).

6. This terminology and the distinction between general causation and specific causation is widely recognized in court opinions. *See, e.g.*, Kelley v. American Heyer-Schulte Corp., 957 F. Supp. 873, 875–76 (W.D. Tex. 1997) (recognizing the different concepts of general causation and specific causation), *appeal dismissed*, 139 F.3d 899 (5th Cir. 1998); Cavallo v. Star Enter., 892 F. Supp. 756, 771 n.34 (E.D. Va. 1995), *aff'd in part and rev'd in part*, 100 F.3d 1150 (4th Cir. 1996), *cert. denied*, 522 U.S. 1044 (1998); Casey v. Ohio Med. Prods., 877 F. Supp. 1380, 1382 (N.D. Cal. 1995). For a discussion of specific causation, see *infra* § VII.

7. Richard Doll & A. Bradford Hill, *Lung Cancer and Other Causes of Death in Relation to Smoking*, 2 Brit. Med. J. 1071 (1956).

8. *See* Kelley v. American Heyer-Schulte Corp., 957 F. Supp 873, 878 (W.D. Tex. 1997), *appeal dismissed*, 139 F.3d 899 (5th Cir. 1998). Association is more fully discussed *infra* § III. The term is used to describe the relationship between two events (e.g., exposure to a chemical agent and development of disease) that occur more frequently together than one would expect by chance. Association does not necessarily imply a causal effect. Causation is used to describe the association between two events when one event is a necessary link in a chain of events that results in the effect. Of course, alternative causal chains may exist that do not include the agent but that result in the same effect. Epidemiologic methods cannot deductively prove causation; indeed, all empirically based science cannot affirmatively prove a causal relation. *See, e.g.*, Stephan F. Lanes, *The Logic of Causal Inference in Medicine*, *in* Causal Inference 59 (Kenneth J. Rothman ed., 1988). However, epidemiologic evidence can justify an inference that an agent causes a disease. *See infra* § V.

9. *See infra* § IV.

the strengths and weaknesses of the study's design and implementation, as well as a judgment about how the study findings fit with other scientific knowledge. It is important to emphasize that most studies have flaws.[10] Some flaws are inevitable given the limits of technology and resources. In evaluating epidemiologic evidence, the key questions, then, are the extent to which a study's flaws compromise its findings and whether the effect of the flaws can be assessed and taken into account in making inferences.

A final caveat is that employing the results of group-based studies of risk to make a causal determination for an individual plaintiff is beyond the limits of epidemiology. Nevertheless, a substantial body of legal precedent has developed that addresses the use of epidemiologic evidence to prove causation for an individual litigant through probabilistic means, and these cases are discussed later in this reference guide.[11]

The following sections of this reference guide address a number of critical issues that arise in considering the admissibility of, and weight to be accorded to, epidemiologic research findings. Over the past couple of decades, courts frequently have confronted the use of epidemiologic studies as evidence and recognized their utility in proving causation. As the Third Circuit observed in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*: "The reliability of expert testimony founded on reasoning from epidemiological data is generally a fit subject for judicial notice; epidemiology is a well-established branch of science and medicine, and epidemiological evidence has been accepted in numerous cases."[12]

Three basic issues arise when epidemiology is used in legal disputes and the methodological soundness of a study and its implications for resolution of the question of causation must be assessed:

1. Do the results of an epidemiologic study reveal an association between an agent and disease?
2. What sources of error in the study may have contributed to an inaccurate result?
3. If the agent is associated with disease, is the relationship causal?

Section II explains the different kinds of epidemiologic studies, and section III addresses the meaning of their outcomes. Section IV examines concerns about the methodological validity of a study, including the problem of sampling er-

10. *See In re* Orthopedic Bone Screw Prods. Liab. Litig., MDL No. 1014, 1997 U.S. Dist. LEXIS 6441, at *26–*27 (E.D. Pa. May 5, 1997) (holding that despite potential for several biases in a study that "may . . . render its conclusions inaccurate," the study was sufficiently reliable to be admissible); Joseph L. Gastwirth, *Reference Guide on Survey Research*, 36 Jurimetrics J. 181, 185 (1996) (review essay) ("One can always point to a potential flaw in a statistical analysis.").

11. *See infra* § VII.

12. 911 F.2d 941, 954 (3d Cir. 1990); *see also* Smith v. Ortho Pharm. Corp., 770 F. Supp. 1561, 1571 (N.D. Ga. 1991) (explaining increased reliance of courts on epidemiologic evidence in toxic substances litigation).

Far more courts have confronted the role that epidemiology plays with regard to the sufficiency of the evidence and the burden of production. The civil burden of proof is described most often as requiring the fact finder to "believe that what is sought to be proved . . . is more likely true than not true."[135] The relative risk from epidemiologic studies can be adapted to this 50% plus standard to yield a probability or likelihood that an agent caused an individual's disease.[136] An important caveat is necessary, however. The discussion below speaks in terms of the magnitude of the relative risk or association found in a study. However, before an association or relative risk is used to make a statement about the probability of individual causation, the inferential judgment, described in section V, that the association is truly causal rather than spurious is required: "[A]n agent cannot be considered to cause the illness of a specific person unless

concluded that an association between tampon use and menstrually related TSS [toxic shock syndrome] cases exists."), *aff'd sub nom.* Kehm v. Procter & Gamble Mfg. Co., 724 F.2d 613 (8th Cir. 1984).

Hearsay concerns may limit the independent admissibility of the study (*see supra* note 3), but the study could be relied on by an expert in forming an opinion and may be admissible pursuant to Fed. R. Evid. 703 as part of the underlying facts or data relied on by the expert.

In *Ellis v. International Playtex, Inc.*, 745 F.2d 292, 303 (4th Cir. 1984), the court concluded that certain epidemiologic studies were admissible despite criticism of the methodology used in the studies. The court held that the claims of bias went to the studies' weight rather than their admissibility. *Cf.* Christophersen v. Allied-Signal Corp., 939 F.2d 1106, 1109 (5th Cir. 1991) ("As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility . . . ."), *cert. denied*, 503 U.S. 912 (1992).

134. Even if evidence is relevant, it may be excluded if its probative value is substantially outweighed by prejudice, confusion, or inefficiency. Fed. R. Evid. 403. However, exclusion of an otherwise relevant epidemiologic study on Rule 403 grounds is unlikely.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591 (1993), the Court invoked the concept of "fit," which addresses the relationship of an expert's scientific opinion to the facts of the case and the issues in dispute. In a toxic substance case in which cause in fact is disputed, an epidemiologic study of the same agent to which the plaintiff was exposed that examined the association with the same disease from which the plaintiff suffers would undoubtedly have sufficient "fit" to be a part of the basis of an expert's opinion. The Court's concept of "fit," borrowed from *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985), appears equivalent to the more familiar evidentiary concept of probative value, albeit one requiring assessment of the scientific reasoning the expert used in drawing inferences from methodology or data to opinion.

135. 2 Edward J. Devitt & Charles B. Blackmar, Federal Jury Practice and Instruction § 71.13 (3d ed. 1977); *see also* United States v. Fatico, 458 F. Supp. 388, 403 (E.D.N.Y. 1978) ("Quantified, the preponderance standard would be 50%+ probable."), *aff'd*, 603 F.2d 1053 (2d Cir. 1979), *cert. denied*, 444 U.S. 1073 (1980).

136. An adherent of the frequentist school of statistics would resist this adaptation, which may explain why so many epidemiologists and toxicologists also resist it. To take the step identified in the text of using an epidemiologic study outcome to determine the probability of specific causation requires a shift from a frequentist approach, which involves sampling or frequency data from an empirical test, to a subjective probability about a discrete event. Thus, a frequentist might assert, after conducting a sampling test, that 60% of the balls in an opaque container are blue. The same frequentist would resist the statement, "The probability that a single ball removed from the box and hidden behind a screen is blue is 60%." The ball is either blue or not, and no frequentist data would permit the latter statement. "[T]here is no logically rigorous definition of what a statement of probability means with reference to an individual instance . . . ." Lee Loevinger, *On Logic and Sociology*, 32 Jurimetrics J. 527, 530 (1992); *see*

it is recognized as a cause of that disease in general."[137] The following discussion should be read with this caveat in mind.[138]

The threshold for concluding that an agent was more likely than not the cause of an individual's disease is a relative risk greater than 2.0. Recall that a relative risk of 1.0 means that the agent has no effect on the incidence of disease. When the relative risk reaches 2.0, the agent is responsible for an equal number of cases of disease as all other background causes. Thus, a relative risk of 2.0 (with certain qualifications noted below) implies a 50% likelihood that an exposed individual's disease was caused by the agent. A relative risk greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent.[139] A substantial number of courts in a variety of toxic substances cases have accepted this reasoning.[140]

also Steve Gold, Note, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion and Statistical Evidence*, 96 Yale L.J. 376, 382–92 (1986). Subjective probabilities about discrete events are the product of adherents to Bayes Theorem. *See* Kaye, *supra* note 57, at 54–62; David H. Kaye & David A. Freedman, Reference Guide on Statistics § IV.D, in this manual.

137. Cole, *supra* note 53, at 10284.

138. We emphasize this caveat, both because it is not intuitive and because some courts have failed to appreciate the difference between an association and a causal relationship. *See, e.g.*, Forsyth v. Eli Lilly & Co., Civ. No. 95-00185 ACK, 1998 U.S. Dist. LEXIS 541, at *26–*31 (D. Haw. Jan. 5, 1998). *But see* Berry v. CSX Transp., Inc., 709 So. 2d 552, 568 (Fla. Dist. Ct. App. 1998) ("From epidemiological studies demonstrating an association, an epidemiologist may or may not infer that a causal relationship exists.").

139. *See* Davies v. Datapoint Corp., No. 94-56-P-DMC, 1995 U.S. Dist. LEXIS 21739, at *32–*35 (D. Me. Oct. 31, 1995) (holding that epidemiologist could testify about specific causation, basing such testimony on the probabilities derived from epidemiologic evidence).

140. *See* DeLuca v. Merrell Dow Pharms., Inc., 911 F.2d 941, 958–59 (3d Cir. 1990) (Bendectin allegedly caused limb reduction birth defects); *In re* Joint E. & S. Dist. Asbestos Litig., 964 F.2d 92 (2d Cir. 1992) (relative risk less than 2.0 may still be sufficient to prove causation); Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1320 (9th Cir.) (requiring that plaintiff demonstrate a relative risk of 2), *cert. denied*, 516 U.S. 869 (1995); Pick v. American Med. Sys., Inc., 958 F. Supp. 1151, 1160 (E.D. La. 1997) (recognizing that a relative risk of 2 applies a 50% probability of specific causation, but recognizing that a study with a lower relative risk is admissible, although ultimately it may be insufficient to support a verdict on causation); Sanderson v. International Flavors & Fragrances, Inc., 950 F. Supp. 981, 1000 (C.D. Cal. 1996) (acknowledging a relative risk of 2 as a threshold for plaintiff to prove specific causation); Manko v. United States, 636 F. Supp. 1419, 1434 (W.D. Mo. 1986) (swine flu vaccine allegedly caused Guillain-Barré syndrome), *aff'd in part*, 830 F.2d 831 (8th Cir. 1987); Marder v. G.D. Searle & Co., 630 F. Supp. 1087, 1092 (D. Md. 1986) (pelvic inflammatory disease allegedly caused by Copper 7 IUD), *aff'd without op. sub nom.* Wheelahan v. G.D. Searle & Co., 814 F.2d 655 (4th Cir. 1987); *In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740, 835–37 (E.D.N.Y. 1984) (Agent Orange allegedly caused a wide variety of diseases in Vietnam veterans and their offspring), *aff'd*, 818 F.2d 145 (2d Cir. 1987), *cert. denied*, 484 U.S. 1004 (1988); Cook v. United States, 545 F. Supp. 306, 308 (N.D. Cal. 1982) (swine flu vaccine allegedly caused Guillain-Barré syndrome); Landrigan v. Celotex Corp., 605 A.2d 1079, 1087 (N.J. 1992) (relative risk greater than 2.0 "support[s] an inference that the exposure was the probable cause of the disease in a specific member of the exposed population"); Merrell Dow Pharms., Inc. v. Havner, 953 S.W.2d 706, 718 (Tex. 1997) ("The use of scientifically reliable epidemiological studies and the requirement of more than a doubling of the risk strikes a balance between the needs of our legal system and the limits of science."). *But cf. In re* Fibreboard Corp., 893 F.2d 706, 711–12 (5th Cir. 1990) (The court disapproved a trial in which several representative

exposure to the agent caused the plaintiff's disease. Similarly, an individual plaintiff may be able to rule out other known (background) causes of the disease, such as genetics, that increase the likelihood that the agent was responsible for that plaintiff's disease. Pathological-mechanism evidence may be available for the plaintiff that is relevant to the cause of the plaintiff's disease.[145] Before any causal relative risk from an epidemiologic study can be used to estimate the probability that the agent in question caused an individual plaintiff's disease, consideration of these (and similar) factors is required.[146]

Having additional evidence that bears on individual causation has led a few courts to conclude that a plaintiff may satisfy his or her burden of production even if a relative risk less than 2.0 emerges from the epidemiologic evidence.[147] For example, genetics might be known to be responsible for 50% of the incidence of a disease independent of exposure to the agent.[148] If genetics can be ruled out in an individual's case, then a relative risk greater than 1.5 might be sufficient to support an inference that the agent was more likely than not responsible for the plaintiff's disease.[149]

145. *See* Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528 (6th Cir.) (plaintiff's expert relied predominantly on pathogenic evidence), *cert. denied*, 510 U.S. 914 (1993).

146. *See* Merrell Dow Pharms., Inc. v. Havner, 953 S.W.2d 706, 720 (Tex. 1997); Mary Carter Andrues, Note, *Proof of Cancer Causation in Toxic Waste Litigation*, 61 S. Cal. L. Rev. 2075, 2100–04 (1988). An example of a judge sitting as fact finder and considering individual factors for a number of plaintiffs in deciding cause in fact is contained in *Allen v. United States*, 588 F. Supp. 247, 429–43 (D. Utah 1984), *rev'd on other grounds*, 816 F.2d 1417 (10th Cir. 1987), *cert. denied*, 484 U.S. 1004 (1988); *see also* Manko v. United States, 636 F. Supp. 1419, 1437 (W.D. Mo. 1986), *aff'd*, 830 F.2d 831 (8th Cir. 1987).

147. *See, e.g.*, Grassis v. Johns-Manville Corp., 591 A.2d 671, 675 (N.J. Super. Ct. App. Div. 1991): "The physician or other qualified expert may view the epidemiological studies and factor out other known risk factors such as family history, diet, alcohol consumption, smoking . . . or other factors which might enhance the remaining risks, even though the risk in the study fell short of the 2.0 correlation." *See also In re* Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124 (2d Cir. 1995) (holding that plaintiff could provide sufficient evidence of causation without proving a relative risk greater than 2); *In re* Joint E. & S. Dist. Asbestos Litig., 964 F.2d 92, 97 (2d Cir. 1992), *rev'g* 758 F. Supp. 199, 202–03 (S.D.N.Y. 1991) (requiring relative risk in excess of 2.0 for plaintiff to meet burden of production); Jones v. Owens-Corning Fiberglas Corp., 672 A.2d 230 (N.J. Super. Ct. App. Div. 1996).

148. *See In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758–59 (3d Cir. 1994) (discussing the technique of differential diagnosis to rule out other known causes of a disease for a specific individual).

149. The use of probabilities in excess of .50 to support a verdict results in an all-or-nothing approach to damages that some commentators have criticized. The criticism reflects the fact that defendants responsible for toxic agents with a relative risk just above 2.0 may be required to pay damages not only for the disease that their agents caused, but also for all instances of the disease. Similarly, those defendants whose agents increase the risk of disease by less than a doubling may not be required to pay damages for any of the disease that their agents caused. *See, e.g.*, 2 American Law Inst., Reporter's Study on Enterprise Responsibility for Personal Injury: Approaches to Legal and Institutional Change 369–75 (1991). To date, courts have not adopted a rule that would apportion damages based on the probability of cause in fact in toxic substances cases.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,
Plaintiff,
vs.
ELI LILLY AND COMPANY,
Defendant.

Case No. 3AN- 06-05630CI

ROUTINE PRETRIAL ORDER

Pursuant to the Uniform Pretrial Order "UPO"; Administrative Order 3AO-03-04 this Court hereby issues the Routine Pretrial Order in this case.

Trial Date

Trial will commence at 8:30 A.M. on March 3, 2008.

Trial Length/Division

The trial will last 20 trial days, divided between the parties as follows: Plaintiff 10.0 trial days and Defendant 10.0 trial days. The trial day allocation includes each parties' jury selection, opening statement, witness examination (including cross-examination of other parties' witnesses) and closing statement.

Jury

A jury trial has been timely requested by a party. The jury will consist of 12 persons and 2 alternates.

Summary of Pretrial Deadlines

The following is a summary of the deadlines imposed by the Routine Pretrial Order. The parties and their attorneys are responsible for reading and following the Alaska Civil Rules and the UPO, which contain the detailed requirements associated with these deadlines. The dates listed are based on the forgoing trial date. These dates remain the same even if the actual trial date changes, unless otherwise ordered by this Court.

Move to Amend RPO	March 11, 2007
Amend Pleadings and Join Parties without Motion	February 9, 2007
Preliminary Witness Lists	March 1, 2007
Retained Expert ID	August 1, 2007
Supplemental Retained Expert ID	September 1, 2007
Final Date to Serve Written Discovery	October 29, 2007
Join Specifically Identified Potentially Responsible Persons and Determine whether a Sufficient Opportunity to Join is Lacking	October 29, 2007
Other Expert Opinion Testimony Summary	November 5, 2007
Retained Expert Reports	November 12, 2007
Final Date to Depose Lay Witnesses	December 10, 2007
Dispositive and Rule of Law Motions	December 10, 2007
Motions Re Expert Opinion Evidence	January 7, 2008
Final Date to Depose Expert Witnesses	January 7, 2008
Discovery Motions	January 7, 2008

Deposition/Telephonic Designations	January 21, 2008
Deposition Objections/ Counter - Designations	January 28, 2008
Other Motions	February 4, 2008
Deposition Counter - Designation Objections	February 4, 2008
Serve Jury Instructions/Exhibits	February 4, 2008
Meet Re Jury Instructions/Exhibits	February 11, 2008
Trial Briefs	February 18, 2008
Objections Re Jury Instructions/Exhibits	February 18, 2008
Plaintiff's Final Witness List	February 18, 2008
Defendant's Final Witness List	February 22, 2008
File Jury Instructions	February 25, 2008
Pretrial Conference	February 22, 2008 at 3:00 p.m.
File Joint Exhibit List With Clerk	March 3, 2008

Dated at Anchorage, Alaska this 10th day of January, 2007

Mark Rindner

Mark Rindner
Superior Court Judge

I certify that on 1-10-07 a copy of the above order was mailed to each of the following at their addresses of record:
E. Sanders C. Sniffen
B. Jamison

Administrative Assistant

3AN-137CIV
Routine Pretrial Order
Case No. 06-05630CI
Page 3 of 3

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	Case No. 3AN-06-5630 CIV
Defendant.	)	
	)	

ORDER APPOINTING DISCOVERY MASTER

Pursuant to Alaska R. Civ. P. 53, the Court hereby appoints _____ as the discovery master ("DM") in the above-captioned matter. Subject to the procedures set forth in this Order, the DM is hereby authorized to decide all issues arising under Alaska R. Civ. P. 26-37 in this action. The Court hereby sets the following procedures and guidelines to be followed in submitting disputes to the DM for consideration.

1. Before submitting a discovery dispute to the DM for resolution, the parties shall make a good faith effort to resolve any such dispute. Any motion filed with the DM must have the certification required by Civil Rule 37(a)(2)(A) stating that the parties attempted to resolve the dispute prior to seeking the DM's assistance.

not used 1-10-07

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2. If the parties are unable to resolve the dispute, motions may be filed with the DM. The party or parties to whom the motion is directed shall file an opposition within seven days from the date the motion is served (10 days if mailed). Any motion and any opposition shall be limited to 10 pages of argument and 30 pages of exhibits, unless the filing party can make a good cause showing why additional pages are needed. The party filing the motion may file a reply memorandum. Any reply shall be filed within three days from the date the opposition is served (six days if mailed). Any reply shall be limited to five pages of argument and 10 pages of exhibits, unless the party filing the reply memorandum can make a good cause showing why additional pages are needed. Each side shall submit a proposed order for the DM's signature.

3. In the event that a discovery issue arises which requires immediate resolution in order to prevent undue expense or delay (e.g., an issue arising over an instruction to a deponent not to answer a deposition question at an out-of-state deposition attended by multiple counsel), one or more parties may attempt to contact the DM by telephone for his expedited ruling on the discovery issue. If the DM cannot be reached, the party(ies) seeking immediate resolution of the discovery issue may attempt to contact the trial judge for his similar resolution of the issue.

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4. Except as otherwise noted herein, all discovery disputes must first be submitted to the DM for resolution. In his discretion, the DM may schedule oral argument on any dispute presented to him for resolution.

5. The DM shall decide the motions in the order they are received, unless a party can make a good cause showing why they should be taken out of order. The DM shall endeavor to decide the motions promptly. The DM will issue a written decision on each dispute presented to him for resolution.

6. The parties shall give telephonic notice to the DM's secretary that a motion is ripe for decision.

7. Once the DM issues a decision, a party has a right to appeal the decision to the Court. An appeal shall be filed with the Court within three days of the DM's decision (six days if mailed) and will consist of a notice of appeal indicating which motion is being appealed, the DM's decision, and the papers filed with the DM. The DM will decide if his ruling will be stayed pending the Court's decision on appeal. If the Court affirms the DM's decision in its entirety the Court shall award the prevailing party costs and fees. The Court shall have the discretion to make any award of costs and fees against an appealing party if it determines that the appealing party did not substantially improve its position from the DM's order or if there was not a good faith basis to file the appeal. In support of the appeal to the court, the party appealing may file supplemental pleadings

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addressing the perceived error of the DM's order of not more than five pages. A single response shall be allowed, with no reply, within five days of service of the supplemental pleading in support of the appeal.

8. The DM shall schedule status conferences with the parties when necessary. Any party may request a status conference with the DM to promptly resolve discovery disputes.

9. The DM's fee is $_____ per hour. All parties shall pay an equal share of the fees and costs of the DM unless he orders that the fees be allocated in some other fashion.

DATED this ____ day of _____, 200_____.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

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06-05630

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA FILED
THIRD DISTRICT
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CLERK, TRIAL COURTS
BY _____ DEPUTY

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

MOTION OF NONRESIDENT ATTORNEY FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska R. Civ. P. 81(a)(2), defendant moves to permit Andrew R. Rogoff of Pepper Hamilton LLP, 3000 Two Logan Square, Philadelphia, Pennsylvania 19103-2799, phone number 215-981-4881, to appear and participate as attorney for defendant in the above-captioned action. Mr. Rogoff, as shown by the attached certificate, is a member in good standing of the Bar of the Commonwealth of Pennsylvania, as well as the United States District Court for the Eastern District of Pennsylvania, and is not otherwise disqualified from practicing law in the State of Alaska.

Applicant will be associated with Brewster H. Jamieson, ASBA No. 8411122, of Lane Powell LLC, whose address is 301 West Northern Lights Boulevard, Suite 301, Anchorage, Alaska 99503-2648, phone number 907-277-9511, and who is authorized to practice in this court and the courts of this state. Brewster H. Jamieson consents to this association.

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

A B C

Pursuant to Civil Rule 81(a)(2)(D), proof of payment of the fee required to be paid to the Alaska Bar Association is also attached.

DATED this 8th day of January, 2007.

LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122

I certify that on January 8, 2007, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

_____
Nanci L. Biggerstaff, CPS, PLS
009867.0038/158004.1

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

06-05630

Supreme Court of Pennsylvania

CERTIFICATE OF GOOD STANDING

Andrew R. Rogoff, Esq.

DATE OF ADMISSION

October 25, 1977

The above named attorney was duly admitted to the bar of the Commonwealth of Pennsylvania, and is now a qualified member in good standing.

Witness my hand and official seal
Dated: January 5, 2007

Patricia A. Johnson
Chief Clerk

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06-05630

ALASKA BAR ASSOCIATION
P.O. Box 100279, Anchorage, Alaska 99510-0279
(907) 272-7469

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	Andrew Rogoff NA —		
	assoc. w/ Brewster Jamieson 84/1122		
	Case # 3AN-06-05630		
	check # 647867		
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06-05630

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT' RESPONSE TO PLAINTIFF'S SCHEDULING AND PLANNING CONFERENCE MEMORANDUM

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
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In response to the Scheduling and Planning Conference Memorandum submitted by Eli Lilly and Company ("Lilly"), the State of Alaska's Memorandum virtually ignores the serious and complex issues relating to liability and discovery. While the discussion that follows does not contain a comprehensive analysis of the elements of plaintiff's claims or the proof problems inherent in them, Lilly replies briefly to emphasize the complex nature of this case and urge the Court not to leapfrog the difficult liability issues raised in the Complaint.

Necessary Discovery

The State of Alaska claims that its Medicaid program paid for Zyprexa® prescriptions that would not have been written but for Lilly's alleged "off-label" marketing. It seeks restitution for all Medicaid funds paid for Zyprexa prescriptions, as well as past, present and future healthcare costs for Medicaid recipients allegedly injured by Zyprexa.

Ignoring the importance of individual case discovery and the statutory and common law burdens it bears, the State asserts that it "intends to prove damages at trial through statistical and epidemiological evidence," by identifying selected Medicaid recipients who took Zyprexa and comparing the "number of diabetes-related injuries in that group with a control group of patients with equivalent diagnoses who did not take Zyprexa. . . . The proof will focus on the loss to Alaska's Medicaid program and will not require proof of loss to any individual participant." State's Memorandum, at p. 4. Accordingly, the State envisions

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limited Alaska-specific discovery, no discovery of individual patients or prescribing physicians, and an ambitious discovery and trial schedule.

In fact, the State's burden of proof goes far beyond "statistical and epidemiological" damages evidence. First, the State will need to prove that conduct by Lilly supports liability, and that the same conduct caused monetary damages. If the State meets these burdens, it will then have to quantify and substantiate its damages to satisfy its burden.

Discovery Related to the State's Restitution Claims

First, the State seeks restitution for Zyprexa prescriptions that allegedly would not have been written were it not for Lilly's marketing practices. To prove these claims, the State will need to establish the causal link it alleges, i.e., that physicians prescribing Zyprexa did so in reliance on misrepresentations by Lilly. Then, to the extent that the State is able to satisfy its burden on causation, it will need to document the costs it seeks to recover.

To defend against the State's claims, Lilly will need discovery of the physicians alleged to have prescribed Zyprexa for Medicaid recipients, and documentation of each such prescription. For each prescription of Zyprexa, the State will have to prove that Lilly improperly influenced the prescribing physician. Further, with regard to restitution, the State will need to quantify the inappropriate Lilly-induced Zyprexa prescriptions written for Medicaid recipients, and the cost of each such prescription. Because the State has not limited its restitution claim in time or in any other manner, this alone presents a formidable discovery task. The State's failure to limit its claims in time also raises complex issues related to the applicable statute of limitations.

Discovery Related to the State's Claim for Recovery of Healthcare Costs

As noted, the State seeks recovery of past, present and future healthcare costs for Medicaid recipients allegedly injured by Zyprexa. Once again, the State will face a heavy burden of proof with respect to these claims. Though the State asserts that it requires no discovery of individual patients, its claims for healthcare costs depend on proof that

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individual Medicaid recipients have suffered Zyprexa-related injuries in a population that is disproportionately afflicted with diabetes and often the subject of varying medication regimens. In other words, the State must prove the injuries it alleges, and will be required, for every Medicaid recipient allegedly injured by Zyprexa, to prove that Zyprexa caused the alleged injuries. In addition, because the State alleges that Zyprexa was prescribed for Medicaid patients as the result of Lilly's marketing practices, it must prove that the patients allegedly injured by Zyprexa would not have received the medication were it not for the Lilly's alleged misconduct. Finally, if the State can meet these burdens on liability, it will be required to quantify and document the costs it seeks to recover.

To defend against these claims, Lilly will seek medical records and/or depositions of individual patients, depositions of prescribing physicians, and records related to all relevant healthcare costs and projected costs. Defendant's proposed schedule, contemplating ten Lilly depositions and no discovery related to individual prescriptions and treatment, fails to account for the issues of individual proof required for the State to sustain its burdens on both liability and damages.

Coordination with MDL Discovery

As discussed in its Scheduling and Planning Conference Memorandum, Lilly asks this Court to enter an Order similar to that entered by the Superior Court of California in the case of *Joel Algario, et al. v. Eli Lilly and Company,* Case No. BC347855, a copy of which is attached as Exhibit A to that Memorandum. The *Algario* Order recognizes that coordination of discovery in that state court case with discovery already completed in the Zyprexa MDL will avoid duplication of effort and will conserve the resources of the parties, attorneys, witnesses, and the Court, and Lilly hereby renews its request that this Court enter a similar Order. At this point, Lilly does not envision a need for a discovery master.

06-05630

Specific Proposed Deadlines

It is Lilly's understanding that, with the re-classification of this matter as non-routine, the upcoming conference was scheduled to allow discussion of issues that should enter into the Court's calculation of appropriate pretrial deadlines. Accordingly, rather than submit proposed deadlines to counter the unrealistic deadlines suggested by the State, Lilly requests that the Court enter an Order setting pretrial deadlines after discussion of the relevant issues with the parties.

Trial Witnesses

At this time, Lilly is unable to estimate the number of witnesses it will call at trial or the number of days trial of this matter will take. As discovery progresses, Lilly will be better able to make these estimates.

DATED this 4th day of January, 2007.

LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122

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301 West Northern Lights Boulevard, Suite 301
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I certify that on January 4, 2007, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-5911

_____
Nanci L. Biggerstaff, CPS, PLS
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06-05630

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

FILED
STATE OF ALASKA
THIRD DISTRICT
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CLERK, TRIAL COURTS
BY _____ DEPUTY

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

NOTICE OF CHANGE OF HEARING DATE

PLEASE TAKE NOTICE that the scheduling and planning conference set on December 8, 2006, is vacated. The hearing has been rescheduled for January 8, 2007, at 3:00 p.m. before Judge Mark Rindner.

DATED this 1 day of December, 2006

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiffs

BY _____
Eric T. Sanders
AK Bar No. 7510085

Certificate of Service
I hereby certify that a true and correct copy of
The foregoing Notice of Change of Hearing Date
was served by mail on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy S Crowe
Date 12/1/06

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06-05630

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

PLAINTIFF STATE OF ALASKA'S SCHEDULING AND PLANNING CONFERENCE MEMORANDUM

INTRODUCTION

To assist the Court in conducting the scheduling and planning conference, both parties agreed to submit a brief description of the issues presented in this case and a proposal for managing discovery and setting deadlines for moving this case toward trial. Plaintiff State of Alaska ("Alaska") submits this memorandum to address these topics.

ISSUES PRESENTED IN THIS CASE

Alaska's Claims

Alaska administers a Medicaid program, under which it reimburses doctors and pharmacies for services and medications provided to eligible patients. Over the

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years, Alaska has paid pharmacies substantial sums for Zyprexa, a drug manufactured and promoted by defendant Eli Lilly and Company. Alaska has also paid physicians and hospitals to treat diseases caused by the use, misuse, and overuse of Zyprexa.

Alaska contends that Lilly was aware of dangerous side effects of Zyprexa, yet engaged in deliberately deceptive marketing and advertised the drug as safe. Alaska contends further that Lilly heavily promoted Zyprexa for use by inappropriate patients, when safer and less expensive drugs could have been prescribed. Alaska's complaint states causes of action for negligence, strict liability, violation of Alaska's Unfair Trade Practices and Consumer Protection Act, and violation of other consumer protection statutes. Alaska seeks to recover costs that it paid for over-prescription of Zyprexa and for treatment of diseases caused by Zyprexa; it seeks compensatory damages, civil penalties, and other pecuniary relief.

Background Facts

Lilly has provided this court with a lengthy, one-sided, statement of background facts. Alaska understands that this is not the time and place to litigate the merits of the case, but feels compelled to provide some balance through a brief statement of the other side of the case, highlighting some of the facts that it will rely on to prove its claims. Alaska is prepared to prove the following:

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Zyprexa was developed as an antipsychotic drug, intended to be prescribed for the treatment of schizophrenia and certain aspects of bipolar disorder. The FDA approved the prescription of Zyprexa for these purposes in 1996 and 2000. When Lilly applied for approval, it failed to advise the FDA of facts that it had learned through clinical tests. The FDA approved the drug, and Lilly thereafter promoted it as "risk free," although Lilly knew that the drug in fact tended to cause significant weight gain and thus to increase the risks of diabetes, high blood pressure, and high cholesterol. Many physicians were impressed by Lilly's promotions, and Zyprexa rapidly became a top-selling drug.

While Zyprexa was on the market, Lilly continued to amass data indicating that the drug had serious side effects -- yet Lilly did little or nothing to warn of the problems it had discovered. Instead, Lilly continued to promote Zyprexa heavily, both for its "on-label" (i.e., FDA-approved) uses as well as for a variety of "off-label" uses, including insomnia, dementia, depression, and other mood and thought disorders. Lilly knew that the FDA had not approved, and likely never would approve, Zyprexa as effective for the treatment of these mood symptoms, particularly if the FDA were made aware of the risks (such as diabetes) that greatly outweigh any possible benefits. The off-label promotions were aimed especially at primary care physicians, and greatly expanded

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the number of patients for whom prescribing doctors might consider Zyprexa to be a drug of choice.

Even after foreign regulatory authorities required Lilly to add warnings to the labels used in Japan and the European Union, Zyprexa failed to revise the labels it used in the United States until forced to do so by the FDA in September 2003.

Alaska's Damages

Alaska intends to prove damages at trial through statistical and epidemiological evidence. For example, Alaska will identify members of the Medicaid population who took Zyprexa and compare the number of diabetes-related injuries in that group with a control group of patients with equivalent diagnoses who did not take Zyprexa. Once the increase in diabetic and other related injuries has been determined, Alaska will apply that figure to the costs of diagnoses, treatment, and management of these conditions. The proof will focus on the loss to Alaska's Medicaid program, and will not require proof of loss to any individual participant. Similarly, using statistics, Alaska will prove the damages that it suffered from the over-prescription of Zyprexa to treat symptoms for which it was not effective.

ALASKA'S DISCOVERY NEEDS

Alaska needs to engage in discovery focused specifically on issues related to Alaska's case. Alaska also expects to rely on documents produced and depositions

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taken in the federal Multi-District Litigation (MDL). Alaska has absolutely no desire to do reinvent the wheel or to create unnecessary work for itself or for Lilly. The task for this court is to craft discovery rules that permit Alaska to develop its case fully and fairly, without unnecessary restriction, while protecting Lilly against unnecessary duplicative discovery.

Alaska suggests that the standard discovery rules, set forth in Alaska Civil Procedure Rules 26-37, serve admirably for the present purposes. They permit liberal discovery, while allowing a party to seek protection against specific discovery demands that are unduly burdensome. Alaska strongly recommends this approach, as distinct from the narrow, restrictive approach that Lilly has advocated, where the standard burden of proof would be reversed and Alaska would be forced to show why it should be allowed to engage in discovery, rather than Lilly having the burden of showing why certain discovery should be denied.

The following subsections address specific types of discovery, and discuss in greater detail why this court should not adopt in full the *Algario* Order that Lilly has urged upon this court.

Interrogatories and Requests for Production

Alaska requires documents from Lilly that were not requested in the MDL, including, for example, documents that relate to Lilly's marketing and detailing efforts,

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copies of documents provided to Alaska physicians, and documents concerning Lilly's contacts with this state. Alaska also requires documents concerning Lilly's over promotion of Zyprexa for off-label uses.

The *Algario* Order provides that plaintiffs' counsel in that case must be given access, without charge, to the repository of documents maintained in the MDL case. Alaska agrees with that part of the *Algario* Order. The *Algario* Order further provides that Lilly shall not be required to make copies of materials in the MDL Repository, but that the state case counsel at their own expense "shall be permitted to make copies of documents from the MDL Repository and copies of any electronic media on which the MDL Repository documents are stored." Alaska agrees with this part of the *Algario* Order as well, provided Lilly will stipulate to the authenticity and admissibility of the documents in the MDL Repository.

To the extent that the *Algario* Order and Lilly's memorandum to this court suggest that the only written discovery that Alaska will be allowed is access to the MDL Repository, Alaska strongly objects. As discussed in the first paragraph in this section, Alaska requires discovery of documents that were not produced in the MDL. Alaska may serve interrogatories on those subjects as well.

Alaska sees no reason to adopt limitations on discovery beyond those established in Alaska Civil Procedure Rules 26, 33, and 34. Lilly may seek specific

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protective orders, if it contends that Alaska's discovery demands are repetitive or unduly burdensome, but this court should not start by entering an order that restricts Alaska's right to seek written discovery.

Depositions

The *Algario* Order distinguishes between depositions already taken in connection with the MDL and depositions that might be scheduled in the future.

Completed depositions. As to depositions completed during the MDL, the *Algario* Order provides that Lilly must provide plaintiffs' counsel (at plaintiffs' expense) with copies of any deposition transcripts requested. Alaska agrees with that portion of the *Algario* Order.

The *Algario* Order then provides that, if plaintiffs' counsel wish to redepose any witness, plaintiffs' counsel must confer with Lilly's counsel, and then move the court for permission to redepose a witness if the parties cannot agree on the scope and need for the redeposition. Alaska strongly opposes adopting this part of the *Algario* Order.

Alaska anticipates the need to depose approximately ten Lilly employees, some or all of whom have been or will be deposed in the MDL. Re-deposing certain witnesses (rather than relying on the transcripts from prior depositions) is necessary for a number of reasons, including the focus on Alaska and the need to ask questions that were not asked before, the fact that some witnesses were deposed before key documents were

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produced (Lilly in recent months produced hundreds of thousands of additional documents), and the fact that some documents, though produced, were improperly redacted (and the rulings disallowing the redactions came only after some of the depositions were completed).

Alaska should not have the burden of having to explain first to Lilly and then to this court why it sees a need to depose a particular witness. Ten witnesses is not an oppressive amount of discovery in a case such as this. The MDL cases, while related to the present case, are not identical, and this case raises some distinct issues. Further, lawyers are not fungible; it is not appropriate to require Alaska to be bound by the questions asked by other lawyers with different cases, simply to save Lilly some time and expense. Lilly chose to do business in and to make money from the State of Alaska. It is not unfair for Lilly to have to deal separately with litigation brought by Alaska, for redress of harms caused by Lilly in Alaska. The procedures of the *Algario* Order, which Lilly asks this court to adopt, invite unnecessary delay. Moreover, by requiring Alaska to justify any deposition it wishes to conduct, the *Algario* procedures would require Alaska to disclose its theories about each witness's relevance and the types of questions Alaska will ask; this is advantageous to Lilly and unfairly prejudicial to Alaska.

Future depositions. Discovery in the MDL currently is scheduled to close on November 20, 2006. Unless that deadline is extended, there will be no future

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depositions in the MDL case, and the provisions of paragraph 4 of the *Algario* Order would be irrelevant.

If the discovery deadline in the MDL is extended, as may occur, then this court must decide how to handle future depositions. Lilly again asks this court to adopt the *Algario* procedures. Alaska again objects. Alaska's statement, *supra,* that it expects to depose approximately 10 Lilly employees encompasses both those who have been deposed and those who have not yet been deposed. That is a very modest amount of discovery for a case of this nature.

The *Algario* Order, if adopted for this case, would require Alaska to participate in any deposition scheduled in the MDL case, at the risk of having no other chance to ask questions of that witness. Whether Alaska's counsel would receive any time to ask their own questions, rather than being bound by the questions of the MDL counsel assigned to conduct the deposition, would be controlled by Lilly. If Alaska declines to participate, then seeks to depose the witness in connection with this case, the *Algario* Order would put the burden on Alaska to bring a motion to allow a deposition; to support such a motion, Alaska would need to reveal its theories to justify its need to conduct independent discovery. As discussed above, reversal of the normal rules of discovery is unwarranted. Alaska should not be required to participate in discovery scheduled in another case, particularly when Alaska has not yet had the chance to review

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the voluminous discovery collected in the MDL Repository, or the chance to conduct written discovery pertinent to the unique issues of its own case. Lilly should not have the authority to decide whether or not Alaska may ask its own questions.

Alaska's recommendation. Alaska should be permitted to depose a modest number -- say 10 -- of Lilly's witnesses without any special procedure or prerequisites. If Lilly wants to block one or more of these depositions, Lilly certainly may move pursuant to Alaska Civil Procedure Rule 26(c) for a protective order -- but this court should make clear that depositions will not be prohibited merely because the witness was deposed once in the MDL case. Given this state's liberal attitude toward allowing discovery of relevant matters, any burden should be assigned to Lilly if it wants to preclude a particular deposition, rather than forbidding all redepositions, subject to Alaska's right to move for an exception to that rule.

Deadline to complete depositions. Assuming a discovery master is appointed (*see infra*), and assuming Alaska will need to depose no more than 10 Lilly employees (former and current), Alaska expects to complete all discovery under Civil Rule 30 on or before July 1, 2007.

Discovery Master

As the proceedings to date likely already suggest, it is foreseeable that the discovery in this case may become contentious, regardless of what rules this court adopts.

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Alaska respectfully suggests that this court consider appointing a discovery master, who would be assigned to resolve discovery disputes quickly, subject, of course, to review by this court. Alaska submits a proposed order describing the duties and responsibilities of a discovery master. (*See* Exhibit 1 attached hereto.) The discovery master could address specific issues on who can be deposed, time limits for depositions, location and dates for depositions, and protective orders governing the scope of any deposition.

TRIAL WITNESSES

Alaska expects to call approximately 20 witnesses at trial, including 10 experts. Alaska anticipates needing 10 trial days to present its case on liability and damages.

PRETRIAL SCHEDULE

Based upon the foregoing, Alaska proposes the following schedule:

Preliminary witness lists	February 1, 2007
Disclosure of expert reports	September 1, 2007
Close of non-expert discovery	August 1, 2007
Close of expert discovery	November 1, 2007
Trial commences	March 1, 2008

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DATED this 22 day of November, 2006

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Certificate of Service
I hereby certify that a true and correct copy of the foregoing Plaintiff State of Alaska's Scheduling and Planning Conference Memorandum was served by mail / messenger / facsimile on:

Brewster H. Jamieson
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By Peggy S. Crowe
Date 11/22/06

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

FILED
STATE OF ALASKA
THIRD DISTRICT
06 OCT -6 PM 4:06
CLERK OF THE TRIAL COURTS
BY: DEPUTY CLERK

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT ELI LILLY AND COMPANY'S SCHEDULING AND PLANNING CONFERENCE MEMORANDUM

Comes now the defendant, Eli Lilly and Company ("Lilly"), by and through the undersigned counsel, and submits the following for the information of the Court, in preparation for the Scheduling and Planning Conference currently scheduled for December 8, 2006 at 3:00 p.m.:

A. FACTUAL BACKGROUND

In this lawsuit, filed on March 20, 2006, the State of Alaska principally seeks: (i) past, present and future health care costs for Medicaid recipients allegedly injured by Zyprexa,® a prescription medication manufactured by Lilly; and (ii) restitution for all funds paid for Medicaid reimbursement of Zyprexa prescriptions. The State's claims rest on the premise that, due to aggressive marketing by Lilly, including marketing for so-called "off-label" uses – indications not approved by the Food and Drug Administration – Alaska Medicaid recipients have been injured by Zyprexa. Plaintiff argues that, had Lilly adequately

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warned it of the risk of diabetes and related conditions, it would not have spent its money reimbursing Zyprexa prescriptions.

To prevail on its claims, the plaintiff must prove, *inter alia,* that Zyprexa caused the claimed injuries, and that Lilly failed to provide adequate warnings of the relevant risks. With respect to these factual issues, Lilly incorporates by reference its Preliminary Zyprexa Backgrounder,[1] similar versions of which other courts have found useful. The Backgrounder provides the Court with information regarding Zyprexa; the mental illnesses it has been approved to treat, the prevalence of, and risk factors for, diabetes; and the regulatory history of the medicine.

B. PROCEDURAL BACKGROUND

Plaintiff filed its Complaint in this Court on March 20, 2006. On April 19, 2006, Lilly removed this action to the United States District Court for the District for Alaska. On plaintiff's motion, the federal court remanded the case on July 28, 2006. Lilly filed its Answer in this Court on August 31, 2006. On August 24, 2006, this Court issued an Initial Pretrial Order. In response, plaintiff filed a Motion to Characterize Case as Non-Routine, in response to which Lilly filed a Qualified Non-Opposition, disagreeing with some of

[1] A copy of Lilly's Preliminary Zyprexa Backgrounder is attached as Exhibit A. Lilly has not attached the reference materials cited in the backgrounder, as they are voluminous. Lilly will provide any or all such materials to the Court upon request.

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plaintiff's factual assertions but not opposing the Motion. This Court's Scheduling and Planning Conference Order was issued on September 18, 2006.

1. **The Zyprexa MDL**

As this case proceeds through the initial stages of litigation, nearly 1,000 consolidated federal Zyprexa cases, involving more than 5,000 plaintiffs, are pending before the Honorable Jack B. Weinstein in the United States District Court for the Eastern District of New York. These cases include two actions filed by the Attorney General of Louisiana in which, as here, the state seeks restitution of the cost of Zyprexa prescriptions reimbursed under its Medicaid program. In addition, similar actions filed by the Attorneys General of West Virginia and Mississippi have been removed to federal district courts in those states and currently await transfer to the MDL.[2]

Since April 14, 2004, when the first group of these cases was transferred by the Federal Judicial Panel on Multidistrict Litigation, *see In re Zyprexa Litigation,* MDL 1596, 314 F. Supp.2d 1380 (J.P.M.L. 2004) Lilly has produced nearly ten million documents, and depositions of approximately forty current and former Lilly employees have been taken. On May 6, 2006, Judge Weinstein issued a case management order permitting all depositions

[2] In addition, several putative class actions brought on behalf of third-party payors seeking, *inter alia,* reimbursement for money paid for Zyprexa are pending before Judge Weinstein.

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taken in the MDL to be cross-noticed in all pending state court cases.[3] Eight depositions have already been cross-noticed pursuant to Case Management Order 15 ("CMO 15"). In an attempt to begin coordinating discovery in this case with discovery taking place in the MDL, Lilly recently served cross-notices of two MDL depositions on the State of Alaska. The State filed a Motion to Quash, which this Court granted with cautions to plaintiff's counsel against attempting to use duplicative discovery for a "second bite at the apple."

C. COORDINATION WITH MDL DISCOVERY

Recently, in the multi-plaintiff Zyprexa case of *Joel Algario, et al. v. Eli Lilly and Company,* Case No. BC347855, the Superior Court of California considered the issue of coordination of discovery in its state court action with discovery ongoing and already completed in the Zyprexa MDL. The Court noted that the case had been designated "complex" under California rules, with the goals of "(1) expediting the case, (2) keeping costs reasonable and (3) promoting effective decision making by the court, the parties and counsel."[4] In furtherance of those goals, and "to avoid unnecessary, duplicative production of documents," *id.,* at 2, the court ordered that plaintiffs in the state court action "be given access to the MDL Repository, including access to any document coding supplied by Lilly," under an appropriate protective order to be entered by the Court. *Id.*. The Court further

[3] *See* Case Management Order No. 15 (Deposition Guidelines), *In re Zyprexa Products Liability Litigation,* MDL No. 1596 (JBW), dated May 6, 2006 ("CMO 15"), a copy of which is attached as Exhibit B.

[4] *See* Order dated September 21, 2006 ("*Algario* order"), a copy of which is attached as Exhibit C, at 1.

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ordered, "Plaintiff's counsel in this California litigation shall not require that any counsel in the MDL litigation make copies of documents from the MDL Repository or impose any unreimbursed expense on counsel in the MDL litigation." *Id.* Rather, California counsel, at their own expense, were to be permitted to make copies of MDL documents or electronic media storing such documents. *Id.*

With respect to depositions, the Court ordered that, "to limit unnecessary and repetitive depositions,"[5] plaintiffs counsel participate in all cross-noticed MDL depositions pursuant to CMO 15 and that they submit to the Court any request to re-depose such witnesses.[6]

As noted, the core factual issues underlying the State of Alaska's lawsuit are identical to the factual issues being litigated in thousands of personal injury cases in the MDL. Lilly requests that, in the interest of eliminating duplicative discovery and conserving the resources of the parties, counsel, witnesses, and the Court, this Court enter an Order substantially identical to that entered in *Algario*, requiring the plaintiff to coordinate the discovery in this case with discovery ongoing and already completed in the MDL.

D. OTHER ISSUES

In its Motion to Characterize case as Non-Routine, the state expressed the view that its case in chief could be tried in seven trial days. Lilly submits that the testimony required to

[5] *Algario* order, at 2.

[6] *Id.*, at 3.

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resolve plaintiff's claims, including testimony related to the injuries each Medicaid patient has allegedly suffered as a result of Zyprexa, will take a great deal longer than plaintiff estimates. Lilly estimates that trial of this case will take a minimum of four to six weeks.

DATED this 6th day of October, 2006.

LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122

I certify that on October 6, 2006, a copy of the foregoing was served by mail on:

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT ELI LILLY AND COMPANY'S ZYPREXA BACKGROUNDER

Defendant Eli Lilly and Company, by and through counsel, provides the following background information regarding the Zyprexa litigation.

I. INTRODUCTION

This litigation involves Lilly's prescription medicine Zyprexa® (olanzapine), which is one of a class of medications known as "atypical" or "second generation" antipsychotics approved by the United States Food and Drug Administration ("FDA") for the treatment of schizophrenia and bipolar disorder. The FDA first approved Zyprexa on September 30, 1996, for use in treating schizophrenia.[1] Thereafter, the FDA approved Zyprexa for maintenance treatment of schizophrenia[2] and for the short-term treatment of acute manic episodes associated with bipolar I disorder as monotherapy[3] and in combination with lithium or valproate.[4] Most recently, Zyprexa became the first medication in more than 30 years to be approved for maintenance in the treatment of bipolar disorder.[5] More than 19 million patients have been treated with Zyprexa worldwide.

The following sections provide information about federal multidistrict litigation pending in the Eastern District of New York, as well as medical and regulatory background relevant to the key factual issues presented by all pending cases, including cases filed by states' Attorneys General.

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II. THE ZYPREXA MDL

Congress created the Judicial Panel on Multidistrict Litigation ("The MDL Panel") in 1968 and charged it with the tasks of (1) determining whether civil actions pending in different federal districts involve one or more common questions of fact such that the actions should be transferred to one court for consolidated and coordinated pretrial proceedings; and if so, (2) selecting the judge or judges and court to which such proceedings should be assigned. The transfer and centralization process in the MDL avoids duplication of discovery, prevents inconsistent pretrial rulings, and conserves the resources of the parties, their counsel and the judiciary.

The first Zyprexa actions were filed in the latter part of 2003. The MDL Panel, by Order dated April 14, 2004, created the Zyprexa MDL under the caption *In re Zyprexa Products Liability Litigation, MDL 1596,* and assigned it to the Honorable Jack B. Weinstein in the Eastern District of New York. The MDL now includes cases involving more than 5,000 plaintiffs.

While the majority of cases transferred to the MDL have been individual personal injury actions, two actions filed by the Attorney General of Louisiana are pending in the MDL, while actions filed by the Attorneys General of West Virginia and Mississippi have been removed to federal district courts in those states and currently await transfer to the MDL. Like the pending lawsuit filed by the Attorney General of the State of Alaska, these actions seek, among other damages, restitution of the cost of Zyprexa prescriptions reimbursed under the respective states' Medicaid program.[6]

Subject to various case management orders in the Zyprexa MDL, Lilly has produced nearly 10 million pages of Zyprexa-related materials in the MDL. These materials are available to plaintiff's counsel in this litigation by virtue of their participation in the Zyprexa MDL. In addition to this extensive document production, more than 40 current and

former Lilly employees have been deposed in joint MDL-state court depositions on a broad range of issues.

Federal-State Coordination

Given the extensive discovery that has occurred in the MDL, and the participation of many of the Zyprexa MDL plaintiffs' lawyers in state court actions, Judge Weinstein and Special Master Peter Woodin (who was appointed to resolve all discovery disputes in the MDL) have acted to coordinate the MDL with state court litigation. When done effectively, federal-state coordination ensures to courts and claimants with actions pending in state courts around the country the benefit of the efficiencies offered through the MDL process. Effective coordination also minimizes the risk of duplicative discovery, inconsistent pretrial rulings, and it conserves the resources of the parties, their counsel and the Court.

Judge Weinstein has invited state court Judges with pending Zyprexa actions to advise him as to how he might assist them in their management of Zyprexa litigation. He also invited state court Judges to sit with him on the Eastern District of New York bench during hearings and has offered to visit the state courts if requested.

Because state courts may be asked to revisit discovery disputes already resolved in the MDL, Special Master Woodin has asked Lilly and all MDL counsel who file motions in state courts that relate to his prior rulings or Case Management Orders to provide him with copies of such motions. Finally, Special Master Woodin communicates with state court Judges and Special Masters to keep them apprised of developments in the MDL. As a result, for example, the court managing consolidated state court cases in California has issued an order requiring state court plaintiffs to coordinate both document discovery and depositions with discovery ongoing and completed in the MDL.[7]

III. FACTUAL BACKGROUND

At the heart of all of the pending litigation, including personal injury suits, third-party payor litigation, and suits by state attorneys general, is a claim that Lilly failed to

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adequately warn of the alleged increased risk of diabetes mellitus and related conditions, including hyperglycemia, ketosis, diabetic acidosis and diabetic coma,[8] in patients who use Zyprexa. From the time Zyprexa was first marketed in October 1996, however, its labeling has listed diabetes mellitus, hyperglycemia, ketosis and diabetic acidosis among the infrequent (*i.e.,* 1/100-1/1000 patients) or rare (*i.e.,* fewer than 1/1000 patients) adverse reactions observed in patients during clinical trials.[9] Zyprexa's original labeling also stated that weight gain was a commonly observed adverse event in clinical trials.[10]

Since its launch of Zyprexa, Lilly has monitored all post-marketing reports of diabetes-related adverse events, and provided the FDA with regular periodic safety update reports based on post-marketing experience with Zyprexa. The approximate .01% rate (*i.e.,* 1/10,000) at which diabetes-related conditions have been reported in post-marketing spontaneous reports is consistent with the infrequent or rare occurrence of these adverse events during the clinical trials. As a result of its ongoing pharmacovigilance, Lilly added diabetic coma to Zyprexa's labeling as an adverse event seen in post-marketing experience.[11]

Beginning in May 2000, the FDA, with cooperation of the manufacturers of atypical antipsychotic medications, undertook targeted monitoring and analysis of data regarding diabetes mellitus or hyperglycemia-related adverse events in patients using these medicines. The FDA's evaluation included "a thorough review from a number of sources, including clinical trial data, spontaneous post-marketing reports, epidemiological studies, published case series, published clinical pharmacology studies, published preclinical studies, and unpublished studies" for each atypical antipsychotic medication.[12]

After completing an exhaustive review of the data, on September 11, 2003, the FDA notified manufacturers of its conclusion that "the product labeling for *all* atypical antipsychotics should be updated to include information about these events."[13] The FDA explained that "[w]hile we acknowledge that the relationship between atypical antipsychotic use and diabetes mellitus adverse events has not been completely described, we believe the

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safe use of Zyprexa [and other atypicals] can be enhanced by informing prescribers and patients about these events."[14] The agency also concluded that there was a "lack of evidence to support a ranking of risk [for diabetes] among the atypical antipsychotics."[15]

In accordance with the FDA's request, Lilly immediately revised its labeling for Zyprexa to include the following:

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing.[16]

In contrast to most other prescription medicines that have been the subject of multidistrict litigation, the FDA has not required that Zyprexa's labeling include a "black box" warning regarding the possible increased risk of hyperglycemia-related conditions; nor has it sought to remove Zyprexa from the market.[17] Rather, the FDA has concluded that the question of whether there is a causal connection between the use of atypical antipsychotic

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medications and the development of diabetes or related conditions is a complex inquiry that has yet to be answered. Even if one were to assume that Zyprexa has the capacity to increase the risk of these conditions (which is disputed), whether Zyprexa was a substantial factor in causing the injuries alleged by each of the plaintiffs in this litigation is a "highly individualistic" determination.[18] This is particularly true where, as appears to be the situation in many (if not all) cases here, plaintiffs have pre-existing major risk factors for diabetes.

IV. THE MEDICAL CONTEXT

A. SCHIZOPHRENIA AND ITS TREATMENT

Schizophrenia is a severe, debilitating mental illness that afflicts over 1% of the general population, often beginning in late adolescence or early adulthood.[19] The diagnostic features of this disabling condition include overt psychotic, or "positive," symptoms, such as auditory hallucinations and delusions, as well as deficit, or "negative," symptoms, such as "an inability to pay attention, the loss of a sense of pleasure, the loss of will or drive, disorganization or impoverishment of thoughts and speech, flattening of affect, and social withdrawal."[20] Another core feature of schizophrenia is cognitive dysfunction, which leads to dysfunction in work, interpersonal relationships and self-care.[21] The lifetime rate of completed suicide among people with schizophrenia is about 10%.[22] The number of deaths in the schizophrenic population is as much as 3 times that of the general population, with 38% of deaths associated with suicide and homicide.[23]

Although so-called "typical" or "first-generation" antipsychotic medications (*e.g.*, Haldol (haloperidol) and Thorazine (chlorpromazine)) have been used for many years to treat the positive symptoms of schizophrenia, these drugs provide minimal benefit in alleviating schizophrenia's negative symptoms.[24] Furthermore, *all* typical antipsychotics "can produce significant extrapyramidal side effects at clinically effective doses. These side effects, which include dystonic reactions, drug-induced parkinsonism, akathisia, and tardive dyskinesia, can make treatment intolerable for some people, leading to subjective distress,

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diminished function, stigma, and nonadherence."[25] Approximately 30% of schizophrenic patients are treatment-resistant to typical antipsychotics and, even among patients who respond, approximately half will become noncompliant, due largely to these extrapyramidal symptoms ("EPS").[26] Noncompliance increases the risk of relapse and hospitalization.

Over the past 15 years, "atypical" or "second-generation" antipsychotic medications have been introduced in an attempt to improve the therapeutic effects and decrease the EPS associated with typical antipsychotics.[27] The medical literature documents that these atypical antipsychotics – including Zyprexa[28] – are more effective and have a better profile regarding EPS than the typical antipsychotics:

> [T]hese drugs have an efficacy that is equivalent to or exceeds the efficacy of first-generation antipsychotic agents, without many of the extrapyramidal effects of the first-generation drugs. These newer agents also entail a greatly reduced risk of tardive dyskinesia. Their increased efficacy with respect to negative schizophrenic symptoms is particularly noteworthy, and the rate of relapse is significantly less than that with the first-generation drugs.[29]

Zyprexa, in particular, has generally demonstrated a superior treatment effect than have typical antipsychotic medications, such as Haldol, with respect to the negative symptoms of schizophrenia, and comparable benefits with respect to positive symptoms.[30] Zyprexa has demonstrated a superior safety profile with respect to EPS as well.[31]

While comparative studies show that Zyprexa and Risperdal® (risperidone), another atypical antipsychotic medication, are similarly effective in treating overall psychopathology symptoms of schizophrenia,[32] some studies have reported significantly greater improvements with Zyprexa in treating negative and depressive symptoms and cognitive dysfunction.[33] Zyprexa has also been associated with fewer EPS than Risperdal® (risperidone).[34] In addition, a recent long-term, prospective study of atypical antipsychotics found that Zyprexa was more effective than other study medications (several atypical

antipsychotics and one typical antipsychotic) as measured by time to discontinuation of treatment.[35] The Clinical Antipsychotic Trials of Intervention Effectiveness ("CATIE"), sponsored by the National Institute of Health, studied almost 1,500 schizophrenic patients. It demonstrated that the time to discontinuation of treatment for any cause was longer in the Zyprexa group than the Seroquel® (quetiapine) and Risperdal groups. Time to discontinuation for lack of efficacy was longer in the Zyprexa group than the perphenazine, Seroquel, Risperdal, and Geodon® (ziprasidone) groups. Duration of successful treatment was also significantly longer in the Zyprexa group than the Seroquel, Risperdal, and perphenazine groups. Fewer patients in the Zyprexa group than in the other four groups were hospitalized for an exacerbation of schizophrenia.[36]

B. BIPOLAR DISORDER AND ITS TREATMENT

Bipolar disorder is a serious, lifelong mental illness marked by dramatic shifts in mood, from abnormally elevated, expansive or irritable moods to states of extreme sadness and hopelessness, often with periods of normal mood in between.[37] About 2.6% of the population, including more than 5.7 million American adults, suffer with bipolar disorder, also known as manic-depressive disorder.[38]

The most common type of bipolar disorder is bipolar I disorder, which involves episodes of full-fledged mania alternating with periods of major depression. Bipolar II disorder features alternating episodes of depression and periods of "hypomania," a relatively mild, nonpsychotic mania. A "mixed" bipolar state includes both depressive and manic (or hypomanic) symptoms, such as tearfulness during a manic state or racing thoughts while depressed.[39] Severe episodes of mania or depression can include symptoms of psychosis, such as auditory and visual hallucinations.[40]

Without treatment, the periodic cycling from mania to depression to euthymia (normal mood) can increase in frequency,[41] length and severity, and the results can be catastrophic. There is a high rate of suicide among bipolar patients.[42] In addition:

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> Bipolar disorder causes substantial psychosocial morbidity, frequently affecting patients' relationships with spouses or partners, children, and other family members as well as their occupation and other aspects of their lives. Even during periods of euthymia, patients may experience impairments in psychosocial functioning or residual symptoms of depression or mania/hypomania. It is estimated that as many as 60% of people diagnosed with bipolar I disorder experience chronic interpersonal or occupational difficulties and subclinical symptoms between acute episodes. . . . The occupational status of patients with bipolar disorder is twice as likely to deteriorate as that of comparison subjects.[43]

Thus, bipolar disorder must be treated and carefully managed.[44]

Zyprexa was the first atypical antipsychotic medication to be approved by the FDA for use in treating acute bipolar mania. (For many years, lithium was the standard treatment for bipolar mania, but it carries a very significant risk of blood toxicity.) Not only is Zyprexa effective in treating this condition,[45] but it has a superior profile with respect to EPS and, therefore, is preferred by many physicians over typical antipsychotics.[46] Zyprexa has proven in clinical trials to have efficacy similar to or greater than Depakote (valproate) in treating bipolar mania.[47] The FDA has also approved Zyprexa in combination with lithium or valproate for treating acute manic episodes.[48] In clinical trials, bipolar patients in acute manic or mixed episodes demonstrated improved manic and depressive symptoms when treated with Zyprexa in combination therapy as compared to patients treated with lithium or valproate alone.[49]

In addition, Zyprexa has proven in clinical trials to be effective in maintenance treatment of manic, mixed manic or depressive episodes, thereby prolonging periods of stability.[50] Approved by the FDA for this indication in January 2004, Zyprexa is the first treatment since lithium to be approved for both the treatment of acute manic episodes of bipolar I disorder and in bipolar maintenance.

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C. DIABETES MELLITUS: ITS PREVALENCE AND RISK FACTORS

Over the last decade, diabetes mellitus has been increasing in the general population at an alarming rate. The Centers for Disease Control and Prevention ("CDC") estimates that, as of 2005, 20.8 million people in the United States – or 7.0% of the population – had diabetes.[51] Approximately 14.6 million people had been diagnosed with diabetes as of 2005, while 6.2 million people had the disease but had not been diagnosed.[52] The number of people in the U.S. with diabetes is projected to increase to 30.3 million by 2030.[53]

While diabetes in the general population has reached epidemic proportions, its prevalence among persons with schizophrenia and bipolar disorder is two to four times greater than the general population.[54] An association between schizophrenia and diabetes was recognized as early as the mid-1920's,[55] and a more recent body of evidence similarly points to an association between bipolar disorder and diabetes.[56] Estimates of the current prevalence of diabetes in patients with schizophrenia range from 10% to 36%, and an estimated 10% to 26% of bipolar patients have the disease.[57] Data from CATIE also illustrate that schizophrenic patients have a higher baseline prevalence of metabolic syndrome,[58] which, in those without diabetes, represents a prediabetic state that, over time, progresses to overt diabetes in a significant proportion of individuals.[59] In addition, 25.7% of the CATIE patients had prediabetes – that is, a fasting blood glucose level greater than or equal to 100 mg/dL at baseline.[60]

There are two types of diabetes: Type 1 diabetes (also called insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes), and Type 2 diabetes (also called non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes).[61] Type 1 diabetes, which usually strikes children and young adults and accounts for about 5% to 10% of all diagnosed cases of diabetes, develops when the body's immune system destroys pancreatic beta cells, the only cells that make insulin, the hormone that regulates blood

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glucose. In contrast, Type 2 diabetes, which accounts for about 90% to 95% of all known cases of diabetes, is a progressive disorder. Type 2 diabetes "usually begins as insulin resistance, a disorder in which the cells do not use insulin properly. As the need for insulin rises, the pancreas gradually loses its ability to produce insulin."[62] However, many people with insulin resistance never develop diabetes.

According to the American Diabetes Association ("ADA"), the major risk factors for developing type 2 diabetes include:[63]

- Age ≥ 45
- Overweight (BMI ≥ 25 kg/m^2)
- Family history of diabetes (*i.e.*, parents or siblings with diabetes)
- Habitual physical inactivity
- Race/Ethnicity (*e.g.*, African-Americans, Hispanic-Americans, Native-Americans, Asian-Americans, and Pacific Islanders)
- Previously identified impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)[64]
- History of gestational diabetes[65] or delivery of a baby weighing > 9 lbs.
- Low HDL cholesterol level (≤ 35 mg/dl) and/or high triglyceride level (≥ 250 mg/dl)
- Polycystic ovary syndrome
- Acanthosis nigricans
- History of vascular disease, such as hypertension

Other risk factors include smoking and prolonged and heavy alcohol consumption.[66]

Studies have shown that having hypertension or a family history of diabetes can double the risk of having the disease, and that the risk factors of age, obesity, poor lipid profile, and gestational diabetes can more than double the risk.[67] Moreover, the greater the

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number of risk factors present in an individual, the greater the chance that he or she has or is developing diabetes.[68]

Because Type 2 diabetes is often asymptomatic and can remain undiagnosed for as long as seven to ten years,[69] persons at risk should receive regular diabetes screening. The ADA recommends that individuals be screened for diabetes at three-year intervals beginning at age 45, regardless of the presence of other risk factors.[70] People who are overweight and have one or more of the other risk factors, however, should be screened at an earlier age and/or more often.[71]

"Many people with type 2 diabetes can control their blood glucose by following a healthy meal plan and exercise program, losing excess weight, and taking oral medication."[72] Weight loss and increased physical activity by persons with prediabetes and other risk factors for developing type 2 diabetes may prevent or delay the onset of the disease.[73] Medications, too, have been successful in preventing diabetes in certain population groups.[74] Indeed, both lifestyle changes and medication have been shown to increase the probability of reverting from IGT to normal glucose tolerance.[75]

V. THE REGULATORY CONTEXT

D. ZYPREXA'S APPROVED INDICATIONS

In September 1995, after collecting and analyzing the safety and efficacy data from approximately 2,500 patients in clinical trials, Lilly filed its New Drug Application ("NDA"), seeking approval to market Zyprexa for the treatment of schizophrenia. After a thorough review of all data and analyses in the original NDA, a safety update, and additional information provided by Lilly in response to FDA requests, the FDA determined that Zyprexa was safe and effective and approved it for "the treatment of the manifestations of psychotic disorders" on September 30, 1996.[76] At the time of approval, the clinical trials supporting the Zyprexa NDA were the most extensive ever done for an antipsychotic compound.

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Since approving Zyprexa for the treatment of schizophrenia, the FDA has reviewed data in supplemental NDA submissions for more than 80 additional Zyprexa clinical studies and has approved the drug as safe and effective for the treatment of acute mania associated with bipolar I disorder as monotherapy (March 2000)[77] as well as in combination with lithium or valproate (July 2003),[78] for maintaining a treatment response in schizophrenic patients (November 2000),[79] and in patients with bipolar disorder (January 2004).[80] Zyprexa continues to be approved by the FDA for the treatment of schizophrenia and bipolar disorder. More than 19 million patients worldwide have been treated with Zyprexa.

In addition to these FDA-approved indications, physicians may prescribe Zyprexa for any other ("off-label") uses that, in their medical judgment, will best serve their patients. As explained in *Washington Legal Foundation v. Henney*: "A physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA. . . . [T]he prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties."[81] The FDA, which has no authority to regulate the practice of medicine, has long recognized the benefits of off-label use:

> Once a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature. . . . Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations. . . .[82]

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E. CHRONOLOGY OF LABELING CHANGES REGARDING DIABETES-RELATED ADVERSE EVENTS

Since Zyprexa was approved in 1996, the Adverse Reactions section of its package insert[83] has identified four diabetes-related adverse events as having been observed infrequently (*i.e.*, 1/100-1/1000 patients) or rarely (*i.e.*, fewer than 1/1000 patients) in patients during clinical trials: diabetes mellitus, hyperglycemia, ketosis and diabetic acidosis. In addition, the product labeling has always listed weight gain as an adverse event "commonly observed" in clinical trials.[84]

Throughout the ten years Zyprexa has been on the market, Lilly has monitored all post-marketing reports of diabetes-related adverse events, and provided the FDA and foreign regulatory agencies (such as the European Medicines Evaluation Agency or EMEA) with regular periodic safety update reports based on this post-marketing experience.[85] The rate at which diabetes mellitus, hyperglycemia, ketosis and diabetic acidosis have been reported in post-marketing spontaneous reports is not significantly different from what was observed in the clinical trials. Moreover, as a result of its ongoing pharmacovigilance, Lilly added diabetic coma in April 2000 and pancreatitis[86] in November 2001[87] to Zyprexa's labeling as post-marketing adverse events.

Based upon a review of spontaneously reported post-marketing reports[88] of new onset diabetes, diabetic coma and diabetic ketoacidosis in patients who used atypical antipsychotic medications, the FDA, on May 1, 2000, asked that all manufacturers of medicines in this class of antipsychotics provide a comprehensive review of their preclinical, clinical and post-marketing data pertaining to alterations to glucose metabolism as well as correspondence with foreign regulatory authorities regarding these data.

On July 31, 2000, Lilly responded to the FDA's request by providing three volumes of analyses of data, information regarding the addition of a special diabetes warning/precaution in Europe, and correspondence between Lilly and several regulatory

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agencies on the topic of diabetes. On May 21, 2001, Lilly supplemented its July 2000 submission with the results of two pharmacoepidemiological studies regarding the risk of diabetes in patients treated with typical and atypical antipsychotics, based on data in two computerized health databases. However, these retrospective epidemiological studies have a number of limitations, including inadequate information in the databases regarding patients' preexisting risk factors for diabetes and the severity of their mental illnesses, and small numbers of new cases of diabetes. These limitations preclude any conclusions regarding causation, which requires investigation in well-controlled clinical trials.

In an annual report to the FDA for 2001, Lilly stated that there had been several worldwide regulatory inquiries about hyperglycemia. In April 2002, Lilly notified the FDA that the Japanese Ministry of Health, Labour and Welfare ("MHLW") had required that Lilly include information regarding diabetes and hyperglycemia in the warnings, contraindications and precautions sections of product labeling. Lilly provided the FDA with the data on which the MHLW had based its decision as well as a "Dear Doctor letter" sent to physicians in Japan.

In October 2002, Lilly submitted additional information to the FDA on "Olanzapine and Glucose Homeostasis," including, *inter alia*, additional clinical trial data, analyses of published literature on diabetes and antipsychotic use, and an evaluation of post-marketing data regarding diabetes and patients treated with Zyprexa. In March 2003, Lilly supplemented its October 2002 submission with a detailed analysis of post-marketing data regarding Zyprexa and diabetes, reflecting experience in over 9 million patients. The reporting rate of diabetes-related adverse events was .01%. In June 2003, Lilly provided the FDA with yet more clinical trial data and published literature regarding diabetes and antipsychotic use.

Not until September 11, 2003, after completing its multi-year review of all the available data from all atypical antipsychotic manufacturers, did the FDA conclude that the

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labeling regarding all atypical antipsychotics should be changed. The FDA asked that the product labeling for *every* atypical antipsychotic medication be updated to include a warning regarding diabetes-related adverse events. In its letter to all manufacturers of atypicals, the FDA acknowledged that the relationship between atypical antipsychotic use and diabetes mellitus adverse events "ha[d] not been completely described."[89] As the FDA explained:

> After reviewing the available data pertaining to the use of atypical antipsychotic medications and diabetes mellitus adverse events, we have concluded that the product labeling for all atypical antipsychotics should be updated to include information about these events.[90]

On September 16, 2003, Lilly updated its product labeling for Zyprexa in accordance with the FDA's request.[91]

The FDA's deliberation with respect to the September 11, 2003 class labeling change is consistent with the agency's policy that any significant labeling change be "scientifically substantiated." As the FDA has recently explained:

> FDA's regulation of prescription drugs is designed to ensure each drug's optimal use through requiring scientifically substantiated warnings. Under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment, could well frustrate the purpose of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects.[92]

Indeed, in the case of Zyprexa, FDA officials explained that one reason they took several years to reach a conclusion regarding whether the product labeling should include a warning with regard to diabetes is that "they [were] very much aware that requiring a warning could influence doctors to prescribe it less often [and] that they [did not] want to act in a way that might divert patients to other drugs, when it could turn out the rival medications cause the same problems."[93] These officials also explained that, "in recent years, [the FDA's neuropharmacological division has] gradually moved away from requiring

manufacturers to warn about 'possible' side effects [and] aims instead to define risks with more certainty."[94]

F. THE FDA HAS NOT DETERMINED THAT A CAUSAL CONNECTION BETWEEN ZYPREXA AND DIABETES-RELATED CONDITIONS HAS BEEN ESTABLISHED

The FDA's September 11, 2003 labeling directive neither states nor implies that there is a causal connection between atypical antipsychotic use and diabetes. Indeed, the labeling language requested by the FDA notes that "the relationship between atypical antipsychotic use and diabetes mellitus adverse events has *not* been completely described."[95] Thus, the mere fact that a patient who took Zyprexa develops a diabetes-related condition does *not* mean that Zyprexa was the cause. As discussed earlier, an association between schizophrenia, affective disorders and diabetes was described long before the introduction of medications for the treatment of schizophrenia and bipolar disorder. Moreover, initial discovery has already revealed that many plaintiffs have one or more major risk factors for diabetes in addition to schizophrenia or bipolar disorder.

Plaintiffs have placed substantial reliance on the number of spontaneous adverse event reports submitted to the FDA regarding diabetes-related adverse events. Spontaneous reporting of adverse events, however, cannot establish a causal link between the use of Zyprexa and the onset of type 2 diabetes for numerous reasons, including the following:[96]

- Rates of reporting of adverse events are not an accurate reflection of the frequency of those adverse events in a specific population.[97]
- The FDA's AERS data frequently do not provide information regarding (1) duration or amount of medication used; (2) pre-existing conditions; (3) use of concomitant medication; (4) duplicate reports;[98] or (5) injuries attributed to the prescribing physician (*e.g.*,

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improper dosage or diagnosis) or the user (*e.g.*, failure to follow instructions for use).

- Distortions in spontaneous adverse event reporting may occur as prescribers become aware of a particular adverse event from experience, literature, product labeling, or other sources.[99]

Given these shortcomings, adverse event reporting rates derived from AERS data are not generally accepted as a scientific basis for making a valid assessment of the relationship between ingestion of a drug and a subsequent adverse event. In addition, the raw number of spontaneously reported adverse events fails to account for the total number of patients who received Zyprexa. To illustrate this point: there were approximately 900 spontaneous adverse event reports of diabetes-related adverse events for patients who were prescribed Zyprexa from September 30, 1996 (the date of its approval for the treatment of schizophrenia) through March 31, 2002. Yet, approximately 9,070,000 patients were treated with Zyprexa during that same time period, yielding a reporting rate of approximately .01% or 1 in 10,000. The reporting rate of potentially severe glucose adverse events involving death, coma and acidosis was substantially less. Thus, even assuming that these adverse events were underreported by a conservative factor of up to 30:1, such incidence is consistent with the infrequent (1/100-1/1000) occurrence of diabetes and hyperglycemia during clinical trials, and moreover, is not unexpected given the high prevalence of diabetes in the general population, particularly among people with schizophrenia and bipolar disorder.

Although a temporal association between a number of psychotropic medications (including Zyprexa) and changes in glucose regulation has been reported in anecdotal reports and small case series, the available scientific data from well-controlled, randomized, double-blind clinical trials and epidemiological studies do not establish a causal relationship between Zyprexa and diabetes.

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Several epidemiological studies examining a possible association between antipsychotic medications and diabetes have been reported. These studies vary in design, sample size, methods, specific comparisons, and outcomes. Overall, the results suggest that patients treated with antipsychotics may have a greater likelihood of diabetes than patients who are not treated with these medications; however, they do not establish whether the increased risk is caused by treatment with antipsychotic medication or by other factors, including the increased risk of diabetes observed in the seriously mentally ill (with or without antipsychotic treatment).[100]

There are, however, data from Lilly's Zyprexa clinical trials that have been analyzed to determine what factors significantly predicted treatment-emergent diabetes ("TED"). This analysis of over 5,000 patients in clinical trials of up to one year's duration found that treatment with Zyprexa was not significantly associated with an increased risk of diabetes, as compared to a non-Zyprexa treatment cohort (haloperidol, risperidone, and placebo combined). Risk factors for TED were found to be: elevated non-fasting glucose at baseline, baseline weight, weight gain, being over 45 years old, non-Caucasian ethnicity, and having two or more diabetes risk factors at baseline. The most significant predictors of TED were elevated baseline glucose levels or the presence of multiple baseline risk factors (identical to those well-established in the general population).[101]

In addition, in the CATIE study,[102] treatment with Zyprexa was not associated with a significant risk of developing diabetes.[103] Patients taking Zyprexa were not significantly more likely to receive new prescriptions for antidiabetic therapies than patients treated with other study medications.[104]

Finally, even if it were possible to establish a causal connection between the use of Zyprexa and diabetes-related conditions, plaintiffs must prove that it was a substantial factor in causing the injuries alleged to have been suffered by Alaska's Medicaid recipients. If these patients are similar to the plaintiffs in the MDL, discovery will show that they had

one or more of the major risk factors for diabetes at the time they began taking Zyprexa. In addition, discovery will show that many of these individuals were also on diabetogenic drugs at the time of diagnosis or death, which may have contributed to their alleged injuries. Moreover, research on the etiology of diabetes continues to identify new markers for the disease. Many factors that may cause or contribute to the development of diabetes are still unknown.

VI. CONCLUSION

Atypical antipsychotics have proven to be more effective than typical antipsychotics and conventional medications used to treat schizophrenia and bipolar I disorder. Despite these and other new advances in the neuroscience of mental health, nearly half of all Americans who have a severe mental illness do not seek any treatment at all.[105] With bipolar disorder ranked sixth and schizophrenia ranked ninth among the ten leading causes of disability worldwide,[106] the Surgeon General has challenged policymakers to reduce the crippling burden of mental illness on our society by making public policy decisions that *encourage* rather than *discourage* individuals with serious mental illnesses from seeking effective treatment.[107] Consistent with this objective and in recognition of the lack of evidence of a causal connection between atypical antipsychotic use and diabetes, the FDA has neither withdrawn atypical antipsychotic medications from the market nor required that their labeling bear a black box warning.

Certain judicial and litigant actions, too, discourage patients from complying with their physicians' directions to take Zyprexa and, therefore, may be contrary to the best interests of the patient and those persons who bear the burden of his disability. Patients who stop taking Zyprexa on their own may relapse, resulting in hospitalization and, perhaps, harm to themselves or others.

Lilly invites the Court to conduct a full and complete analysis of the medical and regulatory facts that form the backdrop of this litigation so that its decisions will be

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consistent with sound public mental health policy. Accordingly, Lilly will provide additional information should the Court so desire.

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[1] FDA 9/30/96 approval letter.

[2] FDA 11/9/00 approval letter.

[3] FDA 3/17/00 approval letter.

[4] FDA 7/10/03 approval letter.

[5] FDA 1/14/04 approval letter.

[6] In addition, several putative class actions brought on behalf of third party payors seeking, *inter alia,* reimbursement for monies paid for Zyprexa are currently pending before Judge Weinstein.

[7] *See* Order dated September 21, 2006 in the case of *Joel Algario, et al. v. Eli Lilly and Company,* Superior Court of California, Case No. BC347855, attached as Exhibit C to Lilly's Scheduling Conference Submission.

[8] Diabetes mellitus is a group of metabolic diseases characterized by an abnormally elevated glucose level – or hyperglycemia - resulting from defects in insulin production, insulin action, or both. *See* Am. Diabetes Assoc., *Diagnosis and Classification of Diabetes Mellitus,* 29 Diabetes Care (Supp.) S43, S43 (2006) [hereinafter *Diabetes Diagnosis*]. Diabetic acidosis is an acid condition of the body resulting from abnormal amounts of acid, such as acetoacetic and beta hydroxybutyric acids. This condition occurs in people who are not producing insulin or who do not receive enough insulin. Ketosis occurs when there is a buildup of ketones in the body as a result of excessive breakdown of fat caused by insufficient insulin in a person with diabetes mellitus. Acidosis precedes and causes ketosis; the combination (ketosis and acidosis) is called ketoacidosis. Diabetic coma is unconsciousness occurring during ketoacidosis. *See* WebMDHealth, *Glossary of Diabetes-Related Terms,* at http://my.webmd.com/ content/pages/1/1667_50207 (last visited July 10, 2006) [hereinafter *Diabetes Glossary*].

[9] *See* Zyprexa package insert (10/02/96).

[10] *Id.*

[11] *See* Zyprexa package insert (revised 4/12/00).

[12] FDA 4/19/04 Warning Letter to Janssen Pharmaceutica, Inc. at 2.

[13] FDA 9/11/03 letter at 1 (emphasis added). Lilly received this letter on September 15, 2003.

[14] *Id.*

[15] FDA 4/19/04 Warning Letter to Janssen Pharmaceutica, Inc. *supra* note 10 at 4.

[16] Zyprexa package insert (revised 9/16/03).

[17] For example, the diet drugs Fenfluramine and Redux as well as Baycol and Rezulin were withdrawn from the market, and the FDA required that the labeling for Premarin and Serzone include black box warnings. The FDA orders that drugs be withdrawn from the market when post-marketing experience shows that they are not safe for use. 21 C.F.R. § 314.150 (a) (2) (ii). The FDA requires prominently displayed or "black box"

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warnings where "[s]pecial problems, particularly those that may lead to death or serious injury" have been identified. 21 C.F.R. § 201.57 (e).

[18] *Cf. In re "Agent Orange" Prod. Liab. Litig.*, 818 F.2d 145, 165 (2d Cir. 1987) (recognizing that, because epidemiological studies showed only that Agent Orange may or may not cause harm depending upon the nature of exposure and other factors, the relevant causation question for purposes of determining liability "is not whether Agent Orange has the capacity to cause harm, the generic causation issue, but whether it *did* cause harm and to whom. That determination is highly individualistic, and depends upon the characteristics of individual plaintiffs (*e.g.* state of health, lifestyle) and the nature of their exposure to Agent Orange") (emphasis in original).

[19] *See* Robert Freedman, *Schizophrenia*, 349 (18) New Eng. J. Med. 1738, 1738 (2003); Gary D. Tollefson & Cindy C. Taylor, *Olanzapine: Preclinical and Clinical Profiles of a Novel Antipsychotic Agent*, 6 (4) CNS Drug Reviews 303, 304 (2000); U.S. Dep't of Health & Human Serv., *Mental Health: A Report of the Surgeon General* 273 (1999), *available at* http://www.mentalhealth.org/features/ surgeongeneralreport/ home.asp [hereinafter *Surgeon General's Report*].

[20] Freedman, *supra* note 17, at 1738.

[21] *Id.* at 1738-39.

[22] *Id.* at 1738. For a more detailed description of schizophrenia, *see Surgeon General's Report*, *supra* note 17, at 269-79.

[23] *See* E. Clare Harris & Brian Barraclough, *Excess Mortality of Mental Disorder*, 173 Brit. J. Psychiatry 11-53 (1998).

[24] Tollefson, *supra* note 17, at 304; *Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes*, 27 (2) Diabetes Care 596, 596 (2004) [hereinafter *Consensus Statement*].

[25] *Consensus Statement*, *supra* note 22, at 596. *See also* Freedman, *supra* note 17, at 1743. These extrapyramidal side effects, or movement disorders, have been described as follows:

> Acute dystonia is involuntary muscle spasms resulting in abnormal and usually painful body positions. Parkinsonism is defined by tremors, muscle rigidity, and stuporous appearance. Dyskinesias are involuntary repetitive movements, often of the mouth, face, or hands, and akathisia is painful muscular restlessness requiring the person to move constantly.

Surgeon General's Report, *supra* note 17, at 281 n.15.

[26] Tollefson, *supra* note 17, at 304.

[27] Freedman, *supra* note 17, at 1744; Tollefson, *supra* note 17, at 305.

[28] Other atypical antipsychotic medications marketed in the United States include: Clozaril® (clozapine), Risperdal® (risperidone), Seroquel® (quetiapine fumarate), Geodon® (ziprasidone), and Abilify® (aripiprazole). *See* Freedman, *supra* note 17, at 1743.

[29] Freedman, *supra* note 17, at 1745 (internal citations omitted). *See also* Jan Volavka et al., *Clozapine, Olanzapine, Risperidone, and Haloperidol in the Treatment of Patients With Chronic Schizophrenia and Schizoaffective Disorder*, 159 (2) Am. J. Psychiatry 255, 261 (2002) (concluding that atypical antipsychotics "are more effective than Haldol in chronic patients with a history of suboptimal response to treatment"); *Consensus Statement*, *supra* note 22, at 596 (recognizing that atypical antipsychotics "have fewer or no

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extrapyramidal side effects at clinically effective doses. Many of these newer medications are also more effective than the older agents at treating the negative, cognitive, and affective symptoms of psychotic illnesses."); *Surgeon General's Report*, *supra* note 17, at 281-82. *Cf.* John M. Davis et al., *A Meta-analysis of the Efficacy of Second-Generation Antipsychotics*, 60 Arch. Gen. Psychiatry 553, 559-60 (2003) (concluding from meta-analysis that Zyprexa, Clozaril® (clozapine), Risperdal® (risperidone), and Solian® (amisulpride) had proven to be significantly more efficacious than typical antipsychotics, but that other atypicals had not).

[30] Volavka, *supra* note 27, at 260-61; Davis, *supra* note 27, at 559-60; Nila Bhana et al., *Olanzapine: An Updated Review of its Use in the Management of Schizophrenia*, 61 (1) Drugs 111, 112-15, 125-27, 130-31 (2001) [hereinafter *An Updated Review*]; Tollefson, *supra* note 17, at 318-20, 352.

[31] Davis, *supra* note 27, at 559-60; *An Updated Review*, *supra* note 28, at 113, 116, 141-42; Tollefson, *supra* note 17, at 337-38, 352.

[32] Volavka, *supra* note 27, at 260-61.

[33] *An Updated Review*, *supra* note 28, at 113, 115, 127-32.

[34] *Id.* at 113, 116, 142.

[35] *See* Jeffrey Lieberman, et al., *Effectiveness of Antipsychotic Drugs in Patients With Chronic Schizophrenia*, 353(12) N. Engl. J. Med. 1209, 1212 (2005).

[36] *Id.* at 1212-1215.

[37] Nat'l Inst. of Mental Health, *Bipolar Disorder*, *at* http://www.nimh.nih.gov/publicat/bipolar.cfm (last visited July 10, 2006) [hereinafter *Bipolar Disorder*].

[38] *Id.*

[39] *See Surgeon General's Report*, *supra* note 17, at 249; *Bipolar Disorder*, *supra* note 35; *The Merck Manual of Diagnosis and Therapy* § 15, ch. 200 (Mark H. Beers, M.D. & Robert S. Porter, M.D., eds., 18th ed. 2006), [hereinafter *Merck Manual*].

[40] *Bipolar Disorder*, *supra* note 35.

[41] Some people with bipolar disorder experience "rapid-cycling," which technically means four or more episodes of illness within a 12-month period, but can even take place within a single week or, worse, a single day. *Bipolar Disorder*, *supra* note 35.

[42] Robert M.A. Hirschfeld, et al., *Practice Guideline for the Treatment of Patients With Bipolar Disorder (Revision)* pt. B, § IV.B, APA Clinical Resources, *available at* http://www.psych.org/edu/cme/apacme/courses/course15/Bipolar2ePG.doc (2002).

[43] *Id. See also Bipolar Disorder*, *supra* note 35.

[44] *Bipolar Disorder*, *supra* note 35.

[45] *See* Tollefson, *supra* note 17, at 343-44.

[46] *See* Hirschfeld, *supra* note 40, at pt. A, § I.B.1, pt. B, § V.A.5.

[47] *See* Mauricio Tohen et al., *Olanzapine Versus Divalproex in the Treatment of Acute Mania*, 159 (6) Am. J. Psychiatry 1011, 1016 (2002). *See also* John M. Zajecka et al., *A Comparison of the Efficacy, Safety, and Tolerability of Divalproex Sodium and Olanzapine in the Treatment of Bipolar Disorder*, 63 (12) J. Clin.

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Psychiatry 1148, 1154 (2002) (finding that the two agents demonstrate equivalent efficacy in treatment of acute mania in bipolar disorder).

[48] FDA 7/10/03 approval letter, *supra* note 4.

[49] Mauricio Tohen et al., *Efficacy of Olanzapine in Combination With Valproate or Lithium in the Treatment of Mania in Patients Partially Nonresponsive to Valproate or Lithium Monotherapy*, 59 Arch. Gen. Psychiatry 62, 64-65, 68-69 (2002).

[50] Mauricio Tohen et al., *Olanzapine Versus Lithium in the Maintenance Treatment of Bipolar Disorder: A 12-Month, Randomized, Double-Blind, Controlled Clinical Trial*, 162 Am. J. Psychiatry 1281, 1284-1285 (2005); Mauricio Tohen et al., *Randomized, Placebo-Controlled Trial of Olanzapine as Maintenance Therapy in Patients With Bipolar Disorder Responding to Acute Treatment With Olanzapine*, 163 Am. J. Psychiatry 247, 251-253 (2006).

[51] U.S. Dep't of Health & Human Serv., Centers for Disease Control & Prevention, *National Diabetes Fact Sheet: General Information and National Estimates on Diabetes in the United States, 2005* (2006) [hereinafter *Diabetes Fact Sheet*]. Among people aged 20 and older in the United States, about 9.6% have diabetes. *Id.*

[52] *Id.*

[53] Sarah Wild et al., *Global Prevalence of Diabetes: Estimates for the Year 2000 and Projections for 2030*, 27 (5) Diabetes Care 1047, 1051 (2004).

[54] The Canadian Diabetes Association has recognized schizophrenia as a risk factor for diabetes. *See* Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, *Canadian Diabetes Association 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada.* Can. J. Diabetes 27 (suppl 2) S1, S10 (2003).

[55] J. Kasanin, *The Blood Sugar Curve in Mental Disease*, 16 Arch. Neurol. Psychiatry 414 (1926).

[56] *See* Frederick Cassidy et al., *Elevated Frequency of Diabetes Mellitus in Hospitalized Manic-Depressive Patients*, 156 Am. J. Psychiatry 1417, 1419 (1999); Shelley L. Lilliker, *Prevalence of Diabetes in a Manic-Depressive Population*, 21 (4) Comparative Psychiatry 270, 273-74 (1980).

[57] *See* William T. Regenold et al., *Increased Prevalence of Type 2 Diabetes Mellitus Among Psychiatric Inpatients with Bipolar I Affective and Schizoaffective Disorders Independent of Psychotropic Drug Use*, 70 J. Affective Disorders 19, 22 (2002); Cassidy, *supra* note 54, at 1418; Sukdeb Mukherjee et al., *Diabetes Mellitus in Schizophrenic Patients*, 37 (1) Comparative Psychiatry 68, 69 (1996); Lilliker, *supra* note 54, at 273-74.

[58] *See* Joseph P. McEvoy et al., *Prevalence of the Metabolic Syndrome in Patients With Schizophrenia: Baseline Results From the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) Schizophrenia Trial and Comparison With National Estimates From NHANES III*, 80 Schizophrenia Research 19, 20-21 (2005). "The metabolic syndrome is defined by a cluster of clinical features that include increased abdominal or visceral adiposity (measured by waist circumference), atherogenic dyslipidemia (low high density lipoprotein (HDL) and elevated fasting triglycerides), hypertension, and impaired fasting glucose or overt diabetes mellitus (DM)." *Id.* at 20-21.

[59] The Third National Health and Nutrition Examination Survey found that 87% of diabetics among the cohort over age 50 met metabolic syndrome criteria. *Id.* at 21-22. (citation omitted).

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[60] *Id.* at 25.

[61] *Diabetes Fact Sheet*, *supra* note 49.

[62] *Id.* It can take several years for the pancreatic beta cells to lose their ability to compensate for insulin resistance by producing more insulin, but when they do, insulin levels fall below supernormal values, glucose levels begin to rise above normal and hyperglycemia develops. *See* Am. Diabetes Assoc., *Diagnosis and Classification of Diabetes Mellitus*, 27 Diabetes Care (Supp.) S5, S5-S7 (2004).

[63] Am. Diabetes Assoc., *Position Statement: Standards of Medical Care in Diabetes-2006*, 29 Diabetes Care (Supp.) S4-S42, S6 [hereinafter *ADA Position Statement*]; *see also* Florence J. Dallo & Susan C. Weller, *Effectiveness of Diabetes Mellitus Screening Recommendations*, 100 (18) PNAS 10574, 10578.

[64] A person has IFG if his fasting blood sugar level is elevated, *i.e.*, 100-125 mg/dl, after an overnight fast. With IGT, a person's blood sugar level is elevated, *i.e.*, 140-199 mg/dl, after a 2-hour oral glucose tolerance test. (If a person's IFG is $\geq$ 126 mg/dl or his IGT is $\geq$ 200 mg/dl, he has diabetes. *See* ADA *Position Statement supra* note 62, at S5.) A person with this elevated blood glucose has hyperglycemia. People with either IFG or IGT have "prediabetes" and an increased risk of developing type 2 diabetes. *See Diabetes Fact Sheet*, *supra* note 49. In addition to the fasting plasma glucose (FPG) test and the 75-g oral glucose tolerance test (OGTT), the casual (random) plasma glucose test can be used to screen for diabetes. A casual plasma glucose level $\geq$ 200 mg/dl (11.1 mmol/L) with symptoms of diabetes is considered diagnostic of diabetes. ADA *Position Statement*, *supra* note 62, at S5.

[65] Gestational diabetes is a form of glucose intolerance that some women experience during pregnancy. These women have a 20% to 50% chance of developing type 2 diabetes in the next 5-10 years. *Diabetes Fact Sheet*, *supra* note 49.

[66] *See* The Cleveland Clinic, *Type 2 Diabetes Mellitus*, *at* http://www.clevelandclinic.org/health/health-info/docs/1700/1734.asp?index=7073&src=news (last visited July 10, 2006).

[67] Dallo, *supra* note 62, at 10578.

[68] Am. Diabetes Assoc., *Screening for Type 2 Diabetes*, 27 Diabetes Care (Supp.) S11 (2004).

[69] Am. Diabetes Assoc., *Frequently Asked Questions About the Risk Test, at* http://www.diabetes.org/ risk-test/faq.jsp (last visited July 10, 2006).

[70] ADA *Position Statement*, *supra* note 62, at S6.

[71] *Id.* Some studies have suggested that screening should take place where one risk factor is present. *See* Dallo, *supra* note 62, at 10578.

[72] *Diabetes Fact Sheet*, *supra* note 49. *See also Diabetes Diagnosis, supra* note 6, at S43.

[73] *ADA Position Statement, supra* note 62, at S7. Participants in a large diabetes prevention study who had a high risk of diabetes were able to reduce development of the disease by 58% over 3 years. *Id.*

[74] *Id.* ("a 31% relative reduction in the progression of diabetes was observed in the metformin group compared with control subjects").

[75] *Id.*

[76] FDA 9/30/96 approval letter, *supra* note 1.

[77] FDA 3/17/00 approval letter, *supra* note 3.

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[78] FDA 7/10/03 approval letter, *supra* note 4.

[79] FDA 11/9/00 approval letter, *supra* note 2.

[80] FDA 1/14/04 approval letter, *supra* note 5.

[81] 202 F.3d 331, 333 (D.C. Cir. 2000) (internal citations omitted).

[82] *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bulletin 4, 5 (1982). The FDA has reaffirmed this policy on numerous occasions. *See, e.g.*, James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths & Misconceptions*, 53 Food & Drug L.J. 71, 77-78 (1998).

[83] *See* Zyprexa package insert (10/02/96), *supra* note 7.

[84] *Id.*

[85] Pharmaceutical companies are legally required to provide periodic reports of all post-marketing adverse drug experience information to the FDA. 21 C.F.R. 314.80 (b), (c) (2). An adverse drug experience includes "any adverse event associated with the use of the drug in humans, whether or not considered drug related . . . ." 21 C.F.R. 314.80(a).

[86] Pancreatitis has been defined as:

> A rare disease in which the pancreas becomes inflamed. . . . The most common causes for pancreatitis are alcohol and gallstones. There are two forms of pancreatitis, acute and chronic. The acute form occurs suddenly and may be a severe, life-threatening illness with many complications. Usually, the patient recovers completely. A chronic form of the disease may develop if injury to the pancreas continues, such as when a patient persists in drinking alcohol, bringing severe pain and reduced functioning of the pancreas that affects digestion and causes weight loss.

The Cleveland Clinic, *Gastrointestinal Glossary of Terms*, *at* http://www.clevelandclinic.org/health/health-info/docs/1600/1693.asp?index=7038&src=news (last visited July 10, 2006).

A few complaints against Lilly aver pancreatitis as an injury allegedly caused by Zyprexa. Pancreatitis, however, is not considered a diabetes-related condition and is *not* the subject of the FDA's September 11, 2003 letter (*see* FDA 9/11/03 letter, *supra* note 11.)

[87] *See* Zyprexa package insert (revised 4/12/00) *supra* note 9; Zyprexa package insert (revised 11/01/01).

[88] The FDA's Adverse Event Reporting System ("AERS") enables the agency to review and evaluate all spontaneous reports of post-marketing adverse events. *See* Evelyn M. Rodriguez et al., *The Role of Databases in Drug Postmarketing Surveillance*, 10 (5) Pharmacoepidemiology & Drug Safety 407, 407-408 (2001).

[89] FDA 9/11/03 letter, *supra* note 11, at 1.

[90] *Id.*

[91] *See* Zyprexa package insert (revised 9/16/03), *supra* note 14.

[92] Brief of Amicus Curiae FDA at 23, *Motus v. Pfizer, Inc.* (9th Cir. 2004) (Nos. 02-55372, 02-55498) [hereinafter "FDA *Motus* Brief"].

[93] Geet Anand & Thomas M. Burton, *Drug Debate: New Antipsychotics Pose a Quandary for FDA, Doctors*, Wall St. J., April 11, 2003, at 3; *see also* Thomas M. Burton, *FDA to Require Diabetes Warning on Class of Schizophrenia Drugs*, Wall St. J., Sept. 18, 2003.

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[94] Anand, *supra* note 92, at 2.

[95] FDA 9/11/03 letter, *supra* note 11, at 1 (emphasis added).

[96] *See* Elizabeth A. Koller & P. Murali Doraiswamy, *Olanzapine-Associated Diabetes Mellitus*, 22 (7) Pharmacotherapy 841, 848, 850 (2002); Rodriguez, *supra* note 87, at 408.

[97] *See* Koller, *supra* note 95, at 848.

[98] *Id.*

[99] *See id.*

[100] *See, e.g.*, Michael J. Sernyak et al., *Association of Diabetes Mellitus with Use of Atypical Neuroleptics in the Treatment of Schizophrenia*, 159 (4) Am. J. Psychiatry 561, 565 (2002) (retrospective study did not definitively establish a causal relationship between the use of atypical antipsychotic medications and diabetes); Michael E.J. Lean & Frank-Gerald Pajonk, *Patients on Atypical Antipsychotic Drugs: Another High-Risk Group for Type 2 Diabetes, Response to Hardy and Breier*, 26 (11) Diabetes Care 3202, 3202 (2003) (acknowledging that retrospective studies "do not claim to demonstrate causation but are primarily for hypothesis generation to highlight an emerging issue to address in further research"); Leslie Citrome et al., *Relationship Between Antipsychotic Medication Treatment and New Cases of Diabetes Among Psychiatric Inpatients*, 55(9) Psychiatric Servs. 1006, 1012 (2004) (noting that long-term prospective epidemiological cohort studies, as well as randomized clinicial trials, are needed to ascertain whether there is a cause-and-effect relationship between atypical antipsychotics and diabetes).

[101] Patrizia Cavazzoni et al., *Retrospective Analysis of Risk Factors in Patients With Treatment-emergent Diabetes During Clinical Trials of Antipsychotic Medications*, 185 (Supp. 47) Brit. J. Psychiatry S94, S98-S100 (2004); Patrizia Cavazzoni et al., *2005 Summary Description of Errors and Corrections, available at:* http://bjp.rcpsych.org.

[102] *See supra* Section II.A.

[103] *See* Lieberman, *supra* note 33.

[104] *Id.*

[105] *Surgeon General's Report, supra* note 17, Executive Summary.

[106] *See The Executive Summary of The Global Burden of Disease and Injury Series* § 3.2, at 21, *available at* http://www.hsph.harvard.edu/organizations/bdu/GBDseries.html.

[107] *See Surgeon General's Report, supra* note 17, Executive Summary.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------x

In re: ZYPREXA
PRODUCTS LIABILITY LITIGATION

MDL No. 1596 (JBW)

----------x

THIS DOCUMENT RELATES TO:

ALL ACTIONS

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CASE MANAGEMENT ORDER No. 15
(Deposition Guidelines)

IT IS ORDERED that depositions in the above-captioned matter shall be conducted in accordance with the following rules:

1. **GENERAL PROVISIONS**

a. **Cooperation.** Counsel are expected to cooperate with and be courteous to each other and deponents in both scheduling and conducting depositions.

b. **Lead Deposition Counsel.** Depositions and matters related to depositions shall be coordinated by a Lead Deposition Counsel for plaintiffs and a Lead Deposition Counsel for defendant. Lead Deposition Counsel for plaintiffs shall be Plaintiff Liaison Counsel or his designee, and Lead Deposition Counsel for defendant shall be Nina Gussack or her designee. The name and contact information for any designee shall be promptly communicated to the other

parties.

c. **Attendance.**

i. Who May Be Present. Unless otherwise ordered under Fed. R. Civ. P. 26(c), depositions may be attended by counsel of record, members and employees of their firms, attorneys specially engaged by a party for purposes of the deposition, the parties or the representative of a party, court reporters, videographers, the deponent, and counsel for the deponent. Upon application, and for good cause shown, the Court may permit attendance by a person who does not fall within any of the categories set forth in the preceding sentence. While the deponent is being examined about any stamped confidential document or the confidential information contained therein, persons to whom disclosure is not authorized under an MDL - 1596 Protective Order shall be excluded from the deposition. Any portion of the deposition transcript containing confidential information shall be sealed so as not to waive confidentiality when the transcript or video medium is placed in the document depository.

ii. Unnecessary Attendance. Unnecessary attendance by counsel is discouraged and may not be compensated in any fee application to the Court. Counsel who have only marginal interest in a proposed deposition or who expect their interests to be adequately represented by other counsel should elect not to attend.

iii. Notice of Intent to Attend a Deposition. In order for counsel to make arrangements for adequate deposition space, counsel who intend to attend a deposition noticed in this MDL should advise Lead Deposition Counsel for the noticing party not fewer than seven (7) business days prior to the deposition, whenever feasible.

2. CONDUCT OF DEPOSITIONS

a. **Examination.** Except in depositions that have been cross-noticed in actions pending in state court (see below), questioning should ordinarily be conducted by two attorneys for all plaintiffs and one attorney for defendant in MDL No. 1596, designated by Lead Deposition Counsel for each side. Once the witness has fully answered a question, that same or substantially the same question shall not be asked again. Counsel for plaintiffs who have individual or divergent positions, which cannot be resolved by good faith negotiations with plaintiffs' Lead Deposition Counsel, may examine a deponent limited to matters not previously covered. This limitation shall be strictly construed against the examining attorney. Three (3) days before a deposition requested or noticed by plaintiffs or defendant, Lead Deposition Counsel for the noticing party shall give Lead Deposition Counsel for the other side notice of the identity of the attorney(s) who may examine the deponent. Smoking by deponents or counsel during the deposition will not be permitted.

b. **Duration.** Counsel should consult prior to a deposition to agree upon the time required to depose a particular witness. Absent agreement of the parties or order of Special Master Woodin based on a showing of good cause, the length of depositions shall be controlled by Fed. R. Civ. P. 30(d)(2). Counsel should cooperate so examinations by multiple attorneys do not result in a deposition exceeding the allotted time.

c. **Scheduling.** Absent extraordinary circumstances, counsel should consult in advance with opposing counsel and counsel for proposed deponents in an effort to schedule depositions at mutually convenient times and locations. Counsel are expected to cooperate and coordinate the scheduling of depositions. There shall be no multi-tracking of depositions of former or current

officers or management personnel of Eli Lilly and Company ("Lilly"). Distributors, sales representatives, detail personnel, or other fact witnesses may be multi-tracked and the parties shall meet and confer on the establishment of a reasonable schedule for the multi-tracking of those depositions. To the extent that the parties cannot agree on a proposed schedule for such multi-tracking, the parties shall file with Special Master Woodin separate proposed schedules.

After counsel, through consultation, have arrived on a mutually acceptable date and location for a deposition, each side shall be notified of the scheduled deposition at least thirty (30) days in advance.

d. **Deposition Day.** A deposition day shall commence at 9:30 a.m. and terminate no later than 5:30 p.m. local tune. Modest variations in this schedule may be made by agreement of counsel who noticed the deposition and counsel for the witness. There shall be a 15 minute morning break and a 15 minute afternoon break, with one (1) hour for lunch.

Depositions may not take place in more than three consecutive weeks out of every four consecutive weeks. The fourth week shall be an "off" week. In any given calendar month, the Plaintiffs in the MDL will ordinarily take the depositions of no more than nine (9) current or former employees of Lilly..

e. **Depositions of Witnesses Who Have No Knowledge of the Facts.** An officer, director, or managing agent of a corporation or a government official served with a notice of a deposition or subpoena regarding a matter about which such person has no knowledge may submit to the noticing party within fifteen (15) days before the date of the noticed deposition a declaration so stating and identifying a person within the corporation or government entity believed to have such knowledge. Notwithstanding such declaration, the noticing party may

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proceed with the deposition. The right of the responding witness to seek a protective order or other appropriate relief during or following the deposition is reserved.

f. **Coordination with State Court Actions.** Counsel for plaintiffs in the MDL shall use their best efforts to coordinate the scheduling of depositions with counsel for state court plaintiffs in order to minimize the number of times that a witness shall appear for a deposition. In a coordinated deposition, the Special Master expects counsel for plaintiffs in the MDL and counsel for state court plaintiffs to cooperate in selecting the primary examiners. Upon the conclusion of the examination by the primary examiners, counsel for plaintiffs in a state court proceeding may ask additional questions prior to the completion of the deposition. It is the intent of this Order that counsel for MDL plaintiffs shall be the primary examiners in a deposition coordinated with a state court proceeding, but that counsel in the state court proceeding have sufficient opportunity to question the deponent so that the deposition may be used in the state proceeding for all purposes consistent with the state's procedure.

g. **Cross-Noticing.** Any deposition in this MDL may be cross-noticed by any party in any Zyprexa-related action pending in state court, and any deposition in any Zyprexa-related action pending in state court may be cross-noticed by any party in this MDL. Each deposition notice shall include the name, address and telephone number of the primary examiner(s) designated by the party noticing the deposition; and the date, time and place of the deposition. If a state court deposition has been cross-noticed in this MDL, then the state court plaintiffs may not take a subsequent deposition of that witness except for good cause shown as determined by Special Master Woodin or because documents which may be relevant to the witness or lead to discoverable information have been produced or discovered after the date of the deposition and,

in that case, any subsequent deposition shall be restricted to such additional inquiry permitted by Special Master Woodin or to subsequently produced or discovered documents. The attorney who conducts the primary examination for the noticing party is responsible for ensuring that a copy of the deposition transcript, a disk, and, where applicable, a videotape or video DVD, are provided to the other side's Lead Deposition Counsel.

h. Postponements. Once a deposition has been scheduled, it shall not be taken off the calendar, rescheduled or relocated less than three (3) calendar days in advance of the date it is scheduled to occur, except upon agreement between the primary examiner designated by the party noticing the deposition and Lead Deposition Counsel for the opposing party witness (if the witness is a party or a current or former employee or an expert designated by a party) or counsel for the witness (if the witness is not a party or a current or former employee or an expert designated by a party) or by leave of Special Master Woodin for good cause.

i. Objections and Directions Not to Answer.

i. Counsel shall comply with Fed. R. Civ. P. 30(d)(l). When a privilege is claimed, the witness should nevertheless answer questions relevant to the existence, extent, or waiver of the privilege, such as the date of a communication, who made the statement, to whom and in whose presence the statement was made, other persons to whom the contents of the statement have been disclosed, and the general subject matter of the statement, unless such information is itself privileged. Any objection made at a deposition shall be deemed to have been made on behalf of all other parties. All objections, except those as to form and privilege, are reserved until trial or other use of the depositions.

ii. Counsel shall refrain from engaging in colloquy during deposition. The

phrase "objection as to form" or similar language shall be sufficient to preserve all objections as to form until the deposition is sought to be used. If requested, the objecting party shall provide a sufficient explanation for the objection to allow the deposing party to rephrase the question.

iii. Counsel shall not make objections or statements which might suggest an answer to a witness.

iv. Counsel shall not direct or request that a witness refuse to answer a question, unless that counsel has objected to the question on the ground that the question seeks privileged information, information that the court has ordered may not be discovered, or a deponent seeks to present a motion to Special Master Woodin for termination of the depositions on the ground that it is being conducted in bad faith or in such a manner as to unreasonably annoy, embarrass or oppress the party or deponent.

v. Private consultations between deponents and their attorneys during the actual taking of the deposition are improper, except for the purpose of determining whether a privilege should be asserted. Unless prohibited Special Master Woodin for good cause shown, conferences may be held during normal recesses, adjournments, or if there is a break in the normal course of interrogation and no questions are pending.

j. **Evidentiary Form of Questions.** It is stipulated by plaintiffs and defendant that in the event the parties seek to use at any trial the deposition testimony of any witness offering an opinion, the parties shall not raise at such deposition or trial the objection that the deposition questions asked or the answers given regarding such expert opinion do not conform to the evidentiary form typically required by the jurisdiction whose law would control the case being tried. For example, if one jurisdiction requires an opinion to be expressed to a reasonable degree

of certainty, the parties shall not object to an opinion given to a reasonable degree of probability.

k. Telephonic and Internet Participation.

i. Telephonic Participation. Telephone facilities shall be provided so that parties wishing to participate in the depositions by telephone may do so. However, technical difficulties with telephonic participation shall not constitute grounds for continuing the deposition or for rendering a deposition inadmissible that would otherwise be admissible in evidence. Counsel attending a deposition in person may terminate telephone participation in a deposition if technical problems with the telephonic facilities create disruptions in the deposition.

ii. Internet Participation. The parties will explore the possibility of providing internet facilities for depositions and court hearings.

l. Avoidance of Duplicative Depositions.

i. Depositions Taken in Other Proceedings. The defendant shall advise the Plaintiffs' Steering Committee of all depositions that have been taken by plaintiffs in other Zyprexa-related proceedings (other than depositions of case-specific witnesses) and shall assist in arranging for the Plaintiffs' Steering Committee to obtain copies of transcripts of those depositions. The plaintiffs in this MDL proceeding shall not, without good cause, re-notice the depositions of witnesses who have already been deposed. In the event that a party re-notices the deposition of a witness who has already been deposed, should a party object, then such objection must be made within ten (10) days of the notice and Lead Deposition Counsel shall meet and confer within five (5) days of the objection to attempt to resolve the dispute. If no agreement can be reached, the matter shall be brought to Special Master Woodin, for resolution at the earliest possible time and without undue delay to avoid postponement of the deposition.

ii. **Successive Depositions in this Proceeding.** As a general rule, no witness should be deposed on the same subject more than once in this proceeding.

m. **Disputes During Depositions.** Disputes between the parties should be addressed to Special Master Woodin rather than the District Court in the District in which the deposition is being conducted. Disputes arising during depositions that cannot be resolved by agreement and that, if not immediately resolved, will significantly disrupt the discovery schedule or require rescheduling of the deposition, or might result in the need to conduct a supplemental deposition, shall be presented to Special Master Woodin, by telephone (212-607-2754). If Special Master Woodin is not available, the deposition shall continue with full reservation of rights of the examiner for a ruling at the earliest possible time. Nothing in this Order shall deny counsel the right to suspend a deposition pursuant to Fed. R. Civ. P. 30 (d)(4), file an appropriate motion with Special Master Woodin at the conclusion of the deposition, and appear personally before Special Master Woodin.

n. **Documents Used in Connection with Depositions.**

i. Production of Documents. Third-party witnesses subpoenaed to produce documents shall, to the extent possible, be served with the document subpoena at least thirty (30) calendar days before a scheduled deposition. Depending upon the quantity of documents to be produced, some time may be needed for inspection of the documents before the examination commences. With respect to experts, arrangements should be made to permit inspection of documents, if possible, seven (7) calendar days before the deposition of expert witnesses.

ii. Copies. Extra copies of documents about which deposing counsel expects to examine a deponent should be provided to primary counsel for the parties and the deponent

during the course of the deposition.

iii. Marking of Deposition Exhibits. All documents previously produced and used as deposition exhibits shall be referred to by the unique alpha-numeric identifiers appearing on the documents.

iv. Objections to Documents. Objections to the relevance or admissibility of documents used as deposition exhibits are not waived, and are reserved for later ruling by the Court or by the trial judge.

o. **Video Depositions.** By so indicating in its notice of a deposition, a party, at its expense, may record a deposition by videotape or digitally-recorded video pursuant to Fed. R. Civ. P. 30(b)(2) subject to the following rules:

i. Real-time Feed. All video depositions will be stenographically recorded by a court reporter with "real-time feed" transcription capabilities.

ii. Video Operator. The operator(s) of the video recording equipment shall be subject to the provisions of Fed. R. Civ. P. 28(c). At the commencement of the deposition, the operator(s) shall swear or affirm to record the proceedings fairly and accurately.

iii. Attendance. Each witness, attorney and other person attending the deposition shall be identified on the record at the commencement of the deposition.

iv. Standards. Unless physically incapacitated, the deponent shall be seated at a table except when reviewing or presenting demonstrative materials for which a change in position is needed. To the extent practicable, the deposition will be conducted in a neutral setting, against a solid background with only such lighting as is required for accurate video recording. Lighting, camera angle, lens setting and field of view will be changed only as

necessary to record accurately the natural body movements of the deponent. Only the deponent and any exhibits or demonstrative aids used in the examination will be video recorded. Sound levels will be altered only as necessary to record satisfactorily the voices of counsel and the deponent. The witness shall appear in ordinary business attire (as opposed to, for instance, a lab coat) and without objects such as a bible, medical equipment, or other props.

v. Filing. The operator shall preserve custody of the original video medium (tape or DVD) in its original condition until further order of the Court. No part of the video or audio record of a video deposition shall be released or made available to any member of the public unless authorized by the Court.

p. **Telephone Depositions**. By indicating in its notice of deposition that it wishes to conduct the deposition by telephone, a party shall be deemed to have moved for such an order under Fed. R. Civ. P. 30(b)(7). Unless an objection is filed and served within ten (10) calendar days after such notice is received, Special Master Woodin shall be deemed to have granted the motion. Other parties may examine the deponent telephonically or in person. However, all persons present with the deponent shall be identified in the deposition and shall not by word, sign or otherwise coach or suggest answers to the deponent. The court reporter shall be in the same room with the deponent.

3. USE OF DEPOSITIONS

Depositions of Lilly employees and former employees taken in this MDL proceeding or in any state action relating to Zyprexa in which Lilly is a party may be used by or against any person (including parties later added and parties in cases subsequently filed in,

removed to or transferred to this Court as part of this litigation):

(i) who is a party to this litigation;

(ii) who was present or represented at the deposition;

(iii) who was served with prior notice of the deposition or otherwise had reasonable notice thereof, or

(iv) who, within thirty (30) calendar days after the transcription of the deposition (or, if later, within sixty (60) calendar days after becoming a party in this Court in any action that is a part of this MDL proceeding), fails to show just cause why such deposition should not be useable against such party.Depositions may be used in any Zyprexa-related action in state court to the extent permitted by that state's law and rules.

4. **FEDERAL RULES OF CIVIL PROCEDURE APPLICABLE**

Unless specifically modified herein, nothing in this order shall be construed to abrogate the Federal Rules of Civil Procedure.

Dated: New York, New York
May 2, 2006

Peter H. Woodin
Special Discovery Master

Paul R. Kiesel, Esq. (CBN 119854)
Patrick DeBlase, Esq. (CBN 167138)
KIESEL BOUCHER LARSON LLP
8648 Wilshire Boulevard
Beverly Hills, California 90211
Telephone: 310/854.4444
Facsimile: 310/854.0812

Attorneys for Plaintiffs

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

JOEL ALGARIO, et al.,

Plaintiffs,

v.

ELI LILLY AND COMPANY, et al.,

Defendants.

And Related Cases: BC347856; BC347857; BC347858; and, BC348211.

LEAD CASE NUMBER: BC347855
(Related Cases: BC347856; BC347857; BC347858; and, BC348211)

NOTICE OF COURT ORDER AND NOTICE OF FURTHER STATUS CONFERENCE

DATE : October 10, 2006
TIME : 9:30 a.m.
DEPT : 323

Assigned for All Purposes to Honorable Carolyn B. Kuhl Presiding

TO ALL PARTIES AND TO THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT THE HONORABLE COURT issued the attached Order regarding discovery.

A Further Status Conference (telephonic) has been scheduled by the Court for October 10, 2006, at 9:30 a.m. The conference call information is as follows: Call-In number is: 888/447.7153, participant code: 7491901#. All parties are requested to call in by 9:25 a.m. PST. Once all parties are on the conference call, the host will contact the Court to join in on the conference call.

/////

/////

Pursuant to the Court's Minute Order, Plaintiffs' counsel hereby gives notice.

KIESEL, BOUCHER & LARSON LLP

DATED: September 22, 2006

By: PAUL R. KIESEL, ESQ.
PATRICK DeBLASE, ESQ.
Attorneys for Plaintiffs

ORIGINAL FILED

SEP 21 2006

LOS ANGELES
SUPERIOR COURT

SUPERIOR COURT OF THE STATE CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

JOEL ALGARIO, et al., Plaintiff, vs. ELI LILLY AND COMPANY, et al., Defendants.	LEAD CASE NO.: BC347855 (Related Cases; BC347856; BC347857; BC347858; and BC348211) ORDER
And Related Cases: BC347856; BC347857; BC347858; and BC348211	

This litigation has been designated as a "complex case" in accordance with California Rule of Court 1800. In accordance with that designation, this Court is to manage the case with the goals of (1) expediting the case, (2) keeping costs reasonable and (3) promoting effective decision making by the court, the parties and counsel. See California Rule of Court 1800(a).

This Court is aware that the federal Zyprexa Multidistrict Litigation, MDL-1596, which raises issues of fact and law similar to the litigation before this Court, has been

pending for some time before the Honorable Judge Jack B. Weinstein in the United States District Court for the Eastern District of New York. This Court has reviewed several of the relevant Case Management Orders and letters from the presiding judge in the federal MDL litigation and has spoken with Special Master Peter Woodin who is assigned to supervise the discovery in the MDL proceeding.

In managing this litigation, and in issuing this Order, it is this Court's desire to coordinate with the substantial work that has been done in the MDL proceeding. Consistent with California Rule of Court 1800(a), it is this Court's intent to attempt to avoid additional, unnecessary expenses for the parties, while allowing all parties in this action an adequate opportunity to develop the facts necessary to prosecute and defend the action.

WRITTEN DISCOVERY

1. This Court is informed that Defendant Eli Lilly and Company ("Lilly") already has produced several million documents that have been placed in the MDL Repository maintained as part of the MDL litigation. In order to avoid unnecessary, duplicative production of documents, plaintiffs and their counsel in this litigation are ordered to be given access to the MDL Repository, including access to any document coding supplied by Lilly. This Court will enter an appropriate Protective Order which will govern any restrictions on plaintiffs' and their counsel's use of the documents in the Repository.

2. Plaintiffs' counsel in this California litigation shall not require that any counsel in the MDL litigation make copies of documents from the MDL Repository or impose any unreimbursed expense on counsel in the MDL litigation. Plaintiffs' counsel in this California litigation shall be permitted to make copies of documents from the MDL Repository and copies of any electronic media on which the MDL Repository documents

are stored, at the expense of counsel in the California litigation. Counsel in the California litigation shall not be charged any fee for access to or maintenance of the MDL Repository. If the MDL Repository is terminated, counsel for plaintiffs in the California litigation shall be given an opportunity to assume responsibility for maintenance of the Repository.

DEPOSITIONS

3. Various current and former employees of Lilly have been deposed as part of the MDL litigation. In order to attempt to avoid additional depositions of these witnesses, Lilly is ordered to produce the deposition transcripts (and accompanying exhibits) of all such witnesses to counsel for plaintiffs in this California litigation within 30 days. Counsel for plaintiffs in the California litigation shall reimburse Lilly for the reasonable costs of duplication of these materials. After plaintiffs' counsel has reviewed these transcripts, counsel for both sides are ordered to meet and confer regarding any request by plaintiffs' counsel to redepose witnesses and, failing agreement, this Court will review such requests.

4. With respect to future depositions in the MDL litigation, Lilly has advised this Court that it intends to issue cross-notices of deposition in the California litigation for current and former employees of Lilly that will be deposed in the MDL proceeding. In order to limit unnecessary and repetitive depositions, this Court orders plaintiffs' counsel in the California litigation to participate in such depositions pursuant to Case Management Order No. 15 entered in the MDL litigation. In considering any request to redepose a witness who was deposed in the MDL litigation under this procedure, this Court will review the coordination and participation that was permitted by the Plaintiffs' Steering Committee in the MDL litigation. Lilly shall be permitted to make its witness available to counsel for plaintiffs in the California litigation for an additional amount of

time agreed to between Lilly and counsel in the California litigation if appropriate to avoid the witness's having to appear for an additional deposition.

IT IS SO ORDERED.

DATED: Sept. 21, 2006

HONORABLE CAROLYN B. KUHL
Judge of the Superior Court

CUKUM Lilly-Order 092906

PROOF OF ELECTRONIC SERVICE

I, CESAR R. GARCIA, declare as follows:

1. I am employed in the County of Los Angeles and am an employee at the law firm of Kiesel Boucher Larson LLP , located at 8648 Wilshire Boulevard, Beverly Hills, California 90211-2910.

2. I am over the age of 18 and not a party to the within action.

3. On September 22, 2006, I served the following documents: **NOTICE OF COURT ORDER AND NOTICE OF FURTHER STATUS CONFERENCE** via electronic filing in accordance with the terms of the stipulation signed into by all parties in this litigation governing the JOEL ALGARIO, et al. v. ELI LILLY AND COMPANY, et al. (and related matters), Los Angeles County Superior Court, Lead Case Number: BC347855, requiring all documents to be served upon interested parties via LexisNexis File and Serve System.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this September 22nd day of September, 2006, at Beverly Hills, California.

CESAR R. GARCIA

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

ORDER GRANTING
MOTION FOR DECISION ON SHORTENED TIME

IT IS HEREBY ORDERED that plaintiff's Motion for Decision on Shortened Time is GRANTED.

DATED this 26 day of Sept., 2006

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on 9-26-06 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

SEP 22 2006

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.	)	Case No. 3AN-06-5630 CIV

ORDER PROHIBITING DISCOVERY

IT IS HEREBY ORDERED that defendant shall cancel the deposition of Jerry Colwell scheduled for October 5, 2006, as well as the deposition of Jared Kerr scheduled for September 29, 2006.

IT IS FURTHER ORDERED that no discovery shall take place in this case until this Court has conducted the planning and scheduling hearing currently set for December 8, 2006, and this Court has issued a discovery order.

DATED this 26 day of Sept., 2006

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on 9-26-06 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

000219

SEP 2 2 2006

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

FOR EXPEDITED CONSIDERATION

Case No. 3AN-06-5630 CIV

UNOPPOSED MOTION FOR DECISION ON SHORTENED TIME

Plaintiff State of Alaska moves this court in accordance with Civil Rule 77(g) for expedited consideration of its Motion for Protective Order Prohibiting Premature Discovery. Defendant served a Cross-Notice of Taking Videotaped Deposition of Jerry Colwell to be taken in St. Louis, Missouri on October 5, 2006, and a Cross-Notice of Taking Videotaped Deposition of Jared Kerr to be taken in Philadelphia, Pennsylvania on September 29, 2006. There has been no discovery in this case, and no initial disclosures.

An expedited ruling is needed because the defendant served notices of the out-of-state depositions without allowing the ordinary response time before the scheduled deposition. A decision is needed by noon, on Thursday, September 28, 2006.

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As attested by the accompanying affidavit, undersigned counsel asked Lilly to withdraw the deposition notices as applied to this case, but Lilly was unwilling to do so. In order to protect its rights, the State of Alaska must ask this court for relief on an expedited basis. Lilly's counsel, Mr. Jamieson, does not oppose an expedited ruling on this motion.

DATED this 22 day of September, 2006

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiffs

BY _____
Eric T. Sanders
AK Bar No. 7510085

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
Counsel for Plaintiffs

RICHARDSON, PATRICK, WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
Counsel for Plaintiffs

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FAX: 907.274.0819

Certificate of Service
I hereby certify that a true and correct copy of plaintiff's **Unopposed Motion for Decision on Shortened Time; Affidavit in Support of Unopposed Motion for Decision On Shortened Time; and (proposed) Order** was served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy S Crowe
Date 9/22/06

LAW OFFICES
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FOURTH FLOOR
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FAX: 907.274.0819

STATE OF ALASKA
THIRD DISTRICT
06 SEP 22 PM 4:34
CLERK, TRIAL COURTS
BY _____ DEPUTY CLERK

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,
Plaintiff,
vs.
ELI LILLY AND COMPANY,
Defendant.

Case No. 3AN-06-5630 CIV

AFFIDAVIT OF COUNSEL IN SUPPORT OF MOTION FOR DECISION ON SHORTENED TIME

STATE OF ALASKA)
) ss.
THIRD JUDICIAL DISTRICT)

Eric T. Sanders, being first duly sworn upon oath deposes and says:

1. I am counsel for the State of Alaska in this case.

2. All of the representations in the Memorandum in Support of Motion for Protective Order are correct.

3. A decision by this court is needed by noon on Thursday, September 28, 2006, because the first deposition is scheduled in Philadelphia on Friday, September 29, 2006.

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FAX: 907.274.0819

Eric T. Sanders

SUBSCRIBED AND SWORN to before me this 22nd day of September, 2006, at Anchorage, Alaska.

Peggy S Crowe
Notary Public, State of Alaska
My commission expires: 7/29/2010

OFFICIAL SEAL
STATE OF ALASKA
NOTARY PUBLIC
PEGGY S. CROWE
My Comm. expires: July 29, 2010

LAW OFFICES
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STATE OF ALASKA
THIRD DISTRICT

06 SEP 22 PM 4:34
CLERK, TRIAL COURTS

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT BY _____ DEPUTY CLERK

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

MOTION FOR PROTECTIVE ORDER PROHIBITING PREMATURE DISCOVERY

The State of Alaska, through counsel, hereby requests that this Court enter an order that prohibits discovery, including the depositions of Jerry Colwell and Jared Kerr, until this Court has conducted the planning and scheduling hearing currently set for December 8, 2006. This motion is supported by the attached Memorandum in Support of Motion for Protective order.

DATED this 22 day of September, 2006

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiffs

BY _____
Eric T. Sanders
AK Bar No. 7510085

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GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
Counsel for Plaintiffs

RICHARDSON, PATRICK, WESTBROOK
& BRICKMAN, LLC
H. Blair Hahn
Counsel for Plaintiffs

Certificate of Service
I hereby certify that a true and correct copy of Plaintiff's **Motion for Protective Order Prohibiting Premature Discovery, Memorandum In Support of Motion for Protective Order, and (proposed) Order Prohibiting Discovery** was served by messenger on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy J Crowe
Date 9/22/06

LAW OFFICES
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

MEMORANDUM IN SUPPORT OF MOTION FOR PROTECTIVE ORDER PROHIBITING PREMATURE DISCOVERY

I. Background

In this case the State of Alaska is seeking damages and penalties from Eli Lilly and Company ("Lilly") arising from its marketing and sale of the prescription drug Zyprexa. The State filed this Complaint on February 28, 2006. Lilly removed the case to Federal Court. In its Notice of Removal, Lilly disclosed its intent to ask the MultiDistrict Judicial Panel to transfer this case to a multidistrict litigation proceeding characterized as In Re Zyprexa Products Liability Litigation, MDL-1596 ("the MDL"), pending in the United States District Court for the Eastern District of New York. In federal court Lilly moved to stay all proceedings pending transfer to the MDL. In short, Lilly argued that no

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action should be taken in Alaska because a "District Court should not waste time" on an action that would be managed by a judge in New York.

While Lilly's motion to stay all proceedings was pending, it served the State with a Cross-Notice of Taking Videotape Deposition of Dr. Charles Beasley. Dr. Beasley's deposition was being taken five days later in the MDL. The State immediately moved for a protective order prohibiting this deposition. (See Exhibit 1.) Because Lilly elected to cancel the deposition, the State's motion was withdrawn.

After briefing and argument, Judge Burgess remanded this case to the Alaska Superior Court on July 28, 2006. Lilly answered the plaintiff's Complaint on August 31, 2006.

This Court issued its Initial Pretrial Order on August 23, 2006. Upon receipt of the pretrial order, the parties discussed the nature of this case, agreed it was Non-Routine, and further agreed that the Court should be asked to conduct a scheduling and planning conference. In making this request, the State informed the Court that it would need to decide when discovery should begin:

> It is anticipated that the parties will disagree about what discovery should be allowed and when it should occur. To the extent the Court can offer guidance at the conference or establish a briefing schedule on the disputed discovery issues, it would certainly streamline this litigation. (Emphasis added.)

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On September 18, 2006, the Court decided that this is a Non-Routine case and set a scheduling and planning conference on December 8, 2006.

II. New Deposition Notice

Less than two weeks after answering the Complaint, Lilly served the State with a Cross-Notice of Taking Videotaped Deposition of Jerry Colwell. Lilly intends to depose Mr. Colwell in St. Louis, Missouri, on October 5, 2006. On September 13, 2006, Lilly served a Cross-Notice of Taking Videotaped Deposition of Jared Kerr. Lilly intends to depose Mr. Kerr in Philadelphia, Pennsylvania, on September 29, 2006. Both of these depositions are being taken in the MDL. The State asked Lilly to cancel the depositions, but it was unwilling to do so.

III. The Court Should Issue a Protective Order

As noted, Lilly answered the State's Complaint less than a month ago. As of this date, the status of this action is:

- No planning and scheduling order to determine when discovery should begin;
- No discovery plan;
- No deadlines for discovery;
- No trial date;
- No initial disclosures by either party;
- No documents produced by either party;
- No interrogatories;

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- No requests for production;
- No requests for admissions;
- No discussion about what discovery is necessary or appropriate.

In requesting the scheduling and planning conference, the State informed the Court that the manner in which discovery would occur in this case was an important issue. The State submits that no discovery should be allowed until the parties meet with the Court on December 8, 2006, and establish a discovery plan.

The State anticipates that Lilly will oppose this motion for protective order on the grounds that nothing in the Civil Rules prohibits depositions at this stage of the litigation. Although it may be unclear whether 3AO-03-04 (Amended) abolished the first date that discovery may begin, it is absurd to contend that depositions should occur in a complex case before the parties have produced even one document.

Lilly's opposition may also assert that the depositions are appropriate because one of the State's attorneys, Blair Hahn, is involved in the MDL. But the State of Alaska's local counsel -- its lead counsel -- has a right to prepare for and participate in any deposition that may be used in the State's lawsuit. Eric Sanders is not prepared to attend these depositions.

Moreover, it is important to point out that the claims asserted by the State of Alaska are not identical to the individual personal injury claims being pursued in the

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MDL. Unique issues of fact and law are presented in the State's lawsuit against Lilly. In pleadings filed with the federal court, the State observed:

> As noted above, the consolidated cases [in the MDL] are primarily individual personal injury cases so discovery has focused on common questions of negligence, strict liability and causation of certain types of damages. The current case is very different. Plaintiff here alleges violation of several Alaska Statutes and asserts State common law claims that differ from the conventional negligence and strict liability claims asserted by individual plaintiffs. Discovery in this case must focus on defendant's conduct and statements vis-à-vis the State of Alaska and its agencies. Much of the discovery will be unique to the State of Alaska.[1] (Emphasis added.)

The instant case is not part of the MDL and the State of Alaska has the right to conduct discovery on a schedule that is fair to both parties. At this time Lilly is attempting to dictate the discovery schedule before the Court has time to act.

Finally, Lilly may assert that its cross-notice of deposition is intended to prevent the witnesses from being deposed twice. This argument suggests that the State's lawsuit against Lilly is not an independent action, but rather a part of the MDL. The parties have already fought this battle and Lilly lost -- its attempt to transfer this case to the MDL was unsuccessful. The State of Alaska should not be required, directly or indirectly, to be joined with the MDL for purposes of conducting discovery.

This lawsuit alleges that Lilly sold a defective product in Alaska and caused serious harm to the residents of this state. It is common for employees of a company

---

1 See Plaintiff's Opposition to Defendant's Motion to Stay, at page 7.

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being sued in different jurisdictions by different parties to be deposed more than once. Lilly does not have the right to insist that all its employees must be deposed only one time or that the State must participate when witnesses are deposed in the MDL. If Lilly later needs protection from abusive discovery, it can seek an appropriate order from this Court.

IV. Conclusion

Based upon the foregoing considerations, this Court should order that no discovery, including the depositions of Mr. Colwell and Mr. Kerr, shall take place until the Court has conducted the hearing on December 8, 2006, and entered an order concerning discovery.

DATED this 22 day of September, 2006

FELDMAN ORLANSKY & SANDERS

BY _____
Eric T. Sanders
AK Bar No. 7510085

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele

RICHARDSON, PATRICK, WESTBROOK & BRICKMAN, LLC
H. Blair Hahn

Counsel for Plaintiffs

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Email: sanders@frozenlaw.com

Attorneys for Plaintiff State of Alaska

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ALASKA AT ANCHORAGE

STATE OF ALASKA, Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	Case No. 3:06-cv-00088-TMB **MEMORANDUM IN SUPPORT OF MOTION FOR PROTECTIVE ORDER PROHIBITING PREMATURE DEPOSITION**

Statement of Facts

This case involves claims by the State of Alaska against Eli Lilly and Company arising out of Lilly's manufacture and distribution of the drug Zyprexa, and the costs incurred by Alaska because of problems caused by this drug. This case was filed only ten weeks ago, and is still in its early stages. Initial disclosures have not been exchanged, and Alaska has received no discovery. Lilly has moved for a stay of all proceedings.

One of Lilly's key witnesses is Dr. Charles Beasley. Dr. Beasley is a Lilly employee who was closely involved in the development of Zyprexa.

Ignoring its own pending motion for a stay, on Thursday, May 18, Lilly's counsel served Alaska's counsel with notice that Dr. Beasley will be deposed in Indianapolis on May 23. [Exhibit 1] Lilly's counsel stated: "Our position is that this is your opportunity to depose Dr. Beazley [sic], and we will resist any attempt to re-depose him in this case." [Exhibit 2]

Numerous other cases related to Zyprexa have been filed in other jurisdictions, and some have been consolidated in a multi-district litigation. The Indiana deposition is scheduled in connection with those other cases. Lilly has moved to consolidate this case with the multi-district litigation, but that motion has not yet been ruled on, and for reasons stated in Plaintiff's Motion for Remand [Docket No. 10] Alaska contends this case should not be consolidated, and should be remanded to state court.

Argument

THIS COURT SHOULD PROHIBIT LILLY FROM SCHEDULING AN OUT-OF-STATE DEPOSITION ON FIVE DAYS, ESPECIALLY AT THIS EARLY STAGE OF THE CASE.

This court should enter an order pursuant to Civil Rule 26(c) prohibiting Lilly from proceeding with the May 23 deposition of Dr. Beasley in this case. Alaska is not asking that this court interfere with the deposition as it is currently

scheduled in connection with other cases that are already a part of the multi-district litigation.

Lilly's attempt to make the May 23 deposition Alaska's sole opportunity to examine Dr. Beasley is completely improper. Regardless of whether this case ultimately is consolidated with the multi-district litigation, Alaska should not be deprived of its right to participate meaningfully in a deposition of one of Lilly's key witnesses. With five days notice and without any discovery, Alaska's counsel cannot reasonably be expected to prepare for a deposition. It is not even certain Alaska's counsel can rearrange all of his previous professional commitments and get a plane reservation to Indianapolis in time to attend the deposition.

Scheduling any deposition in this case is premature pursuant to Alaska Civil Rule 30(a)(2)(C), which requires a party to seek leave of court before noticing a deposition prior to the parties' planning conference in connection with Rule 26(d). That conference has not occurred, and Lilly has not sought leave of court to take this deposition.

Scheduling an out-of-state deposition on five days notice also violates Civil Rule 30(b)(1), which requires a party to give reasonable notice prior to the deposition. Five days notice of an out-of-state deposition is absolutely not reasonable.

This court should require Lilly to abide by standard civil rules and not permit Lilly to deny Alaska its chance to depose Dr. Beasley on reasonable notice,

after Alaska has received reasonable discovery to enable it to prepare for an expert deposition.

DATED this 19th day of May, 2006.

By /s/ Eric T. Sanders

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Attorneys for Plaintiff State of Alaska

Certificate of Service

I certify that on May 19, 2006, a copy of the foregoing Memorandum in Support of Motion for Protective Order Prohibiting Premature Deposition was served electronically on:

Brewster H. Jamieson

By /s/ Eric T. Sanders

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA, Plaintiff, vs. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CIV

ORDER FOR SCHEDULING AND PLANNING CONFERENCE

Having determined that this is a Non-Routine case, the Court will conduct a Scheduling and Planning Conference on the 8th day of December, 2006, at 3:00 p.m. Ten days before the conference each party shall file a memorandum which reviews the factual and procedural background of this case and identifies issues to be considered during the conference.

DATED this 18 day of Sept, 2006

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on 9-18-06 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

000237

SEP - 7 2006

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

FILED
STATE OF ALASKA
THIRD DISTRICT
06 SEP -7 PM 3:55
CLERK, Trial Courts
BY
DEPUTY CLERK

MOTION TO CHARACTERIZE THIS CASE AS NON-ROUTINE

The parties agree that this case should be characterized as Non-Routine based upon the guidelines set forth in Administrative Order 3AO-03-04 (Amended). However, the parties may disagree about why the case should be characterized in this manner.

From the plaintiff's perspective, on the issue of liability, this is a routine pharmaceutical failure to warn claim against Eli Lilly, the manufacturer of Zyprexa. Because many other product liability lawsuits have been filed against Eli Lilly, a substantial amount of discovery concerning liability issues has already been completed in other jurisdictions.

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On the other hand, establishing the damages to the State of Alaska will not be routine since it will require the compilation of thousands of documents from a database maintained by the State. It will also require the depositions of medical and statistical experts to calculate the present value damage to the State for the past and future health care costs of many hundreds of Zyprexa-related diabetics who are Alaska residents. Hence, this case involves "special circumstances."

In addition, the State anticipates that it will take approximately seven days to present its case. Assuming Lilly requires a similar amount of time to present a defense, this case is one "requiring more than 10 trial days . . . ."

The State of Alaska requests that this Court hold a Scheduling and Planning Conference for the purpose of establishing an appropriate Non-Routine pretrial order. To enable the parties to present the Court with anticipated discovery problems at the earliest opportunity, the State requests that the conference be scheduled for 90 minutes.[1] As stated in the proposed order submitted with this motion, the parties agree that prior to the hearing they should file a memorandum explaining the factual and procedural

[1] It is anticipated that the parties will disagree about what discovery should be allowed and when it should occur. To the extent the Court can offer guidance at the conference, or establish a briefing schedule on the disputed discovery issues, it would certainly streamline this litigation.

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background of this lawsuit and identify issues to be considered when they appear before the Court.

DATED this 7 day of September, 2006

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiffs

BY _____
Eric T. Sanders
AK Bar No. 7510085

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
Counsel for Plaintiffs

RICHARDSON, PATRICK, WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
Counsel for Plaintiffs

Certificate of Service
I hereby certify that a true and correct copy of the Motion to Characterize this Case as Non-Routine, and (proposed) Order for Scheduling and Planning Conference were served by mail / messenger / facsimile on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy S Crowe
Date 9/7/06

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

QUALIFIED NONOPPOSITION TO MOTION TO CHARACTERIZE CASE AS NON-ROUTINE

Defendant Eli Lilly and Company ("Lilly"), by and through counsel, and hereby submits its qualified nonopposition to the State of Alaska's Motion to Characterize Case as Non-Routine.

Lilly agrees (1) that this case should be characterized as non-routine, (2) that the court should hold a Scheduling and Planning Conference, and (3) that the parties should submit memoranda ten days before the conference to identify and discuss issues that should be addressed during the conference.

Lilly does not agree, however, with the State's characterization of the liability issue as "a routine pharmaceutical failure to warn claim." On the contrary, Lilly expects that discovery on the liability issues will be unusually extensive. The factual issues underlying plaintiff's claims are similar or identical to the issues underlying hundreds of product liability actions, as well as two actions filed by the Attorney General of Louisiana, consolidated in multi-district litigation, captioned *In re: MDL–1596, Zyprexa Products Liability Litigation*, pending in the United States District Court for the Eastern District of New York (the "MDL"). In that proceeding, more than 10 million documents have been produced, including four databases, and depositions of more than 40 of defendant's current and former employees have been taken. Accordingly, Lilly expects a significant overlap between the discovery in this case and discovery already completed (or yet to be completed) in the MDL.

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Given the number of witnesses involved, the volume of documentation (both on the liability and on the damages issues) and the complex nature of the underlying facts, it is almost certain that the State's claim that it can put its case on in seven trial days is hopelessly optimistic.

Lilly agrees with the relief sought in this motion. Lilly does not agree, however, with the State's simplistic view of liability discovery and the length of trial. Lilly will address these issues in greater detail in the memorandum it will submit in advance of the Scheduling and Planning Conference.

DATED this 14th day of September, 2006.

LANE POWELL LLC
Attorneys for Defendant

By /s/ Brewster Jamieson
Brewster H. Jamieson, ASBA No. 8411122

I certify that on September 14, 2006, a copy of the foregoing was served by mail on:

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/s/ Nancy L. Biggerstaff
Nancy L. Biggerstaff, CPS, PLS
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Rindner
Law Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ALASKA

3AN-06-05630 CI

STATE OF ALASKA, Plaintiff, vs. ELI LILLY & COMPANY, Defendant.	Case No. 3:06-cv-88 TMB ORDER

SEP 01 2006

The State of Alaska brought suit against Defendant Eli Lilly & Company, ("Lilly"), in state court, seeking damages and penalties arising from the marketing and sale of the prescription drug Zyprexa. Docket 1, Exhibit A (Complaint). The State alleges that Lilly knew of risks associated with Zyprexa that were not revealed to the Food and Drug Administration, the state, physicians, or consumers. Id. Furthermore, the State alleges that Lilly advertised and sold Zyprexa for a number of non-approved or "off-label" uses. Id. The State alleges fraud and negligent misrepresentation, negligence, strict liability, and violations of the Unfair Trade Practices and Consumer Protection Act, codified in A.S. § 45.50.471, and seeks relief of an award of damages in excess of $100,000 for Zyprexa-related damages of past, present and future medical expenses for recipients of the Alaska Medicaid program, restitution for the cost of all Zyprexa prescriptions paid by the state, civil penalties of $5,000 per violation of the Unfair Trade Practices Act, costs, interest, and actual attorneys' fees. Id.

Lilly removed this matter to Federal Court on April 19, 2006, alleging that this Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1441, and 1446. Docket 1.

Having reviewed the pleadings and heard oral argument on July 24, 2006, the Court now enters the following Order.

Certified to be a true and correct copy
of original filed in my office.
Dated 8-31-06
IDA ROMACK, Clerk
By [signature] Deputy

DISCUSSION

Pursuant to 28 U.S.C. § 1441(a), a defendant may generally remove to the appropriate federal district court "[a]ny civil action of which the district courts have original jurisdiction founded on a claim or right arising under the Constitution, treaties or laws of the United States." Plaintiff moves for an order of remand pursuant to 28 U.S.C. § 1447(c). Docket 10. Under §1447©), a case shall be remanded "[i]f at any time before final judgment it appears that the district court lacks subject matter jurisdiction." The burden of establishing federal jurisdiction falls to the party invoking the removal statute. California ex rel. Lockyer v. Dynegy, Inc., 375 F.3d 831, 838 (9th Cir. 2004). Section 1441(a) "is strictly construed against removal jurisdiction." Id.

Plaintiffs argue that removal was improper, because there is no ground for asserting federal jurisdiction over this case. Docket 11. Plaintiff argues that removal is generally only appropriate in three circumstances: 1) the parties meet the statutory requirements for the Court's diversity jurisdiction;[1] 2) the Complaint raises a substantial federal question; or 3) under the "complete preemption" doctrine, Plaintiff's state law claims have been totally subsumed by federal law. Docket 11 at 3 (citations omitted). Plaintiff argues that its claims for relief arise exclusively under state statutory and common law, and do not require the construction or application of federal law as essential elements of those claims.[2] Docket 11. Accordingly, there is no substantial federal question, and Plaintiff asserts a remand to state court is required. Id.

Defendant argues that federal question removal is proper, because Plaintiff's Complaint raises substantial and disputed federal questions under the federal Food, Drug and Cosmetic Act, ("FDCA"), and under federal Medicaid law. Docket 23. Defendant relies in part on a decision from In re Zyprexa Products Liability Litigation, 375 F.Supp.2d 170 (E.D.N.Y. 2005), in which the United States District Court for the Eastern District of New York found federal question jurisdiction in a similar case.

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[1] Diversity is not an issue in this matter.

[2] Plaintiff notes that "while Defendant's conduct may also be in violation of federal law, it is state law that Plaintiff seeks to enforce." Docket 27 at 3.

The Well-Pleaded Complaint Rule

In determining the presence or absence of federal jurisdiction, the court first applies the "'well-pleaded complaint rule,' which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint." Lockyer, 375 F.3d at 838 (quoting Caterpillar Inc. v. Williams, 482 U.S. 386 (1987)). "The federal issue 'must be disclosed upon the face of the complaint, unaided by the answer or by the petition for removal.'" Id. (quoting Gully v. First Nat'l Bank in Meridian, 299 U.S. 109, 112 (1936)). "A defense is not part of a plaintiff's properly pleaded statement of his or her claim." Id. (quoting Rivet v. Regions Bank, 522 U.S. 470, 475 (1998)).

On its face, Plaintiff's Complaint does not state a claim arising under federal law. Plaintiffs seek relief under Alaska statutes which prohibit deceptive trade practices, and under common law negligence and strict liability analyses.

The Artful Pleading Doctrine

The court's inquiry does not end there. Lippitt v. Raymond James Financial Services, Inc., 340 F.3d 1033, 1041 (9th Cir. 2003). "Under the artful pleading doctrine, a plaintiff may not avoid federal jurisdiction by 'omitting from the complaint federal law essential to his claim, or by casting in state law terms a claim that can be made only under federal law.'" Rains v. Criterion Systems, Inc., 80 F.3d 339, 344 (9th Cir. 1996)(citation omitted). Courts have applied the artful pleading doctrine in complete preemption cases and substantial question cases, the latter of which includes cases where the claim is necessarily federal in character or where the right to relief depends on the resolution of a substantial, disputed federal question. Lippitt, 340 F.3d at 1041-1042. The Ninth Circuit has described the artful pleading doctrine as "a useful procedural sieve to detect traces of federal subject matter jurisdiction in a particular case," but cautions that "Courts should invoke the doctrine only in limited circumstances as it raises difficult issues of state and federal relationships and often yields unsatisfactory results." 340 F.3d at 1041 (citations and quotations omitted).

– **Substantial Federal Question**

"The artful pleading doctrine allows federal courts to retain jurisdiction over state law claims that implicate a substantial federal question." Lippitt, 340 F.3d at 1042. A state law claim falls in this category when 1) a substantial, disputed question of federal law is a necessary element

of the well-pleaded state claim, or the claim is an "inherently federal claim" articulated in state-law terms, or 2) the right to relief depends on the resolution of a substantial, disputed federal question. Id., (citations omitted). The Lippitt court observed that "no specific recipe exists for a court to alchemize a state claim into a federal claim - a court must look at a complex group of facts in any particular case to decide whether a state claim actually 'arises' under federal law." Id., at 1042-43. The Supreme Court suggests that the relevant inquiry is "does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 125 S.Ct. 2363 (2005).

Plaintiff argues that it has alleged violations of state consumer fraud and unfair trade practice statutes, as well as claims under Alaska common law, and that federal law is implicated only in light of the state statutory and common law violations as a "factual predicate" for such violations, not as an essential element. Docket 11 at 8. "No element of Plaintiff's claims requires either the interpretation or application of federal law." Id. Plaintiff argues that while federal law created the Medicaid program, Congress has delegated to the states the administration and operation of the program through individual state Medicaid agencies. Docket 11 at 11-12, citing 42 U.S.C. 1396a(a). Plaintiff acknowledges that its state law claims may touch upon areas in which FDA regulations are present, but those regulations provide no cause of action for Plaintiff. Docket 27 at 5, citing Grable & Sons, 125 S.Ct., 2370.

Defendant argues that "Plaintiff's case is so infused with federal issues" under the FDCA and Medicaid law that the Complaint raises "substantial and disputed" issues of federal law that provide this Court with original jurisdiction. Docket 23 at 3. Specifically, Defendant suggests that because federal funds constitute at least 50% of Alaska's Medicaid program funds at issue in the lawsuit, federal jurisdiction is proper. Docket 23 at 10. Further, Defendant suggests that federal questions relating to off-label promotion lie at the heart of the Complaint. Docket 23 at 5. "Federal regulations require that all claims in promotional labeling or advertising be consistent with warning, labeling and promotional materials approved and monitored by the FDA." Docket 23 at 5, citing 21 C.F.R. §202.1(e)(4)(2005). Defendant suggests that resolution of the off-label promotion claims

and the warnings-related claims requires construction and application of the relevant federal statutory and regulatory provisions. Docket 23 at 6.

The Supreme Court has counseled that "federal jurisdiction demands not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum." Grable, 125 S.Ct. at 2367 (emphasis added). The Court finds no substantial federal question in this matter at this time. Contra In re Zyprexa Products Liability Litigation, 375 F.Supp.2d 170 (E.D.N.Y. 2005).

– Complete Preemption

"Preempted state law claims may be removed to federal court only in the rare instances where Congress has chosen to regulate the entire field." ARCO Environmental Remediation v. Dept. of Health and Environmental Quality of the State of Montana, 213 F.3d 1108,1114 (9th Cir. 2000). The Ninth Circuit has observed that there are two categories of cases where the Supreme Court has found complete preemption: ERISA and the Labor Management Relations Act.[3] 340 F.3d, at 1042. Complete preemption only applies when "federal law completely preempts state law and provides a federal remedy." ARCO, 213 F.3d, at 1114, (quoting Ethridge v. Harbor House Restaurant, 861 F.2d 1389, 1403 (9th Cir. 1988)). In other words, the exclusive cause of action for the claim under these federal statutes was found within the statute itself.[4]

Defendant suggests that complete preemption exists here because "Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medications that any challenge to such marketing and promotions necessarily states a federal cause of action."

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[3]Plaintiffs note that complete preemption also has been found by the National Bank Act. Docket 11 at 17 (citations omitted).

[4] In contrast, "conflict preemption" exists when state law actually conflicts with federal law. Defendant suggests that conflict preemption exists in light of the FDA's position that is approval of labeling under the act preempts conflicting or contrary state law. Docket 23 at 7. Plaintiff, however, notes that "the FDA recognizes that FDS's regulation of drug labeling will not preempt all State law actions." Docket 27 at 6, citing Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3936. "Unlike complete preemption, preemption that stems from a conflict between federal and state law is a defense to a state law cause of action and, therefore, does not confer federal jurisdiction over the case." ARCO, 213 F.3d at 1114 (emphasis added). Therefore, Defendant's argument that conflict-preemption principles apply to failure-to-warn claims such as those asserted here is not dispositive. Docket 23 at 7-8.

Docket 23, fn. 11. However, as Plaintiff observes, the FDCA does not provide an exclusive cause of action or remedy, and it provides no private right of action. Docket 11 at 17. Similarly, "federal Medicaid law does not provide exclusive remedies, or in some cases remedies at all, for those requests for relief." Docket 27 at 7. Rather, "federal medicaid law delegates the management of the Medicaid program, and recovery of Medicaid funds, to the states. Further, the states are required to have laws in place to facilitate this recovery." Docket 27 at 7. Accordingly, neither the FDCA nor Medicaid completely preempt state law and provide a federal remedy, and complete preemption does not apply.

In light of the foregoing, the Court concludes that the artful pleading doctrine does not apply. Plaintiff's claims do not implicate a substantial federal question, and the Court does not find complete preemption. Plaintiff's claims seek relief to recover damages solely under Alaska law.

CONCLUSION

For the reasons set out above, the Motion for Remand at Docket 10 is **GRANTED**, and this matter is **REMANDED** to the Superior Court for the State of Alaska, Third Judicial District at Anchorage. It is further ordered that Defendant's motion at docket 4 to stay all proceedings, and Plaintiff's motion for hearing at Docket 13 are **DENIED AS MOOT**.

Dated at Anchorage, Alaska, this 28th day of July, 2006.

/s/ Timothy Burgess
Timothy M. Burgess
United States District Judge

U.S. District Court
District of Alaska (Anchorage)
CIVIL DOCKET FOR CASE #: 3:06-cv-00088-TMB
Internal Use Only

State of Alaska v. Eli Lilly and Company
Assigned to: Timothy M. Burgess
Cause: 28:1441 Petition for Removal- Product Liability

Date Filed: 04/19/2006
Jury Demand: None
Nature of Suit: 195 Contract Product Liability
Jurisdiction: Diversity

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V.

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Certified to be a true and correct copy of original filed in my office.
Dated 8-31-06
IDA ROMACK, Clerk
By _____ Deputy

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Date Filed	#	Docket Text
04/19/2006	1	NOTICE OF REMOVAL by Eli Lilly and Company from Superior Court for the State of Alaska, case number 3AN-06-05630 CI. (Filing fee $ 350) (Attachments: # 1 Exhibit A Summons & complaint # 2 Exhibit B Santa Clara & USA # 3 Exhibit C notice to state court)(SMF) (Entered: 04/20/2006)
04/19/2006	2	***Civil Cover Sheet (SMF) (Entered: 04/20/2006)
04/20/2006	3	MINUTE ORDER TO PETITIONER SUBSEQUENT TO REMOVAL. Petitioner to file w/crt w/i days copies of state court docs and svc list.. Signed by Judge Timothy M. Burgess on 04/20/06. (SMF) (Entered: 04/20/2006)
04/20/2006		***Staff Note this is a MDL case therefore, copy of docket sheet and complaint forwarded to Clerk. (SMF) (Entered: 04/20/2006)
04/20/2006	4	MOTION to Stay re 1 Notice of Removal, by Eli Lilly and Company. (Attachments: # 1 Exhibit A # 2 Exhibit B # 3 Exhibit C # 4 Exhibit D # 5 Exhibit E # 6 Exhibit F # 7 Exhibit G # 8 Exhibit H # 9 Exhibit I # 10 Exhibit J # 11 Exhibit K # 12 Exhibit Index & # 13 Text of Proposed Order)(LSC) # 14 Additional Exhibt L added on 4/20/2006 (LSC,). (Entered: 04/20/2006)
04/20/2006		***Set Deadlines as to 4 MOTION to Stay re 1 Notice of Removal,. Responses due by 5/8/2006. (LSC) (Entered: 04/20/2006)
04/20/2006		Docket Annotation re 4 MOTION to Stay re 1 Notice of Removal; Error: Exhibit L inadvertently not attached to

		motion. Correction: Exhibit L attached to motion. (LSC) (Entered: 04/20/2006)
04/24/2006		***Set CMC Pull: CMC to check status 6/18/2006. CMC to check status 7/13/2006. CMC to check to see if case is at issue 8/17/2006. (PLD) (Entered: 04/24/2006)
04/24/2006	5	ANSWER to Complaint by Eli Lilly and Company.(Jamieson, Brewster) (Entered: 04/24/2006)
04/24/2006		***Set CMC Pull: CMC to check status 5/1/2006. Removal documents due. (PLD) (Entered: 04/24/2006)
04/24/2006	6	Corporate Disclosure Statement by Eli Lilly and Company. (Jamieson, Brewster) (Entered: 04/24/2006)
04/24/2006		***Set CMC Pull: CMC awaiting response from chambers 5/30/2006. Email to Judge Burgess 4/24/06, does he want to issue the 16(b) a this time, or wait until the motion to stay is ruled on? (PLD) Modified on 5/18/2006, No response from chambers motion for stay is now U/A(PLD). (Entered: 04/24/2006)
05/03/2006	7	NOTICE *of Compliance re State Court File and Service List* by Brewster H. Jamieson on behalf of Eli Lilly and Company re 3 Order (Attachments: # 1 Exhibit A, State Court File) (Jamieson, Brewster) (Entered: 05/03/2006)
05/08/2006	8	RESPONSE in Opposition re 4 MOTION to Stay re 1 Notice of Removal, filed by State of Alaska. (Attachments: # 1 Exhibit A - April 10, 2006 Order MDL-1596# 2 Exhibit B - Memorandum & Order MDL-1596# 3 Exhibit C - January 30, 2006 Order MDL-1596# 4 Text of Proposed Order)(Sanders, Eric) (Entered: 05/08/2006)
05/08/2006	9	MOTION for Hearing *Re Motion for Stay* by State of Alaska. (Sanders, Eric) (Entered: 05/08/2006)
05/08/2006	10	MOTION to Remand to State Court by State of Alaska. (Attachments: # 1 Text of Proposed Order)(Sanders, Eric) (Entered: 05/08/2006)
05/08/2006		***Set Deadlines as to 4 MOTION to Stay re 1 Notice of Removal,. Replies due by 5/18/2006. (EKS) (Entered: 05/08/2006)
05/08/2006	11	MEMORANDUM *of Law in Support of Motion to Remand to State Court* by State of Alaska 10 MOTION to Remand to

		State Court filed by State of Alaska,. (Sanders, Eric) (Entered: 05/08/2006)
05/08/2006	12	MOTION for Hearing re 10 MOTION to Remand to State Court by State of Alaska.(Sanders, Eric) (Entered: 05/08/2006)
05/08/2006	13	MOTION for Hearing *Regarding Defendant's Communications with Judge Weinstein* by State of Alaska. (Attachments: # 1 Exhibit 1 - April 20, 2006 Letter to JPML Clerk# 2 Exhibit 2 - April 19, 2006 Letter to Judge Weinstein# 3 Exhibit 3 - April 20, 2006 Letter to Judge Weinstein) (Sanders, Eric) (Entered: 05/08/2006)
05/08/2006		***Sett Deadlines as to 13 MOTION for Hearing *Regarding Defendant's Communications with Judge Weinstein*, 12 MOTION for Hearing re 10 MOTION to Remand to State Court, 10 MOTION to Remand to State Court. Responses due by 5/26/2006 (EKS) (Entered: 05/09/2006)
05/15/2006	14	REPLY to Response to Motion re 4 MOTION to Stay re 1 Notice of Removal, *(Pending Transfer to the Judicial Panel on Multidistrict Litigation)* filed by Eli Lilly and Company. (Attachments: # 1 Exhibit A, Order re Stempien v. Eli Lilly# 2 Exhibit B, Complaint)(Jamieson, Brewster) (Entered: 05/15/2006)
05/15/2006	15	Notice to Counsel re 14 Reply to Response re 4 MOTION to Stay, filed by Eli Lilly and Company. A review of the document submitted at dkt 14 confirms that it is over 25 pages in length. Counsel is reminded that, pursuant to D.Ak.LR 10.1 (b), you are required to provide the court with a COURTESY paper copy of your filing at dkt 14. (PLD) (Entered: 05/16/2006)
05/16/2006		***Motions Taken Under Advisement: 4 MOTION to Stay re 1 Notice of Removal. (PLD,) (Entered: 05/16/2006)
05/19/2006	16	MOTION for Protective Order *on Shortened Time Prohibiting Premature Deposition* by State of Alaska. (Attachments: # 1 Text of Proposed Order)(Sanders, Eric) (Entered: 05/19/2006)
05/19/2006	17	MEMORANDUM *in Support of Motion for Protective Order* by State of Alaska 16 MOTION for Protective Order *on Shortened Time Prohibiting Premature Deposition* filed by State of Alaska,. (Attachments: # 1 Exhibit 1 - Cross-Notice of Deposition# 2 Exhibit 2 - Letter dated May 18, 2006)(Sanders,

		Eric) (Entered: 05/19/2006)
05/19/2006	18	MOTION to Expedite *Decision on Motion for Protective Order* by State of Alaska. (Attachments: # 1 Text of Proposed Order)(Sanders, Eric) (Entered: 05/19/2006)
05/19/2006	19	AFFIDAVIT re 18 MOTION to Expedite *Decision on Motion for Protective Order* by State of Alaska. (Sanders, Eric) (Entered: 05/19/2006)
05/19/2006	20	NOTICE *of Supplemental Authority* by Eric T. Sanders on behalf of State of Alaska re 8 Response in Opposition to Motion, (Attachments: # 1 Exhibit A - Memorandum Opinion and Order)(Sanders, Eric) (Entered: 05/19/2006)
05/22/2006	21	NOTICE *of Withdrawal of Motion for Protective Order* by Eric T. Sanders on behalf of State of Alaska re 16 MOTION for Protective Order *on Shortened Time Prohibiting Premature Deposition* (Sanders, Eric) (Entered: 05/22/2006)
05/22/2006	22	CLERK'S NOTICE; Pursuant to Counsel's NOTICE of Withdrawal of Motion for Protective Order and MOTION for Protective Order on Shortened Time Prohibiting Premature Deposition. The Motion for protective order Dkt 16 and motion to expedite Dkt 18 are hereby withdrawn.(PLD) (Entered: 05/22/2006)
05/22/2006		***Motions terminated: 18 MOTION to Expedite *Decision on Motion for Protective Order* filed by State of Alaska 16 MOTION for Protective Order *on Shortened Time Prohibiting Premature Deposition* filed by State of Alaska. (PLD) (Entered: 05/22/2006)
05/23/2006	23	RESPONSE in Opposition re 10 MOTION to Remand to State Court filed by Eli Lilly and Company. (Attachments: # 1 Exhibit A, Amicus Brief in Colacicco v. Apotex# 2 Text of Proposed Order)(Jamieson, Brewster) (Entered: 05/23/2006)
05/23/2006	24	RESPONSE in Opposition re 13 MOTION for Hearing *Regarding Defendant's Communications with Judge Weinstein* filed by Eli Lilly and Company. (Attachments: # 1 Exhibit A, Transcript of 06-15-04 Status Conf# 2 Exhibit C, In re Zyprexa Order 01-12-06# 3 Exhibit D, Transcript of Conf 11-09-05# 4 Text of Proposed Order # 5 Exhibit B, In re Zyprexa Order 01-30-06)(Jamieson, Brewster) (Entered: 05/23/2006)
05/23/2006	25	Notice to Counsel re 24 Response in Opposition to Motion,

		filed by Eli Lilly and Company, 23 Response in Opposition to Motion filed by Eli Lilly and Company. A review of the documents submitted at dkts 23 and 24 confirms that they are over 25 pages in length. Counsel is reminded that, pursuant to D.Ak.LR 10.1(b), you are required to provide the court with a COURTESY paper copy of your filings at dkts 23 and 24. (PLD) (Entered: 05/23/2006)
05/23/2006		***Set Deadlines as to 10 MOTION to Remand to State Court, 13 MOTION for Hearing *Regarding Defendant's Communications with Judge Weinstein. Replies due by 6/5/2006. (PLD) (Entered: 05/23/2006)*
05/24/2006	26	ERRATA *(re Revised Page 7)* by Eli Lilly and Company 23 Response in Opposition to Motion filed by Eli Lilly and Company,. (Attachments: # 1 Errata Revised page 7 to Docket 23)(Jamieson, Brewster) (Entered: 05/24/2006)
05/31/2006	27	REPLY to Response to Motion re 10 MOTION to Remand to State Court filed by State of Alaska. (Attachments: # 1 Exhibit A - Order Granting Motion to Remand)(Sanders, Eric) (Entered: 05/31/2006)
05/31/2006		***Motion Taken Under Advisement: 10 MOTION to Remand to State Court. (PLD) (Entered: 05/31/2006)
05/31/2006		***Motions Taken Under Advisement: 9 MOTION for Hearing *Re Motion for Stay*, 13 MOTION for Hearing *Regarding Defendant's Communications with Judge Weinstein. (PLD,) (Entered: 05/31/2006)*
05/31/2006		***Motions Taken Under Advisement: 13 MOTION for Hearing *Regarding Defendant's Communications with Judge Weinstein. (PLD) (Entered: 05/31/2006)*
05/31/2006		***Motion Taken Under Advisement: 12 MOTION for Hearing re 10 MOTION to Remand to State Court. (PLD) (Entered: 05/31/2006)
06/06/2006		***Set CMC Pull: CMC awaiting response from chambers 6/28/2006. E:mail sent to Judge Burgess 4/24/06 and 6/6/06 re posible MDL case. Does he want to issue a 16(b) mo at this time or wait until he rules on the mot for stay and the mot for remand. (PLD) (Entered: 06/06/2006)
06/07/2006	28	NOTICE *of Supplemental Authority* by Brewster H. Jamieson on behalf of Eli Lilly and Company re 4 MOTION to Stay re 1

		Notice of Removal, (Attachments: # 1 Exhibit A, Copy of Evans v. Trimont Land)(Jamieson, Brewster) (Entered: 06/07/2006)
06/27/2006	29	MOTION for Hearing re 10 MOTION to Remand to State Court by State of Alaska. (Attachments: # 1 Exhibit 1 - May 30, 2006 MDL CTO-52# 2 Exhibit 2 - June 12, 2006 MDL Notice# 3 Proposed Order Granting Request for Hearing) (Sanders, Eric) (Entered: 06/27/2006)
06/30/2006	30	ORDER A hearing on Plaintiff's Motion to Remand 10 is scheduled for Monday, July 24, 2006 at 2:00 p.m. in Courtroom 1. (EKS) (Entered: 06/30/2006)
06/30/2006		***Set Hearing re 10 Motion to Remand to State Court. Motion Hearing set for 7/24/2006 02:00 PM in Anchorage Courtroom 1 before Timothy M. Burgess. (EKS) (Entered: 06/30/2006)
06/30/2006		***Set hrg as to 10 MOTION to Remand to State Court. Motion Hearing set for 7/24/2006 02:00 PM before Timothy M. Burgess. (NKD,) (Entered: 07/03/2006)
07/03/2006		***Motions terminated: 12 MOTION for Hearing re 10 MOTION to Remand to State Court filed by State of Alaska,. (EKS) (Entered: 07/03/2006)
07/06/2006		***Set CMC Pull: No response from Judge re 6/6/06 CMC Pull - awaiting response from chambers 6/28/2006. E:mail sent to Judge Burgess 4/24/06 and 6/6/06 re posible MDL case. Does he want to issue a 16(b) mo at this time or wait until he rules on the mot for stay and the mot for remand. Issue 16(b) if needed after hrg on motion to remand is held 7/24/06. (PLD,) (Entered: 07/06/2006)
07/13/2006	31	MOTION to Expedite *Consideration of Motion for Oral Argument on Its Motion to Stay Proceedings* by Eli Lilly and Company. (Attachments: # 1 Declaration of B. Jamieson# 2 Proposed Order)(Jamieson, Brewster) (Entered: 07/13/2006)
07/13/2006	32	MOTION for Hearing re 4 MOTION to Stay re 1 Notice of Removal, *at Same Time as Oral Argument on Plaintiff's Motion to Remand* by Eli Lilly and Company. (Attachments: # 1 Exhibit A, Order in State of Alaska v. Mereck# 2 Proposed Order)(Jamieson, Brewster) (Entered: 07/13/2006)
07/13/2006		***Set Deadlines as to 32 MOTION for Hearing re 4

		MOTION to Stay re 1 Notice of Removal, *at Same Time as Oral Argument on Plaintiff's Motion to Remand*, 31 MOTION to Expedite *Consideration of Motion for Oral Argument on Its Motion to Stay Proceedings*. Responses due by 7/31/2006 (PLD,) (Entered: 07/14/2006)
07/14/2006	33	MOTION for Nonresident Attorney to Appear and Participate by Eli Lilly and Company. (Attachments: # 1 Declaration of Rachel B. Weil# 2 Certificate of Good Standing# 3 Proposed Order)(Jamieson, Brewster) (Entered: 07/14/2006)
07/14/2006	34	TMB ORDER finding Oral argument on Plaintiff's Motion to Remand is scheduled for July 24, 2006. Also pending before this Court is the Defendant's Motion to Stay. Docket 4. Plaintiff previously has moved for a hearing on Defendant's Motion to Stay. Docket 9. Defendant has now filed a motion for a hearing on the Motion to Stay, seeking expedited consideration of same. Docket nos. 31 and 32. IT IS HEREBY ORDERED that the Motion for Hearing at docket 9 is GRANTED. At the hearing on July 24, 2006, the Court shall hear oral argument on the Motion to Stay at docket 4, and the Motion to Remand at docket 10. The motions at docket nos. 31 & 32 are moot. (PLD,) (Entered: 07/14/2006)
07/14/2006		***Set Deadlinesine as to 4 MOTION to Stay re 1 Notice of Removal, 10 MOTION to Remand to State Court. Motion Hearing set for 7/24/2006 02:00 PM in Anchorage Courtroom 1 before Timothy M. Burgess. (PLD,) (Entered: 07/14/2006)
07/24/2006	35	Minute Entry for proceedings held before Judge Timothy M. Burgess: Motion Hearing held on 7/24/2006 re 4 MOTION to Stay re 1 Notice of Removal, 33 MOTION for Nonresident Attorney to Appear and Participate filed by Eli Lilly and Company, 10 MOTION to Remand to State Court filed by State of Alaska. Court GRANTED Motion for Nonresident Attorney to Appear and Participate. Motion to Stay and Motion for Remand taken under advisement. Court to issue a written ruling. Counsel to file a notice regaring the date of the MDL Panels hearing scheduled for this case. (Court Recorder PLD.)Plaintiff Counsel-Jeffrey Feldman, Eric Sanders; Defense Counsel-Brewster Jamieson, Rachel Weil; (PLD,) (Entered: 07/24/2006)
07/24/2006		***Motion terminated: 33 MOTION for Nonresident Attorney to Appear and Participate filed by Eli Lilly and Company.

		(PLD,) (Entered: 07/24/2006)
07/28/2006	36	ORDER: The Motion for Remand at Docket 10 is GRANTED and this matter is REMANDED to the Superior Court for the State of Alaska, Third Judicial District at Anchorage. It is further ordered that Defendant's motion at docket 4 to stay all proceedings, and Plaintiff's motion for hearing at Docket 13 are DENIED AS MOOT. Signed by Judge Timothy M. Burgess on 7/28/2006. (EKS) (Entered: 07/28/2006)
07/28/2006		***Set DJ CMC Pull : If no motions for reconsideration are pending send certified copy of docket and order to State Court. (EKS) (Entered: 07/28/2006)
07/31/2006		***Help Desk Note 36 Order on Motion to Stay,, Order on Motion to Remand to State Court,, Order on Motion for Hearing, Service on this docket indicates electronic service to "weilr@.pepperlaw.com" which is not correctly formatted. In addition Ms. Weil was not registered electronically, the Help Desk has contacted her and she has sent in her registration. (CLW) (Entered: 07/31/2006)
08/17/2006		***Chamber Note: this case was remanded to state court. MDL scheduled hearing on 09/28/06. Need to resolve with Ida status of case. (SRL, COURT STAFF) (Entered: 08/17/2006)
08/28/2006	37	Certified Copy of Order Vacating Conditional transfer Order and Vacating the 9/28/06 Hearing Session. (PLD, COURT STAFF) (Entered: 08/28/2006)

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
AT ANCHORAGE

State of Alaska Plaintiff(s),

vs.

Eli Lilly & Co Defendant(s)

CASE NO. 3AN-06-05630CI

INITIAL PRETRIAL ORDER

Pursuant to the Uniform Pretrial Order Administrative Order 3AO-03-04, this Court hereby issues the Initial Pretrial Order in this case.

Routine Pretrial Order

The parties shall discuss among themselves possible trial dates and the expected length of trial. Within **15 days** after distribution of the Initial Pretrial Order, the parties shall jointly submit a list of three trial dates that are each approximately **12 months** from the date of the Initial Pretrial Order. The submission to the Court should also state the approximate number of trial days the parties believe will be required. A Routine Pretrial Order will be issued based on the parties' report in accordance with the Uniform Pretrial Order.

Initial Disclosures

Unless an earlier date is or has been agreed to by the parties, initial disclosures required under Alaska Civil Rule 26(a)(1) shall be served not later than **30 days** after distribution of the Initial Pretrial Order.

Alternative Dispute Resolution

Not later than **45 days** after distribution of the Initial Pretrial Order, each attorney will discuss with his or her client(s) the possibility of settling this case (or portions of the case) through mediation, conference, arbitration, or other alternative to litigation. Not later than **60 days** from the date of this order, the parties or their attorneys shall meet to discuss whether some form of alternative dispute resolution can be agreed on. Whenever

practical, the parties are encouraged to meet in person instead of by phone. Within **10 days** of this meeting, the parties shall file a joint report with the Court indicating whether the parties met in person or by phone, whether alternative dispute resolution has been agreed to and if so, the form and timing of the parties intended actions.

Mark Rindner

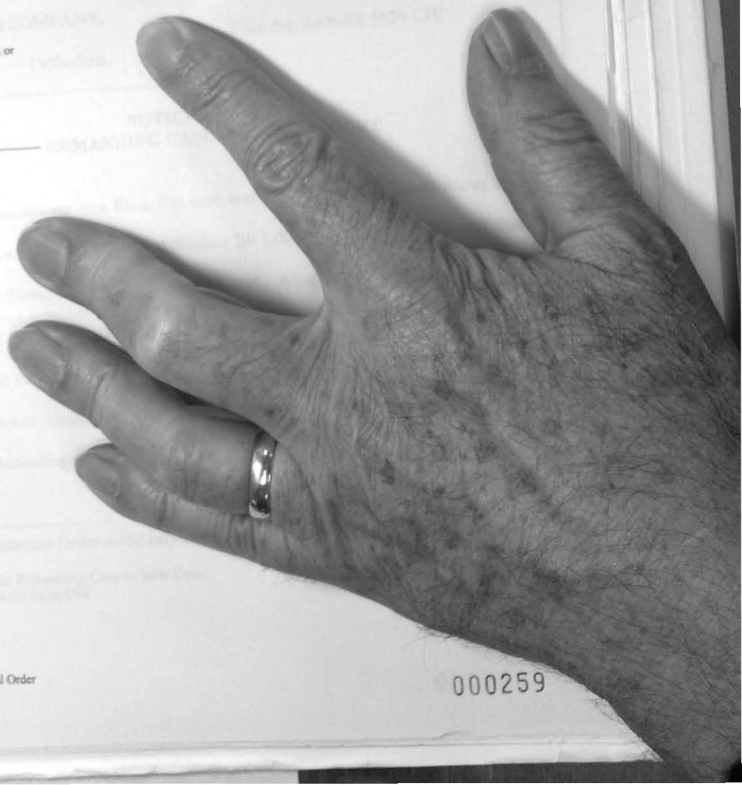
August 23, 2006
Date

Superior Court Judge

I certify that on 8/23/2006,
A copy of this order was mailed or
delivered to:
Eric T Sanders

Brewster H Jamieson

LShaw
Administrative Assistant



IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

FILED
STATE OF ALASKA
THIRD DISTRICT
06 AUG 10 PM 3:45
CLERK, TRIAL COURTS
BY _____
DEPUTY CLERK

NOTICE OF ORDER
REMANDING CASE TO STATE COURT

Before an answer was filed, this case was removed to the United States District Court for the District of Alaska by defendant Eli Lilly and Company. Plaintiff State of Alaska filed a Motion to Remand to State Court. After briefing and a hearing, United States District Court Judge Timothy Burgess issued an Order remanding this case to the Superior Court for the State of Alaska, Third Judicial District at Anchorage.[1]

Pursuant to Alaska Civil Rule 12(a), the defendant must now file an answer to the complaint. Accordingly, the plaintiff asks the court to issue a routine pretrial order at this time.

[1] See attached Order dated July 28, 2006 (Docket 36).

LAW OFFICES
FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

000260

DATED this 17 day of August, 2006

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiffs

BY _____
Eric T. Sanders
AK Bar No. 7510085

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
Counsel for Plaintiffs

RICHARDSON, PATRICK, WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
Counsel for Plaintiffs

Certificate of Service
I hereby certify that a true and correct copy of Notice of Order Remanding Case was served by (mail) / messenger / facsimile on:

Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

By Peggy S. Crowe
Date 8/18/06

LAW OFFICES
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ALASKA

STATE OF ALASKA,
Plaintiff,
vs.
ELI LILLY & COMPANY,
Defendant.

Case No. 3:06-cv-88 TMB

ORDER

The State of Alaska brought suit against Defendant Eli Lilly & Company, ("Lilly"), in state court, seeking damages and penalties arising from the marketing and sale of the prescription drug Zyprexa. Docket 1, Exhibit A (Complaint). The State alleges that Lilly knew of risks associated with Zyprexa that were not revealed to the Food and Drug Administration, the state, physicians, or consumers. Id. Furthermore, the State alleges that Lilly advertised and sold Zyprexa for a number of non-approved or "off-label" uses. Id. The State alleges fraud and negligent misrepresentation, negligence, strict liability, and violations of the Unfair Trade Practices and Consumer Protection Act, codified in A.S. § 45.50.471, and seeks relief of an award of damages in excess of $100,000 for Zyprexa-related damages of past, present and future medical expenses for recipients of the Alaska Medicaid program, restitution for the cost of all Zyprexa prescriptions paid by the state, civil penalties of $5,000 per violation of the Unfair Trade Practices Act, costs, interest, and actual attorneys' fees. Id.

Lilly removed this matter to Federal Court on April 19, 2006, alleging that this Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1441, and 1446. Docket 1.

Having reviewed the pleadings and heard oral argument on July 24, 2006, the Court now enters the following Order.

DISCUSSION

Pursuant to 28 U.S.C. § 1441(a), a defendant may generally remove to the appropriate federal district court "[a]ny civil action of which the district courts have original jurisdiction founded on a claim or right arising under the Constitution, treaties or laws of the United States." Plaintiff moves for an order of remand pursuant to 28 U.S.C. § 1447(c). Docket 10. Under §1447©), a case shall be remanded "[i]f at any time before final judgment it appears that the district court lacks subject matter jurisdiction." The burden of establishing federal jurisdiction falls to the party invoking the removal statute. California ex rel. Lockyer v. Dynegy, Inc., 375 F.3d 831, 838 (9th Cir. 2004). Section 1441(a) "is strictly construed against removal jurisdiction." Id.

Plaintiffs argue that removal was improper, because there is no ground for asserting federal jurisdiction over this case. Docket 11. Plaintiff argues that removal is generally only appropriate in three circumstances: 1) the parties meet the statutory requirements for the Court's diversity jurisdiction;[1] 2) the Complaint raises a substantial federal question; or 3) under the "complete preemption" doctrine, Plaintiff's state law claims have been totally subsumed by federal law. Docket 11 at 3 (citations omitted). Plaintiff argues that its claims for relief arise exclusively under state statutory and common law, and do not require the construction or application of federal law as essential elements of those claims.[2] Docket 11. Accordingly, there is no substantial federal question, and Plaintiff asserts a remand to state court is required. Id.

Defendant argues that federal question removal is proper, because Plaintiff's Complaint raises substantial and disputed federal questions under the federal Food, Drug and Cosmetic Act, ("FDCA"), and under federal Medicaid law. Docket 23. Defendant relies in part on a decision from In re Zyprexa Products Liability Litigation, 375 F.Supp.2d 170 (E.D.N.Y. 2005), in which the United States District Court for the Eastern District of New York found federal question jurisdiction in a similar case.

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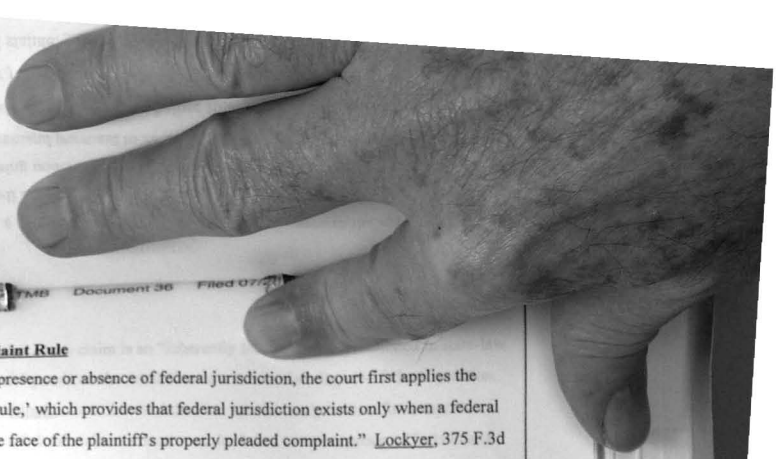
[1] Diversity is not an issue in this matter.

[2] Plaintiff notes that "while Defendant's conduct may also be in violation of federal law, it is state law that Plaintiff seeks to enforce." Docket 27 at 3.



The Well-Pleaded Complaint Rule

In determining the presence or absence of federal jurisdiction, the court first applies the "'well-pleaded complaint rule,' which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint." Lockyer, 375 F.3d at 838 (quoting Caterpillar Inc. v. Williams, 482 U.S. 386 (1987)). "The federal issue 'must be disclosed upon the face of the complaint, unaided by the answer or by the petition for removal.'" Id. (quoting Gully v. First Nat'l Bank in Meridian, 299 U.S. 109, 112 (1936)). "A defense is not part of a plaintiff's properly pleaded statement of his or her claim." Id. (quoting Rivet v. Regions Bank, 522 U.S. 470, 475 (1998)).

On its face, Plaintiff's Complaint does not state a claim arising under federal law. Plaintiffs seek relief under Alaska statutes which prohibit deceptive trade practices, and under common law negligence and strict liability analyses.

The Artful Pleading Doctrine

The court's inquiry does not end there. Lippitt v. Raymond James Financial Services, Inc., 340 F.3d 1033, 1041 (9th Cir. 2003). "Under the artful pleading doctrine, a plaintiff may not avoid federal jurisdiction by 'omitting from the complaint federal law essential to his claim, or by casting in state law terms a claim that can be made only under federal law.'" Rains v. Criterion Systems, Inc., 80 F.3d 339, 344 (9th Cir. 1996)(citation omitted). Courts have applied the artful pleading doctrine in complete preemption cases and substantial question cases, the latter of which includes cases where the claim is necessarily federal in character or where the right to relief depends on the resolution of a substantial, disputed federal question. Lippitt, 340 F.3d at 1041-1042. The Ninth Circuit has described the artful pleading doctrine as "a useful procedural sieve to detect traces of federal subject matter jurisdiction in a particular case," but cautions that "Courts should invoke the doctrine only in limited circumstances as it raises difficult issues of state and federal relationships and often yields unsatisfactory results." 340 F.3d at 1041 (citations and quotations omitted).

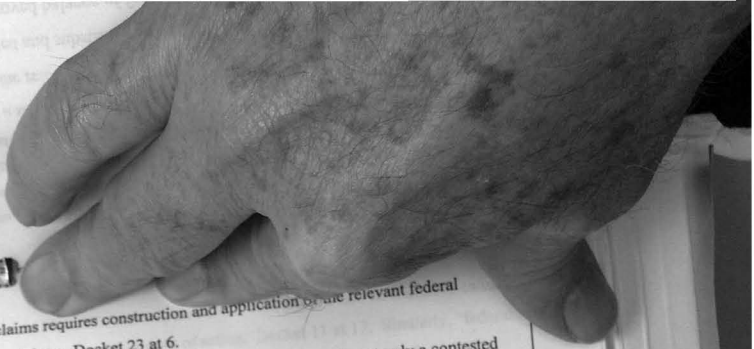
– **Substantial Federal Question**

"The artful pleading doctrine allows federal courts to retain jurisdiction over state law claims that implicate a substantial federal question." Lippitt, 340 F.3d at 1042. A state law claim falls in this category when 1) a substantial, disputed question of federal law is a necessary element

of the well-pleaded state claim, or the claim is an "inherently federal claim" articulated in state-law terms, or 2) the right to relief depends on the resolution of a substantial, disputed federal question. Id., (citations omitted). The Lippitt court observed that "no specific recipe exists for a court to alchemize a state claim into a federal claim - a court must look at a complex group of facts in any particular case to decide whether a state claim actually 'arises' under federal law." Id., at 1042-43. The Supreme Court suggests that the relevant inquiry is "does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 125 S.Ct. 2363 (2005).

Plaintiff argues that it has alleged violations of state consumer fraud and unfair trade practice statutes, as well as claims under Alaska common law, and that federal law is implicated only in light of the state statutory and common law violations as a "factual predicate" for such violations, not as an essential element. Docket 11 at 8. "No element of Plaintiff's claims requires either the interpretation or application of federal law." Id. Plaintiff argues that while federal law created the Medicaid program, Congress has delegated to the states the administration and operation of the program through individual state Medicaid agencies. Docket 11 at 11-12, citing 42 U.S.C. 1396a(a). Plaintiff acknowledges that its state law claims may touch upon areas in which FDA regulations are present, but those regulations provide no cause of action for Plaintiff. Docket 27 at 5, citing Grable & Sons, 125 S.Ct., 2370.

Defendant argues that "Plaintiff's case is so infused with federal issues" under the FDCA and Medicaid law that the Complaint raises "substantial and disputed" issues of federal law that provide this Court with original jurisdiction. Docket 23 at 3. Specifically, Defendant suggests that because federal funds constitute at least 50% of Alaska's Medicaid program funds at issue in the lawsuit, federal jurisdiction is proper. Docket 23 at 10. Further, Defendant suggests that federal questions relating to off-label promotion lie at the heart of the Complaint. Docket 23 at 5. "Federal regulations require that all claims in promotional labeling or advertising be consistent with warning, labeling and promotional materials approved and monitored by the FDA." Docket 23 at 5, citing 21 C.F.R. §202.1(e)(4)(2005). Defendant suggests that resolution of the off-label promotion claims



and the warnings-related claims requires construction and application of the relevant federal statutory and regulatory provisions. Docket 23 at 6.

The Supreme Court has counseled that "federal jurisdiction demands not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum." Grable, 125 S.Ct. at 2367 (emphasis added). The Court finds no substantial federal question in this matter at this time. Contra In re Zyprexa Products Liability Litigation, 375 F.Supp.2d 170 (E.D.N.Y. 2005).

– **Complete Preemption**

"Preempted state law claims may be removed to federal court only in the rare instances where Congress has chosen to regulate the entire field." ARCO Environmental Remediation v. Dept. of Health and Environmental Quality of the State of Montana, 213 F.3d 1108,1114 (9th Cir. 2000). The Ninth Circuit has observed that there are two categories of cases where the Supreme Court has found complete preemption: ERISA and the Labor Management Relations Act.[3] 340 F.3d, at 1042. Complete preemption only applies when "federal law completely preempts state law and provides a federal remedy." ARCO, 213 F.3d, at 1114, (quoting Ethridge v. Harbor House Restaurant, 861 F.2d 1389, 1403 (9th Cir. 1988)). In other words, the exclusive cause of action for the claim under these federal statutes was found within the statute itself.[4]

Defendant suggests that complete preemption exists here because "Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medications that any challenge to such marketing and promotions necessarily states a federal cause of action."

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[3]Plaintiffs note that complete preemption also has been found by the National Bank Act. Docket 11 at 17 (citations omitted).

[4] In contrast, "conflict preemption" exists when state law actually conflicts with federal law. Defendant suggests that conflict preemption exists in light of the FDA's position that is approval of labeling under the act preempts conflicting or contrary state law. Docket 23 at 7. Plaintiff, however, notes that "the FDA recognizes that FDS's regulation of drug labeling will not preempt all State law actions." Docket 27 at 6, citing Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3936. "Unlike complete preemption, preemption that stems from a conflict between federal and state law is a defense to a state law cause of action and, therefore, does not confer federal jurisdiction over the case." ARCO, 213 F.3d at 1114 (emphasis added). Therefore, Defendant's argument that conflict-preemption principles apply to failure-to-warn claims such as those asserted here is not dispositive. Docket 23 at 7-8.

Docket 23, fn. 11. However, as Plaintiff observes, the FDCA does not provide an exclusive cause of action or remedy, and it provides no private right of action. Docket 11 at 17. Similarly, "federal Medicaid law does not provide exclusive remedies, or in some cases remedies at all, for those requests for relief." Docket 27 at 7. Rather, "federal medicaid law delegates the management of the Medicaid program, and recovery of Medicaid funds, to the states. Further, the states are required to have laws in place to facilitate this recovery." Docket 27 at 7. Accordingly, neither the FDCA nor Medicaid completely preempt state law and provide a federal remedy, and complete preemption does not apply.

In light of the foregoing, the Court concludes that the artful pleading doctrine does not apply. Plaintiff's claims do not implicate a substantial federal question, and the Court does not find complete preemption. Plaintiff's claims seek relief to recover damages solely under Alaska law.

CONCLUSION

For the reasons set out above, the Motion for Remand at Docket 10 is **GRANTED**, and this matter is **REMANDED** to the Superior Court for the State of Alaska, Third Judicial District at Anchorage. It is further ordered that Defendant's motion at docket 4 to stay all proceedings, and Plaintiff's motion for hearing at Docket 13 are **DENIED AS MOOT**.

Dated at Anchorage, Alaska, this 28th day of July, 2006.

/s/ Timothy Burgess
Timothy M. Burgess
United States District Judge

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

NOTICE OF REMOVAL

TO: Clerk of Court
The Superior Court for the State of Alaska, Third Judicial District

AND TO: Plaintiff State of Alaska
Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-5911
Tel: 272-3538
Fax: 274-0819

PLEASE TAKE NOTICE pursuant to the provision of 28 U.S.C. §§ 1331, 1441, and 1446 a Notice of Removal, a copy of which is attached hereto as Ex. A, effecting the removal for all purposes of *State of Alaska v. Eli Lilly and Company*, Case No. 3AN-06-05630 CI, to the United States District Court for the District of Alaska from Superior Court for the State of Alaska, Third Judicial District at Anchorage was filed by the above-actual-named defendants on April 19, 2006, with the clerk of the United States District Court for the District of Alaska.

/

/

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

DATED this 19th day of April, 2006.

LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ALASKA AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3:06-cv-_____-____

NOTICE OF REMOVAL

PLEASE TAKE NOTICE that, pursuant to 28 U.S.C. §§ 1331, 1441, and 1446, defendant Eli Lilly and Company ("Lilly"), a corporation, hereby removes this case from the Superior Court for the State of Alaska, Third Judicial District at Anchorage, to the United States District Court for the District of Alaska. In support of this Notice of Removal, Lilly avers as follows:

BACKGROUND

1. Plaintiff, the State of Alaska, commenced this action in the Superior Court for the State of Alaska, Third Judicial District at Anchorage, on March 1, 2006. A copy of the Summons and Complaint is attached hereto as Ex. A. Lilly was served on March 20, 2006.

2. This action involves allegations regarding the FDA-approved medicine Zyprexa®. Multidistrict litigation, *In re Zyprexa Products Liability Litigation*, MDL No. 1596, is pending before the Honorable Jack B. Weinstein in the United States District Court for the Eastern District of New York. Two similar suits filed by the Attorney General of the State of Louisiana are already pending in that MDL proceeding. *See In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170

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EXHIBIT A
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(E.D.N.Y. 2005) (denying motion to remand). Lilly intends to ask the Judicial Panel to transfer this action to MDL No. 1596.

3. Lilly has filed contemporaneously with this Notice of Removal a Motion to Stay All Proceedings Pending Transfer by the Judicial Panel on Multidistrict Litigation, asking this Court to stay this action pending transfer to MDL No. 1596. As explained in the Motion, a stay will conserve the Court's and the parties' resources, avoid duplicative litigation and prevent inconsistent rulings on global issues – including jurisdictional issues – that arise repeatedly in Zyprexa actions. For these reasons, courts in more than 60 cases have granted stays pending transfer of Zyprexa-related actions to MDL No. 1596.[1]

[1] *See, e.g., Johnson v. Eli Lilly Co., Inc & Dr. J. Colvin*, No. 4:05-cv-02139-ERW (E.D. Mo. Feb. 27, 2006) (a stay "will allow for consistent pretrial rulings and will conserve judicial resources because only one court will need to make such rulings . . . with regard to the parties' jurisdictional dispute," and that "prejudice of a [relatively short delay] does not outweigh the judicial economy interests"). *See also Wesley v. Lilly*, CV-06-569 (N.D. Ala., March 27, 2006); *McDonald v. Lilly*, H-06-651 (S.D. Tex., March 9, 2006); *McTier v. Lilly*, CV-05-607 (M.D. Ala., Aug. 9, 2005); *Muhammad v. Lilly*, CV-05-1046 (M.D. Ala., Nov. 22, 2005); *McCray-Martin v. Lilly*, CV-05-1048 (M.D. Ala., Nov. 22, 2005); *Andrews v. Janssen Pharmaceutica, L.P., et al.*, 4:05-cv-02177-CDP (E.D. Mo. Feb. 26, 2006); *Atterberry v. Eli Lilly & Co, et al.*, 4:05-cv-02126-CDP (E.D. Mo. Feb. 26, 2006); *Benton v. Eli Lilly & Co., et al.*, 2:05-cv-04337-NKL (W.D. Mo. Dec. 13, 2005); *Bradley v. Eli Bledsoe v. Janssen Pharmaceutica, L.P. et al.*, 4:05-cv-02330-ERW (E.D. Mo. Feb. 13, 2006); *Buck v. Janssen Pharmaceutica, L.P. et al.*, 4:05-cv-00932-SOW (W.D. Mo. Dec. 27, 2005); *Caffey v. Eli Lilly & Co., et al.*, 6:05-cv-03474-DW (W.D. Mo. Jan. 27, 2006); *Davis v. Eli Lilly & Co., et al.*, 4:05-cv-01922-CEJ (E.D. Mo. Jan. 6, 2006); *Deruyter v. Janssen Pharmaceutica, L.P. et al.*, 6:05-cv-03490-RED (W.D. Mo. Jan. 6, 2006); *Eads v. Eli Lilly & Co., et al.*, 4:05-cv-00987-GAF (W.D. Mo. Jan. 6, 2006); *Easley v. Eli Lilly & Co., et al.*, 4:05-cv-00174-ERW (E.D. Mo. Jan. 17, 2006); *Ewing v. Eli Lilly & Co., et al.*, 2:05-cv-00066-ERW (E.D. Mo. Jan. 17, 2006); *Forbes v. Eli Lilly & Co., et al.*, 2:05-cv-04331-NKL (W.D. Mo. Dec. 13, 2005); *Freeman v. Eli Lilly & Co., et al.*, 6:05-cv-03504-DW (W.D. Mo. Jan. 3, 2006); *Harrington v. Janssen Pharmaceutica, L.P., et al.*, 4:05-cv-02158-ERW (E.D. Mo. Jan. 17, 2006); *Hayes v. Eli Lilly & Co., et al.*, 4:05-cv-02128-AGF (E.D. Mo. Jan. 25, 2006); *Hemphill v. Eli Lilly and Company et al.*, 4:05-cv-01245-DW (W.D. Mo. Mar. 20, 2006); *Hedrix v. Eli Lilly & Co., et al.*, 4:05-cv-01151-DW (W.D. Mo. Mar. 14, 2006); *Henry v. Eli Lilly & Co., et al.*, 4:05-cv-04317-SOW (W.D. Mo. Dec. 22, 2005); *Holden v. Janssen Pharmaceutica, L.P. et al.*, 4:05-cv-02121-SNL (E.D. Mo. Mar. 2, 2006); *Howard v. Janssen Pharmaceutica, L.P., et al.*, 4:05-cv-02122-CDP (E.D. Mo. Feb. 27, 2006); *Howard v. Eli Lilly & Co., et al.*, 4:06-cv-00062-HEA (E.D. Mo. Feb. 27, 2006); *Hurst v. Janssen Pharmaceutica, L.P. et al.*, 4:05-cv-02181-CEJ (E.D. Mo. Jan 20, 2006); *Johnson v. Eli Lilly & Co., et al.*, 4:05-cv-00960-ODS (W.D. Mo. Dec. 20, 2005); *Johnson v. Eli Lilly Co., et al.*, 4:05-cv-02139-ERW (E.D. Mo. Feb. 27, 2006); *Journey v. Janssen Pharmaceutica, L.P. et al.*, 4:05-cv-01924-ERW (E.D. Mo. Jan. 17, 2006); *Karsch v. Eli Lilly & Co., et al.*, 2:05-cv-04339-NKL (W.D. Mo. Dec. 14, 2005); *Keetch v. Janssen Pharmaceutical, L.P. et al.*, 4:05-cv-01931-CAS (E.D. Mo. Mar. 6, 2006); *Kelley v. Eli Lilly & Co., et al.*, 2:05-cv-04327-NKL (W.D. Mo. Dec. 13, 2005); *Lipe v. Eli Lilly & Co., et al.*, 6:05-cv-03487-RED (W.D. Mo. Feb. 15, 2006); *C. M. v. Janssen* (continued . . .)

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4. Venue is proper in this Court pursuant to 28 U.S.C. § 89(c), because it is the "district and division embracing the place where such action is pending." *See* 28 U.S.C. § 1441(a).

5. Lilly will promptly (a) file a true and correct copy of this Notice with the Clerk of Court for the Superior Court for the State of Alaska, Third Judicial District at Anchorage, in accordance with 28 U.S.C. § 1446(d), and (b) serve plaintiff's counsel with a copy of this Notice of Removal, in accordance with 28 U.S.C. § 1446(d).

ALLEGATIONS AND REQUESTED RELIEF

6. Making allegations that implicate federal food and drug regulations, as well as the federal Medicaid statute, the Complaint alleges, *inter alia:*

- "Defendant failed to warn consumers, including the State, its physicians, and Medicaid recipients, of the dangers and permanent health consequences caused by the use of Zyprexa. In fact, Defendant instructed its representatives to minimize and misrepresent the dangers of Zyprexa, affirmatively and consciously placing company profits above public safety. This is particularly true of the prescriptions written for off-label uses. This failure to warn was designed and intended to maximize company profits, even after Lilly's own experts were questioning the safety of Zyprexa." *See* Ex. A, Complaint, at ¶ 19.

(. . . continued)
Pharmaceutica, L.P. et al., 4:05-cv-02183-CAS (E.D. Mo. Feb. 6, 2006); *Martin v. Eli Lilly & Co., Inc. et al.*, 4:05-cv-02150-DJS (E.D. Mo. Jan. 25, 2006); *Maurice v. Janssen Pharmaceutica, L.P. et al.*, 4:05-cv-02293-CAS (E.D. Mo. Mar. 6, 2006); *Mincks v. Eli Lilly & Co., et al.*, 6:05-cv-03485-GAF (W.D. Mo. Jan. 6, 2006); *Morlan v. Eli Lilly & Co., et al.*, 1:05-cv-00189-CAS (E.D. Mo. Dec. 20, 2005); *Prince v. Janssen Pharmaceutica, L.P. et al.*, 4:05-cv-02086-CDP (E.D. Mo. Mar. 8, 2006); *Quebedeaux v. Eli Lilly & Co., et al.*, 2:05-cv-04326-NKL (W.D. Mo. Dec. 13, 2005); *Schmidt v. Eli Lilly & Co., et al.*, 4:05-cv-02331-CDP (E.D. Mo. Feb. 27, 2006); *Schardthorst v. Eli Lilly & Co., et al.*, 4:06-cv-00061-HEA (E.D. Mo. Feb. 24, 2006); Sousley v. *Eli Lilly and Company, et al.*, 2:05-cv-04412-NKL (W.D. Mo. Mar. 14, 2006); *St. Cin v. Eli Lilly & Co.*, 4:05-cv-01596-ERW (E.D. Mo. Jan. 17, 2006); *Starkey v. Janssen Pharmaceutica, L.P., et al.*, 4:05-cv-02141-CDP (E.D. Mo. Feb. 27, 2006); *Stewart v. Eli Lilly & Co., et al.*, 6:05-cv-03473-RED (W.D. Mo. Feb. 15, 2006); *Surface v. Eli Lilly & Co., et al.*, 2:05-cv-04341-NKL (W.D. Mo. Dec. 21, 2005); *Tindall v. Eli Lilly & Co., et al.*, 4:05-cv-01246-DW (W.D. Mo. Mar. 1, 2006); *Wallace v. Eli Lilly & Co., et al.*, 4:05-cv-01152-REL (W.D. Mo. Jan. 13, 2006); *Warson v. Eli Lilly & Co., et al.*, 6:05-cv-03488-DW (W.D. Mo. Dec. 28, 2005); *West v. Janssen Pharmaceutica, L.P., et al.*, 4:05-cv-02124-CDP (E.D. Mo. Feb. 27, 2006); *Wolfe v. Eli Lilly & Co., et al.*, 4:05-cv-00990-DW (W.D. Mo. Dec. 28, 2006); *Wright v. Eli Lilly & Co., et al.*, 2:05-cv-04413-SOW (W.D. Mo. Jan. 30, 2006). Lilly has not attached copies of these unreported decisions due to their volume; however, Lilly will produce copies immediately upon request of the Court.

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- Beginning in the 1990's, Defendant's strategy has been to aggressively market and sell Zyprexa by willfully misleading potential users about serious dangers resulting from the use of Zyprexa. Defendant undertook an advertising blitz, extolling the virtues of Zyprexa in order to induce widespread use. . . . Defendant has also advertised the use of Zyprexa for off-label uses . . . . Ex. A, Complaint, ¶20

- "In making Zyprexa available to Medicaid patients, [Lilly] knowingly misrepresented to the State of Alaska that Zyprexa was safe and effective. The State of Alaska allowed the purchase of Zyprexa for Alaska Medicaid recipients based upon such misrepresentations." Ex A, Complaint, ¶ 25.

- "Zyprexa has been prescribed by Alaska physicians to many recipients of the Medicaid program of the State. As a result of ingesting Zyprexa, Alaska Medicaid patients have suffered serious health effects, which now require further and more extensive medical treatment and health-related care and services. For these individuals, the State is the responsible party for these services. The State has thus suffered and will continue to suffer financial loss in the care of those Medicaid recipients who consumed prescriptions which were ineffective, unsafe and actively harmful." Ex A, Complaint, ¶26.

7. The Complaint also contains substantive counts sounding in negligence, strict liability, and violations of the Alaska Unfair Trade Practices and Consumer Protection Act ("UTPCPA"). It seeks compensatory damages for "past, present and future medical expenses for recipients of the Alaska Medicaid program," restitution for the cost of all Zyprexa prescriptions paid by the State under its Medicaid program, civil penalties of $5,000 for each violation of the UTPCPA, costs, interest, and attorneys' fees.

FEDERAL QUESTION JURISDICTION

8. This Court has jurisdiction under 28 U.S.C. § 1331 and under the principles set forth in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg*, 125 S. Ct. 2363 (2005).

9. The United States Supreme Court's decision in *Grable* held that "federal question" jurisdiction did not require the plaintiff to have asserted a violation of a federal statute providing a private parallel right of action.[2] Rather, a case asserting only state law causes of action is removable

[2] *Grable* limited *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804 (1986), to the extent *Merrell Dow Pharmaceuticals* implied or held that a federal cause of action was required to remove a pharmaceutical product liability case. A case asserting only state law causes of action is removable if it raises a substantial federal question. *See Grable*, 125 S. Ct. at 2369-71.

if it raises a substantial federal question, "actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state responsibilities" *See Grable*, 125 S. Ct. at 2368-71. *See also County of Santa Clara v. Astra USA, Inc.*, No. C 05-03740 (WHA), 2005 U.S. Dist. LEXIS 34453 (N.D. Cal. Dec. 2, 2005) (copy attached hereto as Ex. B).

10. As more fully explained below, plaintiff's claims directly raise issues in two areas of federal law: i) the federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*, which regulates prescription drug manufacturers' public and promotional statements about prescription drugs; and ii) federal Medicaid law, which determines which drugs a State must cover under its Medicaid program and the limited circumstances under which it can decline to pay for such drugs. *See* 42 U.S.C. §§ 1396r-8(d)(1)B, (d)(4).

11. Recently, in *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the court asserted federal question jurisdiction over state law claims involving Lilly's marketing of Zyprexa and the State of Louisiana's payments for Zyprexa under Medicaid. The court found that references in the complaint to federal funding provisions and laws demonstrated "a core of substantial issues [that were] federally oriented." *Id.*, at 172-73.

12. Similarly, in a recent case involving Medicaid drug pricing, the court in *County of Santa Clara v. Astra USA, Inc.*, No. C 05-03740 (WHA), 2005 U.S. Dist. LEXIS 34453 (N.D. Cal. Dec. 2, 2005) (copy attached hereto as Ex. B), invoked federal question jurisdiction under *Grable* because plaintiff's state law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. In concluding that Medicaid drug pricing issues merited federal jurisdiction, the court observed that one measure of evaluating substantiality is "the importance of the federal issue." The court noted that "[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme." Ex. B, *County of Santa Clara*, 2005 U. S. Dist. LEXIS 34453, at *16.

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13. Because these claims, like those in *Grable*, *In re Zyprexa*, and *County of Santa Clara*, will necessarily involve substantial federal questions, this Court has federal question jurisdiction over plaintiff's claims.

A. Alleged Violations of the FDCA and its Implementing Regulations

14. Many of the claims in this case are premised upon alleged violations by Lilly of the FDCA, in particular that Lilly illegally promoted Zyprexa for various off-label uses,[3] thereby causing harm to the state. Very similar allegations were made by the State of Louisiana. *In re Zyprexa Products Liability Litigation*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005). In addition, the State alleges that Lilly illegally promoted an unsafe drug for public use and failed to adequately warn the FDA, doctors, state regulators and consumers of risks. *See, e.g.*, Ex. A, Complaint, ¶¶ 17, 18, 19, 20, 21, 22, 23, 24, 25, 30, 31, 32, 33, 38, 42, 43, 44, 45, 53. Lilly disputes these allegations, including the allegation that it violated the FDCA by marketing Zyprexa for off-label uses.

15. In addition, the Complaint alleges that Zyprexa was not adequately tested, and that the risks of Zyprexa outweighed its benefits. *See, e.g.*, Ex. A, Complaint, ¶¶ 21, 22, 31, 39. Plaintiff therefore directly challenges the FDA's decisions to approve Zyprexa for sale and to continue to allow Lilly to market and sell Zyprexa today.

16. As a currently-marketed prescription drug, Zyprexa is subject to extensive regulation by the FDA. The FDCA requires the FDA to ensure that "drugs are safe and effective" for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by "promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393(b)(1). The Secretary of the FDA has the authority to promulgate regulations to enforce the FDCA, which are codified in the Code of Federal Regulations, 21 C.F.R. § 200, *et seq.* 21 U.S.C. § 371(a).

17. To accomplish its purpose, the FDA maintains a Center for Drug Evaluation and Research (the "CDER"). The CDER regulates pharmaceutical companies' development, testing and research, and manufacture of drugs. The CDER examines data generated by these companies to

[3] "Off-label" promotion is "a promotion that violates the [FDA's] strictures on off-label marketing." *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, No. Civ. A. 96-11651, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003). Accordingly, where, as here, the Complaint alleges "off-label" promotion, it inherently alleges a violation of federal law.

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conduct a risk/benefit analysis and make an approval decision. The CDER also ensures truthful advertising for prescription drugs, in part by approving Package Inserts that properly outline benefit and risk information. Once drugs are marketed, the CDER continues to monitor them for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. In short, the CDER evaluates and monitors the effectiveness and safety of prescription drugs. *See generally* http://www.fda.gov/cder/about/faq/default/htm.

18. Promotional communications to physicians about Zyprexa are contained within, and restricted by, warning, labeling, and promotional materials, such as the Package Insert, that are approved and monitored by the FDA to ensure the provision of accurate information about the drug's comparative risks and benefits. Under federal regulations, even claims in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4)(2005).

19. The FDA's responsibility to regulate prescription drugs sold in the United States, and to enforce laws with respect to such drugs, inclusive of the precise content and format of prescription drug labeling (*e.g.*, the instructions, warnings, precautions, adverse reaction information provided by manufacturers, and marketing materials), is plenary and exclusive. *See* 21 U.S.C. § 301 *et seq.*

20. Plaintiff has made a violation of federal law a critical element of its claims against Lilly. Accordingly, plaintiff's claims regarding the safety, labeling, promotion and marketing of Zyprexa will necessarily raise substantial federal questions by requiring the Court to interpret the meaning of the FDCA and its implementing regulations.

B. Federal Preemption of Drug Labeling and Warning

21. On January 24, 2006, the FDA announced a new rule, which includes a detailed and emphatic statement of the FDA's intention that its approval of product labeling, whether in the "old" format or the format required by the new rule, completely preempt most state law claims related to the adequacy of prescription drug warnings because such claims frustrate "the full objectives of the Federal law." *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3935, 3934 (Jan. 24, 2006) ("FDA believes that under existing preemption principles, FDA approval of labeling under the act . . . preempts conflicting or contrary State law."). Accordingly, there is a substantial federal question with respect to whether, in

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light of the FDA's position on conflict preemption, plaintiffs can claim that, by [redacted] to provide adequate warnings for Zyprexa, Lilly violated state law.

22. The Complaint also creates federal question jurisdiction under the doctrine of complete preemption. Courts find complete preemption where there is a "congressional intent in the enactment of a federal statute not just to provide a federal defense to a state created cause of action but to grant a defendant the ability to remove the adjudication of the cause of action to a federal court by transforming the state cause of action into a federal cause of action." 14B Charles Alan Wright, et al., *Federal Practice and Procedure* § 3722.1 (3d ed. 1998 & Supp. 2005).

23. Here, complete preemption exists because, as explained above, Congress has so thoroughly and intentionally regulated the marketing and promotion of prescription medications that any challenge to such marketing and promotion necessarily states a federal cause of action.

24. Lilly acknowledges that there is no private right of action under the FDCA, and that under existing law a private right of action may be a requirement for the complete preemption doctrine. In *Grable*, however, the United States Supreme Court rejected any bright-line rule that a private right of action is a *sine qua non* to substantial federal question jurisdiction, reasoning that Congressional intent to create a federal forum for an issue could be inferred even in the absence of a private right of action under federal law. *Grable*, 125 S. Ct. at 2370-71. Based on that rationale, courts should not regard Congress' creation of a private right of action as the only means of ascertaining Congressional intent vis-à-vis complete preemption.

C. Alleged Violations of Federal Medicaid Law

25. Plaintiff's claims raise substantial questions of federal law under the federal Medicaid statute because they depend upon the interpretation and application of federal statutory provisions that govern what can be included in or rejected from State Medicaid formularies, including Alaska's, and because federal funds constitute the majority of Alaska's Medicaid program funds, which funds are at issue in this lawsuit.

26. The federal Medicaid program authorizes federal grants to states to provide medical assistance to low income individuals. 42 U.S.C. § 1396, *et seq.* "Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Act and regulations promulgated by the Secretary of Health and Human Services." *Wilder v. Virginia*

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Hosp. Assn., 496 U.S. 498, 502 (1990). In Alaska, the Medicaid pro[illegible]ered by the Department of Health and Social Services.

27. Federal law requires states, subject to certain narrow exceptions, to reimburse FDA-approved prescription drugs of any manufacturer that has entered into and complies with a rebate agreement with the Secretary of Health and Human Services, 42 U.S.C. § 1396r-8(d)(4)(B). Thus, Alaska is required under federal law to reimburse companies for drugs, such as Zyprexa, if the manufacturer complies with federal requirements.

28. The only time a state can exclude from its formulary a covered outpatient drug subject to a rebate agreement is "with respect to the treatment of a specific disease or condition for an identified population . . . if, based on the drug's labeling . . . the excluded drug does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion." 42 U.S.C. § 1396r-8(d)(4)(D). Moreover, even a decision to require prior authorization must satisfy federally mandated requirements. 42 U.S.C. §§ 1396r-8(d)(4)(E), (d)(5). Thus, every step a state takes with regard to coverage of an FDA-approved drug is subject to strict federal mandates.

29. Accordingly, because the Alaska Medicaid program operates within this overarching federal regulatory framework, plaintiffs claims that Zyprexa should not have been part of that program necessarily implicate and turn on questions of federal Medicaid law.

THE FEDERAL INTEREST IN PROVIDING A FORUM

30. The federal government has a strong interest in having a federal court determine whether any conduct of Lilly, including the alleged marketing of Zyprexa for unapproved uses, violated any federal laws or regulations related to the labeling and marketing of Zyprexa, and whether Lilly's alleged dissemination of information about off-label uses was protected by the First Amendment.

31. The federal government also has a strong interest in having a federal court determine whether the FDA-approved Zyprexa label was false and misleading, as alleged by the plaintiffs, and whether a state may impose liability on Lilly for not updating the label to provide more information on hyperglycemia and diabetes, as the plaintiffs contend Lilly should have done. Not only did the

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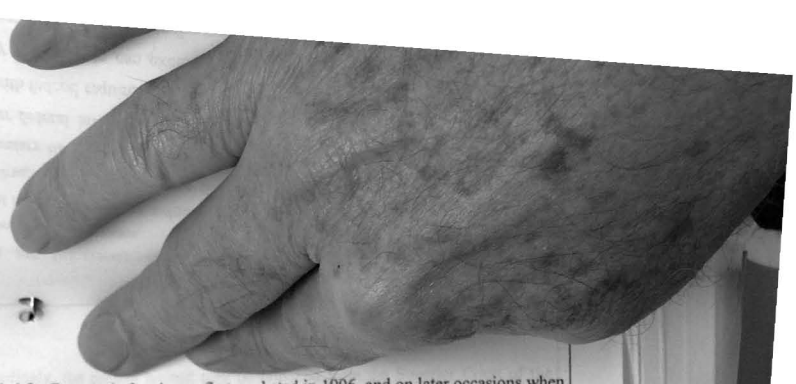

FDA approve the label for Zyprexa before it was first marketed in 1996, and on later occasions when changes were made to the label, but also the FDA was closely involved with the precise labeling issue raised by the plaintiffs in this case. Before requesting a change to the labeling of Zyprexa and all other atypical antipsychotics on September 11, 2003, the FDA had spent several years studying the data relating to all atypical antipsychotic medicines and diabetes. The FDA's decision not to request a label change relating to diabetes before September 11, 2003, was based on sound policy decisions. The FDA believed that any significant label change required scientific support, and that a label change could influence physicians to prescribe less often and possibly divert patients to other drugs, which could cause the same problems.

32. Finally, the federal government has a strong interest in having a federal court construe and interpret federal Medicaid law, including questions related to reimbursement for Zyprexa under Alaska's Medicaid formulary.

33. Plaintiff's claims may be vindicated or defeated only by construction of federal statutes and regulations. The availability of a federal forum to protect the important federal interests at issue is therefore consistent with *Grable*, and determination by a federal court of the substantial and disputed federal issues that lie at the heart of this case would not "disturb any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 125 S. Ct. at 2368.

PROPRIETY OF REMOVAL

34. For the foregoing reasons, this Court has jurisdiction over this matter.

35. This Notice is being filed within 30 days after Lilly's first receipt of a copy of the initial pleading setting forth the claim for relief upon which the action is based, as required by 28 U.S.C. § 1446(b).

36. Apart from the Summons and the Complaint (attached hereto as Ex. A, Summons and Complaint), Lilly has received no other process, pleadings, motions or orders.

37. The United States District Court for the District of Alaska is the federal judicial district embracing the Third Judicial District at Anchorage, Alaska, where this suit was originally filed. Removal to this District is therefore proper under 28 U.S.C. § 1441(a).

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38. Accordingly, the present lawsuit may be removed from the Superior Court of the State of Alaska at Anchorage, and brought before the United States District Court for the District of Alaska pursuant to 28 U.S.C. §§ 1331, 1332(a) and 1441(a).

39. Pursuant to 28 U.S.C. § 1446(d), a copy of this Notice of Removal has been filed with the Clerk of Court for the State of Alaska, Third Judicial District at Anchorage. *See* Ex. C, hereto.

DATED this 19th day of April, 2006.

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I certify that on April 19, 2006, a copy of the foregoing was served by mail on:

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Feldman Orlansky & Sanders
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s/ Brewster H. Jamieson
121873.0001/154723.1

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IN THE ~~DISTRICT~~/SUPERIOR COURT FOR THE STATE OF ALASKA
AT ANCHORAGE

STATE OF ALASKA,
Plaintiff(s),
vs.
ELI LILLY AND COMPANY,
Defendant(s).

CASE NO. 3AN-06-5630CI

SUMMONS

To Defendant: Eli Lilly and Company

You are hereby summoned and required to file with the court a written answer to the complaint which accompanies this summons. Your answer must be filed with the court at 825 W. 4th Ave., Anchorage, Alaska 99501 within 20 days* after the day you receive this summons. In addition, a copy of your answer must be sent to the plaintiff's attorney, Eric T. Sanders, whose address is: 500 L Street, Suite 400, Anchorage, AK 99501.

If you fail to file your answer within the required time, a default judgment may be entered against you for the relief demanded in the complaint.

☒ This case has been assigned to Superior Court Judge Rindner.

☐ This case has been assigned to District Court Judge _____.

CLERK OF COURT

3-1-06
Date

By: _____
Deputy Clerk

* The State or a state officer or agency named as a defendant has 40 days to file its answer.

000281

CIV-100 ANCH (10/97)(st.3)

Civil Rules 4, 5, 12,