STOP!

CASE NO. CV-5630CI

Volume No. 18

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

VOL 19

☐ 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

A B C D E

Jon S. Dawson
Davis Wright Tremaine LLP
701 W. 8th Avenue, Suite 800
Anchorage, Alaska 99501-3468
(907) 257-5300, telephone
(907) 257-5399, facsimile
jondawson@dwt.com

Attorneys for Bloomberg, LLC,
d/b/a Bloomberg New

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-06-05630 CI
	)	

(#89)

[PROPOSED] ORDER GRANTING MOTION TO EXTEND DEADLINE

THIS MATTER having come before the Court on Intervener Bloomberg LLC's Motion to Extend Deadline for Reply Brief,

NOW, THEREFORE, it is hereby ordered that the Motion to Extend Deadline is GRANTED. Eli Lilly's supplemental opposition to Bloomberg's Motion to Intervene and to Unseal Court Records shall be due on April 23 2008. Bloomberg's reply brief shall be due on May 2, 2008.

APR 01 2008

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

005281

A B C D E

DATED this 7th day of April, 2008.

By: Mark Rindner
Superior Court Judge

Certificate of Service:

I certify that on April 1st, 2008, and a true and correct copy of the foregoing document was sent to the following attorneys or parties of record by:

(X) Mail
( ) Facsimile and Mail
( ) Hand Delivery

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

Brewster H. Jamieson, Esq.
Lane Powell LLC
301 W. Northern Lights Blvd., Ste. 301
Anchorage, AK 99503

Joyce Sheppard
Joyce Sheppard

I certify that on 4-7-08 a copy of the above was mailed to each of the following at their addresses of record:
Dawson Sanders Jamieson

Administrative Assistant

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

Jon S. Dawson
Davis Wright Tremaine LLP
701 W. 8th Avenue, Suite 800
Anchorage, Alaska 99501-3468
(907) 257-5300, telephone
(907) 257-5399, facsimile
jondawson@dwt.com

Attorneys for Bloomberg, LLC,
d/b/a Bloomberg New

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-06-05630 CI

Motion to Extend Deadline for Reply Brief Pending Filing of Eli Lilly's Supplemental Brief

Intervener Bloomberg, LLC has been informed that, in light of the settlement of the above-captioned action, this court has granted defendant Eli Lilly leave to file a supplemental opposition to Bloomberg's Motion to Intervene and to Unseal Court Records. The current deadline for Bloomberg's reply to Eli Lilly's filed opposition is March 27. However, inasmuch as it appears that Eli Lilly will be filing a supplemental

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

opposition, Bloomberg requests an extension of time in order to file its reply brief after the filing of that supplemental briefing.

Although Eli Lilly's counsel is willing to stipulate that Bloomberg may have additional time in which to file its reply, he is unwilling to stipulate that Bloomberg's reply will not come due until after Eli Lilly files its supplemental briefing. This is unacceptable and unfair to Bloomberg. The Civil Rules call for a brief in support, an opposition brief, and a reply brief. See Alaska R. Civ. P. 77. Bloomberg should not be required to file its reply without first being afforded the opportunity to review whatever additional arguments may be raised by Eli Lilly in its supplemental opposition, and the Civil Rules certainly do not give Eli Lilly the right to preview Bloomberg's reply brief before filing its supplemental brief. Bloomberg therefore respectfully requests that this court set a deadline for Eli Lilly's supplemental briefing—if one has not already been set—and that the deadline for Bloomberg's reply brief be extended to five days after service (not including weekends and holidays) of Eli Lilly's supplemental opposition.

If this motion is denied, Eli Lilly respectfully requests that it be given five days from the date of certificate of mailing of that order in which to file its reply.

DATED this 26th day of March, 2008.

DAVIS WRIGHT TREMAINE LLP
Attorneys for Bloomberg LLC

By: _____
Jon S. Dawson, ABA #8406022

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

Certificate of Service:

I certify that on March 26th, 2008, and a true and correct copy of the foregoing document was sent to the following attorneys or parties of record by:

( ) Mail
(X) Facsimile and Mail
( ) Hand Delivery

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

Brewster H. Jamieson, Esq.
Lane Powell LLC
301 W. Northern Lights Blvd., Ste. 301
Anchorage, AK 99503

Jake Sheppard
Joyce Sheppard

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

ORDER

The State of Alaska filed a motion seeking to introduce evidence of efforts made by Lilly to influence the state legislature and other decision makers to allow "open access" to Zyprexa in spite of its known toxicity. Having reviewed the State's motion and memorandum in support thereof and all applicable law, the Court hereby orders that the State's motion is GRANTED.

SO ORDERED

March 17, 2008

Mark Rindner, Superior Court Judge

not used 3-26-08

A. David Campana

David Campana is the self-styled "answer man" concerning the State's Medicaid pharmacy program and is the only Rule 30(b)(6) witness produced by the State in discovery. The Campana testimony that Lilly intends to present to the jury addresses key issue that are probative of the State's allegations that Lilly misrepresented the characteristics of Zyprexa to physicians and the State, and that Alaska Medicaid patients developed diabetes as a result of Zyprexa. Campana's testimony establishes the following points:

- Campana believed metabolic effects, including diabetes, to be associated with Zyprexa as early as 2004. As of this date, he had also been of the belief that the Zyprexa label failed to adequately communicate the medicine's safety and efficacy profile. He also testified that the Drug Utilization Review ("DUR") committee sent a letter to physicians in Alaska at this time communicating to them its understanding of Zyprexa's diabetes risk and metabolic effects.

- Campana has kept up with the medical literature regarding medication safety issues.

- Campana has no knowledge of anyone from Lilly ever misrepresenting Zyprexa's safety or efficacy to the State of Alaska.

- Campana has no knowledge of Zyprexa users in Alaska developing diabetes at a greater rate than other Alaska Medicaid recipients, or Alaska Medicaid recipients that use other antipsychotic medicines.

- Despite having being the State's Medicaid pharmacy program manager for seventeen years, with responsibility for budgeting and cost containment, Campana was not involved in the decision to bring this lawsuit.

Simply stated, this testimony touches every significant question the jury must address.

The State acknowledged the relevance of Campan's testimony concerning the DUR committee meeting in 2004 at which Dr. Alex Von Hafften made a presentation regarding antipsychotic medicine, but protests that this testimony would open the door to and invite a mini-trial about Lilly's lobbying efforts. It does nothing of the sort.

First, Dr. Von Hafften is not a state official who was lobbied by Lilly, but rather is an Anchorage psychiatrist. The only connection between this physician and Lilly is a reference in a document used at the deposition of Joey Eski indicating that Lilly wished to "better work" with him. Ms. Eski had no knowledge of what this reference indicated; she testified that the note in the document was not from her.

Second, Campana's testimony about this DUR committee meeting does not concern open access, restrictions on Zyprexa, the State's payments for Zyprexa, or any other issue that could conceivably open the door to lobbying evidence. The testimony focuses on minutes which demonstrate that in 2004 the DUR committee -- a group of volunteer pharmacist and physicians, separate from the State Medicaid P&T committee, and with no role in restricting Medicaid recipients' access to medication -- received a report from Dr. Von Hafften in which he communicated his belief that there is a greater risk of metabolic issues among patients on atypical antipsychotics. Certainly if, as the State suggests, Lilly had successfully lobbied this doctor, he would not have been communicating to the DUR committee the claim that the State's lawyers have been arguing to the jury. Lobbying is simply disconnected from any deposition testimony of Campana that Lilly plans to offer at trial.[1]

B. Lucy Curtiss, M.D.

Lilly intends to present to the jury testimony from Dr. Lucy Curtiss, an Anchorage psychiatrist and the medical director of Anchorage Community Mental Health Services, concerning her use of antipsychotic medications, her understanding of the side effects of these medicines, how that knowledge affects her prescription practices, her sources of

[1] If the Court views Mr. Campana's testimony regarding the 2004 DUR meeting as opening the door to lobbying evidence, Lilly simply will not present this testimony to the jury.

information about these medicines, and her experience with the court-ordered treatment of patients with antipsychotics, including Zyprexa. These are topics on which the State elicited testimony from its own witness Dr. Duane Hopson, and it is disingenuous for the State to argue that such testimony on these topics, is now irrelevant because it is *Lilly* that seeks to offer it into evidence. In light of the State's claim that Lilly's failed to warn of side-effects, Lilly must be allowed to present to the jury its own evidence of background knowledge in the medical community about those side-effects, the source of that knowledge, and its role in the prescription decision.

C. Karleen Jackson and Joel Gilbertson

Karleen Jackson and Joel Gilbertson are the present and former Commissioners of the Alaska Department of Health and Social Services. These individuals testified at deposition that they had no knowledge of any misrepresentations about Zyprexa's safety made by Lilly to the State, that they were ignorant about the claims asserted against Lilly in this lawsuit, and that they played no role in decision to file the lawsuit. The State contends that the DHSS's ignorance of the alleged health risks of Zyprexa, and therefore this testimony, is irrelevant on the grounds that the Attorney General's office has the statutory power to bring this lawsuit. But this is a red-herring argument; Dr. Jackson and Mr. Gilbertson's testimony is relevant to the issue of the State's motive in bringing this lawsuit.

The jury is entitled to receive evidence that the current and former head of the state agency charged with safeguarding the health of Alaskans at the critical time periods at issue in this case were not made aware that State employees (*e.g.*, Campana) came to the conclusion that Lilly was misrepresenting the characteristics of a prescription drug reimbursed by state Medicaid dollars. They are entitled to hear how no one consulted these individuals on Zyprexa, that they played no role in the decision to bring this lawsuit against Lilly, and were not even

aware of its existence until shortly before their depositions in December 2007. The Court has already determined that motive is relevant with respect to the State's case against Lilly and allowed the State to present evidence of Lilly's profit motive. Turnabout is fair play, and Lilly is entitled to present to the jury evidence that the State's primary objective is hardly the protection of the health of Alaska citizens, but rather the replenishment of the State's coffers.

D. Objections to Counter Designations.

Lilly objects to the following pages and lines of the State's Counter Designations for David Campana.

Start	End	Objection
249:02	249:09	Undue prejudice outweigh probative value (State cannot offer evidence of its intention in 9/07 to conduct an intervention, when Lilly is effectively precluded from introducing evidence that State never conducted that intervention or communicated with doctors regarding Zyprexa)
272:13	273:16	Relevance; undue prejudice outweigh probative value

Lilly objects to the following pages and lines of the State's Counter Designations for Lucy Curtiss, M.D.

Start	End	Objection
41:03	41:08	Relevance (Witness testifies that she felt that Remeron sales rep tried to mislead her, but could not recall any other instances, or any instances in which Lilly misled her); undue prejudice outweigh probative value.

Lilly objects to the following pages and lines of the State's Counter Designations for Karleen Jackson.

Start	End	Objection
5:05	5:09	Relevance; no personal knowledge; speculation
32:10	33:01	Relevance (lobbying issues); no personal knowledge; speculation; undue prejudice outweigh probative value

Lilly objects to the following pages and lines of the State's Counter Designations for Joel Gilbertson.

Start	End	Objection
25:10	25:25	Relevance (lobbying issues); no personal knowledge; speculation; undue prejudice outweigh probative value
26:19	27:05	Relevance (lobbying issues); no personal knowledge; speculation; undue prejudice outweigh probative value
28:21	29:06	Relevance (lobbying issues); no personal knowledge; speculation; undue prejudice outweigh probative value
76:20	77:01	Relevance (off-label); undue prejudice outweigh probative value

DATED this 25th day of March, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac* vice
George A. Lehner, admitted *pro hac* vice
John F. Brenner, admitted *pro hac vice*
3000 Two Logan Square
Philadelphia, PA 19103-2799
(215) 981-4618

LANE POWELL LLC

By: _____
Brewster H. Jamieson,
ASBA No. 8411122
Andrea E. Girolamo-Welp,
ASBA No. 0211044

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-06-05630 CI

VIDEOTAPED DEPOSITION OF

LUCY LJUBICICH CURTISS, M.D.

December 13, 2007
1:35 p.m.

Taken at:
Anchorage Community Mental Health
4020 Folker Street, Conference Room C
Anchorage, Alaska

Reported by: Sandra M. Mierop, CRR, CPP, CBC

A. I have -- I have over time changed my practice. I used to have a 30-minute block every other week in which reps could schedule up to 15 minutes. I am less -- much less available now. It's if they catch me between patients.
Q. When did that practice change of having a block and not having a block of time?
A. Probably when I became medical director.
Q. Which was a few years ago?
A. Which was a few years ago.
I am also more cautious, being on the P & T Committee.
Q. Because?
A. Because I am being visited by reps that -- that detail agents that I would never prescribe ophthalmologic agents and all kinds of other things. And I'm -- I'm also very clear that I don't -- I am turned off by sales.
Q. What do you mean by that?
A. That if a rep comes in -- I did one time have a rep say, "I want you to promise to prescribe this for your next X number of patients." I didn't meet with him again.
Q. Do you know what company that rep was from?

A. I'm not sure what company it was.
Q. To what extent do you rely on sales representatives for information about medications that you prescribe to your patients?
A. It's a small, small percentage.
Q. Why is that?
A. Because I assume that they are in the business of sales and that they will tell me good things about their product.
Q. And so you're skeptical of sales reps?
A. Yes.
Q. Has that always been the case?
A. Yes.
Q. When you've met with sales reps from various companies, do they take -- have they taken notes while talking to you?
A. Not often.
Q. Now, since you became medical director, can you characterize how many minutes a week or month that you would spend with a sales rep?
A. Probably less than -- less than 30 minutes a month for all reps.
Q. How many companies are you visited by?
A. Several.
Q. Are you visited by AstraZeneca?

A. Uh-huh.
Q. That's "yes"?
A. Yes.
Q. Johnson & Johnson?
A. I don't think so.
Q. Janssen?
A. I'm sorry?
Q. Janssen?
A. Yes.
Q. Are you visited by reps from GlaxoSmithKline?
A. Yes.
Q. Wyeth?
A. Yes.
Q. Merck?
A. What do they market?
Q. Just about everything.
A. I don't know. I don't know offhand.
Q. How about Pfizer?
A. Yes.
Q. When you've met with sales reps from various companies, do they oftentimes talk to you about their competitors' products?
A. I discourage that.
Q. Why?

A. Again, it is negative and it's not an effective sales technique with me.
Q. Can you recall any instances where you've been -- where you've met with a sales representative from a pharmaceutical company and you believed you've been misled by that representative about his or her product?
A. Possibly.
Q. Can you think of any particular instances?
A. Oh, the one that comes to mind is when Remeron went to solutabs that the representative suggested that pills would not be available. That the only possible switch if I wanted to prescribe mirtazapine was to switch to the solutabs.
Q. Do you recall any other instances?
A. Of reps appearing to try to misinform me?
Q. Yes.
A. Not offhand.
Q. Have you ever been a speaker for any pharmaceutical company?
A. No.
Q. Do speakers from pharmaceutical

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

CERTIFICATE OF SERVICE

The undersigned certifies that on March 25, 2008, a copy of Defendant Eli Lilly and Company's Memorandum Regarding Plaintiff's Objections to Deposition Designations and Objections to Counter-Designations was served by hand on the following:

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

DATED this 25th day of March, 2008.

Jeri Ann Jenson

I certify that on March 25, 2008, 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

009867.0038/163846.1

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

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

PLAINTIFF'S COUNTER-DESIGNATIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS AS OF MARCH 24, 2008

In response to Defendant's designations of the testimony of David Campana, Lucy Curtiss, Joel Gilbertson and Karleen Jackson, the State of Alaska objects generally to these designations in their entirety as being irrelevant, unduly prejudicial, misleading and a waste of time.

Dr. David Campana is the pharmacy program manager of the State of Alaska's Medicaid program. He oversees the program, determining what its budge will be from year to year, looking at cost saving measures and making sure the State complies with applicable federal Medicaid guidelines.[1] While he also testified he plays a role in monitoring drugs for safety, he did not play a role in the State's decision to file this lawsuit, and had no specific knowledge surrounding the State's claims in this case. The only remotely relevant testimony he could offer is that he participated in a drug utilization review meeting in late 2004 regarding

[1] Deposition of David Campana, September 18, 2007, 8.

antipsychotic medications and diabetes. This meeting involved a presentation by Dr. Alex Von Hafften, a psychiatrist who was a focus of Lilly's Alaska State Action Team in the Joey Eski "lobbying" evidence the Court has thus far excluded. The testimony regarding this presentation by Dr. Von Hafften to the drug utilization review committee will open the door to evidence of Lilly's lobbying and thus provoke the mini-trial which the Court has feared. Through this testimony Lilly is again attempting to suggest to the jury the State should have taken some action to restrict access to Zyprexa. As the State has previously argued, allowing Lilly to do this without allowing the State to introduce evidence of Lilly's lobbying to maintain "open access" is fundamentally unfair and prejudicial to the State. Further, presenting this deposition testimony which was taken six months ago will likely require the State to bring the witness live in its rebuttal case, as events have occurred since the time of that testimony which have bearing on issues discussed in his deposition.

Dr. Lucy Curtiss is a psychiatrist who works primarily at Anchorage Community Mental Health Services. The thrust of her testimony is that she prescribes antipsychotic drugs in her practice and how she does that typically. The testimony is not probative on the issues the jury will be asked to decide in this case, that is whether Lilly failed to warn of Zyprexa's risks or violated the Alaska Unfair Trade Practices Act. Dr. Curtiss offers no testimony that tends to prove or disprove any fact at issue at this juncture of the case.

Joel Gilbertson and Karleen Jackson are the former and present

Commissioners of the Alaska Department of Health and Social Services. Neither Mr. Gilbertson nor Ms. Jackson has any knowledge relevant to this legal action by the State, nor can they offer any testimony probative of any issue in this case. To the extent Lilly is offering this testimony to show they were not knowledgeable of or request this action it is irrelevant, misleading and a waste of the Court and jury's time. The Attorney General's office is the legal arm of the State and is charged with enforcing the State's laws. The decision to bring this lawsuit resides in the Attorney General's office and it is completely irrelevant whether or not Mr. Gilbertson or Ms. Jackson played any role, or no role at all, in that decision, or whether either of them wanted to be informed regarding the case or not. As with Dr. Campana's testimony, allowing Lilly to offer this evidence will likely result in the State having to call these witnesses in rebuttal, and will create a mini-trial on issues unnecessary to the jury's determination of the actual legal questions in this case.

To the extent the Court allows the designations of these witnesses, the State hereby offers the following counter-designations:

DAVID CAMPANA
SEPTEMBER 18, 2007

Start	Stop
248:8	249:9
272:13	273:16
316:1	316:4

LUCY CURTISS
DECEMBER 13, 2007

Start	Stop
5:18	5:21
6:8	6:11
26:4	26:9
34:21	35:12
41:3	41:8
47:18	47:23
48:1	48:8
48:11	48:17

JOEL GILBERTSON
DECEMBER 6, 2007

Start	Stop
15:22	17:7
24:17	24:21
25:10	25:25
26:19	27:5
28:21	29:6
76:14	77:8
77:10	77:25
78:3	78:5

KARLEEN JACKSON
DECEMBER 12, 2007

Start	Stop
5:23	6:9
7:15	8:2
10:8	10:12
32:10	33:1

DATED this 24th day of March, 2008.

FELDMAN, ORLANKSY & 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
David L. Suggs
Christiaan A. Marcum
Counsel for Plaintiff

Certificate of Service

I hereby certify that a true and correct copy of **PLAINTIFF'S OBJECTIONS AND COUNTER-DESIGNATIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS AS OF MARCH 24, 2008** was served via hand-delivery on:

George Lehner, Esq.
Pepper Hamilton LLP
Hotel Captain Cook, 19th Floor
Anchorage, Alaska 99501

By _____

Date 7-24-08

Campana, David (Vol. 02) - 09/19/2007 [DEFENSE WITNESS]

1 CLIP (RUNNING 00:03:29.922)

Plaintiff COUNTERS

DCAMPANA COUNTER — 3 SEGMENTS (RUNNING 00:03:29.922)

1. PAGE 248:08 TO 249:09 (RUNNING 00:01:20.469)

Q. The FDA letter you were referring to, what letter is that?
A. The letter on CBX that the FDA sent to Eli Lilly requesting that they improve the labelling on the causation of diabetes.
Q. When did you receive -- do you remember the date of that letter?
A. It was March 28th.
Q. Of --
A. Of -- well, actually, there wasn't an actual date from the FDA, but there was a date on the letter of March 28th.
Q. 2007?
A. 2007.
Q. When did you receive that letter?
A. It was in my notebook again, and so I had received it as from counsel.
Q. And you said -- do you know when you received it?
A. I don't remember exactly when I had received it.
Q. But you said that's now motivating another intervention?
A. That's correct.
Q. What intervention?
A. That will be an intervention to look at Zyprexa and to also remind prescribers that it can cause diabetes and to be on the watch out for metabolic changes.

2. PAGE 272:13 TO 273:16 (RUNNING 00:02:01.364)

Q. I have gathered from your testimony today that the state has filed lawsuits against other prescription drug manufacturers?
A. It's my understanding that we have joined lawsuits filed against other drug manufacturers.
Q. What other drug manufacturers, and if you can identify it by medication as well?
A. Well, as far as the other manufacturers, the first case I worked on was Mylan. That was a national suit that was done through the AG's office where Mylan had conspired to raise prices of generic drugs.
Q. I'm actually glad -- let's put aside price issues and just talk about lawsuits that the state has filed because of, you know, safety issues or improper promotion kind of issues.
A. There are two other cases I know of. I don't know all the particulars about the cases. The OxyContin case where improper marketing was done by the manufacturer, and that case has been recently settled.
Then there was the Neurontin case where I believe it was a qui tam issue and done by the AG's office due to the improper labelling and marketing of the drug.
Q. In either of those cases, has there been any lawsuit filed against the manufacturer of Vioxx?
A. I can't answer that. I don't know.

Zyprexa-Alaska new

13 Q. In either of the cases you identified, OxyContin
14 and Neurontin, did you play any role in deciding whether
15 to file a lawsuit or join a lawsuit?
16 A. No.

3. PAGE 316:01 TO 316:04 (RUNNING 00:00:08.089)

00316:01 Q. You told me a little while ago that you had
02 concluded that Eli Lilly had misrepresented Zyprexa in
03 its package insert?
04 A. Correct.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:03:29.922)

Curtiss, Lucy L. (Vol. 01) - 12/13/2007 [DEFENSE WITNESS]

1 CLIP (RUNNING 00:03:05.908)

Plaintiff Counter

LCURTISS COUNTERS — 8 SEGMENTS (RUNNING 00:03:05.908)

1. PAGE 5:18 TO 5:21 (RUNNING 00:00:06.937)

Are you aware -- were you aware of this lawsuit before you found out you were going to have your deposition taken?
A. Yes.

2. PAGE 6:08 TO 6:11 (RUNNING 00:00:21.182)

Q. What is it that you do know about the case?
A. That it has to do with Zyprexa, and disclosure of risks related to Zyprexa.

3. PAGE 26:04 TO 26:09 (RUNNING 00:00:22.634)

Q. Any other factors that would militate in favor of using perphenazine besides patient preference?
A. Well, it has anti-psychotic effect. You know, I'm looking for effectiveness of a medication, and acceptability to a patient.

4. PAGE 34:21 TO 35:12 (RUNNING 00:00:48.265)

Q. When did your concern about metabolic side effects change?
A. Again, I can't tell you what year, but it has been within the last few years.
Q. Do you recall a classwide label change in 2003 with regard to the second-generation anti-psychotics?
A. I don't. I'm sorry.
Q. Do you recall any label changes for either Zyprexa or the class of medications? And I'm not asking you for a date, but just the -- the event or the fact of it occurring.
A. Well, I know that it has definitely become more of a focus. In my practice what stands out more is the black box warnings about patients with vascular dementia and use of anti-psychotics.

5. PAGE 41:03 TO 41:08 (RUNNING 00:00:27.621)

Q. Can you recall any instances where you've been -- where you've met with a sales representative from a pharmaceutical company and you believed you've been misled by that representative about his or her product?
A. Possibly.

6. PAGE 47:18 TO 47:23 (RUNNING 00:00:13.905)

Q. Have you -- have any of your patients, while using any of the psychiatric medications, developed diabetes?
A. Yes.
Q. Were some of them on Zyprexa?

23 A. Yes.

7. PAGE 48:01 TO 48:08 (RUNNING 00:00:19.057)

00048:01 Q. For those who are taking anti-psychotic
02 medications, do you regularly monitor any of
03 their -- their blood levels -- the glucose
04 levels?
05 A. I try to.
06 Q. How long have you been doing that for
07 your patients?
08 A. Oh, it's been a few years.

8. PAGE 48:11 TO 48:17 (RUNNING 00:00:26.307)

11 Q. For which patients do you test glucose
12 levels?
13 A. I check for anyone who is on -- well, I
14 try to get all my patients to have at least
15 yearly physical health care. For people that are
16 on anti-psychotics, I try, all of them, to get
17 them to do it.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:03:05.908)

Zyprexa-Alaska new

Gilbertson, Joel (Vol. 01) - 12/06/2007

1 CLIP (RUNNING 00:05:08.105)

PLAINTIFF COUNTERS

JGILBERTSON COUNTERS — 8 SEGMENTS (RUNNING 00:05:08.105)

1. PAGE 15:22 TO 17:07 (RUNNING 00:01:29.392)

The functional responsibilities of the Department include overseeing all public health powers, so operating public health laboratories, overseeing the medical examiner's office, public health functions, running public health clinics, disease surveillance, bioterrorism preparedness, those types of functions. Overseeing the Juvenile Justice System for the State of Alaska, so operating juvenile detention facilities, overseeing juvenile probation services.

Overseeing the Medicaid program and its tentacles into other programs, of course. Overseeing the child protection system, so foster care, investigating reports of harm, general social work, targeted case management. Overseeing senior and disability services, so that would include running the Pioneer Home system, which is a collection of assisted living facilities in the State of Alaska.

Overseeing the Developmental Disability Waiver program, the Senior Waiver program, the Personal Care Attendant program. Would also include overseeing all behavioral health programs for the State of Alaska, so that includes running the State Psychiatric Institute, and managing behavioral health grants, which are grants that go out to local community mental health providers for delivering clinic-based outpatient services.

And then there's a collection of regulatory functions, Certificate of Need, licensure certification. I'm probably missing some, but that's sort of a -- it's your broad health and social service functions for a State agency.

2. PAGE 24:17 TO 24:21 (RUNNING 00:00:14.885)

Q Did you do anything as Commissioner to keep yourself apprised about the medications being reimbursed by the State of Alaska?
A At the individual drug level, no. Simply not enough time in the day.

3. PAGE 25:10 TO 25:25 (RUNNING 00:00:45.967)

Q Did you in your role as Commissioner interact with representatives from pharmaceutical companies?
A Yes.
Q Okay. And for what purposes?
A I didn't seek them out, but they seemed to want to visit frequently to lobby the Department on various issues.

Q Was Eli Lilly one of the companies that --
A Eli Lilly hired lobbyists and Eli Lilly did lobby the Alaska state government during my years in office.
Q Okay. Did they personally interact with you?
A Yes, yeah.

4. PAGE 26:19 TO 27:05 (RUNNING 00:00:42.232)

Q What did they lobby you about?
A They lobbied me in 2003 to not implement a preferred drug list, and then during -- when I say "me," I mean the State, not me personally. And then they lobbied the State in 2003 and 2004 to have their drugs -- or mental health drugs carved out from the States's preferred drug list.
00027:01 And I'm sure there were a collection of other issues, I just don't recall them.
Q What did they say to you when they lobbied not to implement a PDL?
A Nothing logical.

5. PAGE 28:21 TO 29:06 (RUNNING 00:00:31.499)

Q And whether Eli Lilly individually or this group collectively, do you recall any discussion about particular products?
A Not as a group, no.
Q Okay.
00029:01 A It became clear later in the legislative session in 2003 that Eli Lilly's lobbyists, while not lobbying me personally, they did lobby in the legislature for legislation that would carve out mental health drugs from the preferred drug list, and that was done by Eli Lilly's lobbyists.

6. PAGE 76:14 TO 77:08 (RUNNING 00:00:45.956)

Q (BY MR. SNIFFEN) Mr. Gilbertson, Ed Sniffen. I'm an Assistant Attorney General with the State. We've talked earlier pertaining to this deposition. Just a couple of follow-up questions to some questions posed to you by Mr. Rothschild.
He'd asked you if you had hoped to know or become aware of certain issues during your tenure as Commissioner relating to Zyprexa, for example, whether it was used for off-label purposes.
Do you recall that question?
00077:01 A I do.
Q He also asked you if you had hoped to become aware of any safety issues with Zyprexa.
Do you recall that?
A I do.
Q Does the fact that you were not aware of those things mean to you that they did not happen or that you just don't recall?

7. PAGE 77:10 TO 77:25 (RUNNING 00:00:35.722)

A It means I don't recall. I think it's fair to say that, you know, there's a good portion of the Department, particularly that which is at the program level, at the clinician level, at the skill professional level where

Zyprexa-Alaska new

those decisions are made, and those experts manage it. There's a certain level of detail that you get involved in at the Commissioner's office, and that I was not aware of it doesn't mean much in terms of did it happen or not.

Q (BY MR. SNIFFEN) So, is it fair to say, then, that there would have been times when some of those issues may have come to the Department's attention through its program administrators or other employees and they would not have been brought to your attention?

8. PAGE 78:03 TO 78:05 (RUNNING 00:00:02.452)

A Certainly that could happen, yes.

MR. SNIFFEN: Thank you. I have nothing further.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:05:08.105)

Zyprexa-Alaska new

Jackson, Karleen (Vol. 01) - 12/12/2007 [DEFENSE WITNESS]

1 CLIP (RUNNING 00:02:03.234)

PLAINTIFF COUNTER

KJACKSON COUNTERS — 4 SEGMENTS (RUNNING 00:02:03.234)

1. PAGE 5:23 TO 6:09 (RUNNING 00:00:29.969)

Q. What's been put in front of you is Exhibit 1 for your deposition. Can you identify that document?
A. It would appear to be a lawsuit, the State of Alaska versus Eli Lilly.
Q. Have you ever seen that document before?
A. No, sir, I have not.
Q. And you're sure of that?
A. It's possible that it may have come through my office, but that -- I would not necessarily remember it, and I have not read it in detail.

2. PAGE 7:15 TO 8:02 (RUNNING 00:00:36.643)

Q. What are the major components or divisions of your department?
A. We're what's referred to by other state agencies as a super agency. So we include everything from children's services, which is Child Protection, Division of Juvenile Justice, Behavioral Health, which is mental health and substance abuse. Boy, this is going to be a test. Division of Senior and Disability Services; our Alaska Pioneer Home System; Public Health. I'm missing a couple here. Let me think for a minute. What am I missing.
Q. It's not a memory test?

3. PAGE 10:08 TO 10:12 (RUNNING 00:00:13.518)

Q. Do you know what the State's expenses were in the last fiscal year for pharmaceuticals in the Medicaid program?
A. I'm sorry, I don't. I have wonderful budget people that do, but I don't.

4. PAGE 32:10 TO 33:01 (RUNNING 00:00:43.104)

Q. Have you ever met with any representatives of Eli Lilly & Company?
A. Often in my former role as deputy commissioner and my role as commissioner we get lobbyists that come to Juneau or want to meet with the commissioner or the commissioner's representative, so I have met with representatives of the major pharmaceutical companies.
Q. Let's talk about your time as deputy commissioner. Do you recall meeting with Eli Lilly & Company representatives?
A. I am sure that I did, but I can't tell you who, when, or where. I mean, I can tell you where; Juneau. But not specifically who or when. And we get a parade of people through during the legislative session that are lobbying.

A B C D E

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

CERTIFICATE OF SERVICE

The undersigned certifies that on March 25, 2008, a copy of Defendant Eli Lilly and Company's Deposition Counter Counter-Designations for Trial and Objections to Plaintiff State of Alaska's Trial Deposition and Exhibit Counter Designations – Patrizia Cavazzoni was served by hand on the following:

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

DATED this 25th day of March, 2008.

Jeri Ann Jenson

I certify that on March 25, 2008, 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

00986/0038/163846.1

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

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

FILED IN OPEN COURT
Date: 3-24-08
Clerk: MCJ

DEFENDANT ELI LILLY AND COMPANY'S DEPOSITION COUNTER COUNTER-DESIGNATIONS FOR TRIAL AND OBJECTIONS TO PLAINTIFF STATE OF ALASKA'S TRIAL DEPOSITION AND EXHIBIT COUNTER DESIGNATIONS

PATRIZIA CAVAZZONI

Defendant Eli Lilly and Company ("Lilly") counter counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for Patrizia Cavazzoni, M.D. (June 27, 2006). To ensure completeness and context, the highlighted excerpts must be played with the State of Alaska's presentation.

Start	End	
228:17	229:6	✓
292:1	292:22	no
362:14	363:8	no

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial Deposition Counter Designations for Patrizia Cavazzoni, M.D. (June 27, 2006).

Start	End	Objection
358:24	361:10	Beyond the scope of Lilly's designations, relevance; probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 602)

Overruled

Respectfully submitted,

Dated: March 23, 2008

LANE POWELL, PC

By: _____
Brewster H. Jamieson
Lane Powell, PC
301 W. Northern Lights Boulevard
Suite 301
Anchorage, AK 99503-2648

Nina M. Gussack
Andrew Rogoff
Eric Rothschild
Pepper Hamilton LLP
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

Attorneys for Defendant
Eli Lilly and Company

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-06-5630 CI

FILED IN OPEN COURT
Date: 3-24-08
Clerk: MCJ

DEFENDANT ELI LILLY AND COMPANY'S DEPOSITION COUNTER COUNTER-DESIGNATIONS FOR TRIAL AND OBJECTIONS TO PLAINTIFF STATE OF ALASKA'S TRIAL DEPOSITION AND EXHIBIT COUNTER DESIGNATIONS

PATRIZIA CAVAZZONI

Defendant Eli Lilly and Company ("Lilly") counter counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for Patrizia Cavazzoni, M.D. (June 27, 2006). To ensure completeness and context, the highlighted excerpts must be played with the State of Alaska's presentation.

Start	End
228:17	229:6
292:1	292:22
362:14	363:8

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial Deposition Counter Designations for Patrizia Cavazzoni, M.D. (June 27, 2006).

Start	End	Objection
358:24	361:10	Beyond the scope of Lilly's designations, relevance; probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 602)

Respectfully submitted,

Dated: March 23, 2008

LANE POWELL, PC

By: _____
Brewster H. Jamieson
Lane Powell, PC
301 W. Northern Lights Boulevard
Suite 301
Anchorage, AK 99503-2648

Nina M. Gussack
Andrew Rogoff
Eric Rothschild
Pepper Hamilton LLP
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

Attorneys for Defendant
Eli Lilly and Company

Page 226

indications for which it is approved or off-label?
A. It depends on the situation. We are interested on learning about it from the safety perspective. When a physician chooses to use a drug off-label for reasons specific to that patient, we are interested, as interested in learning about the safety profile of the drug in those situations as we would be in situations where the drug is indicated for. Safety is safety. It spans the --
Q. How do you learn about it? How do you go about finding out what the safety profile is in off-label use?
A. We learn mainly from adverse events that are reported to our Global Product Safety Department.
Q. Have you ever prescribed Zyprexa? You have prescribed Zyprexa; is that correct?
A. Yes.
Q. Have you ever prescribed Zyprexa for an off-label use?

Page 227

A. Yes.
Q. And what uses?
A. For a mood disorder.
Q. What were the circumstances of that prescription? Was it more than one?
A. Yes.
Q. And can you give me, generally, what the circumstances were?
A. These were circumstances where the patient would have bipolar disorder which can have two components, mania, which are the highs, and depressions, which are the lows. And some patients respond very well to Zyprexa and other atypical antipsychotics, including Clozapine, as we said earlier, for the treatment of these disorders.
So it was a decision that I made as a physician within the context of what the patient's particular situation was.
Q. You have prescribed Zyprexa to schizophrenics as well; is that correct?
A. Yes.
Q. When you prescribe Zyprexa to a schizophrenic, did you take a blood glucose

Page 228

reading?
A. No.
Q. And why is that?
A. Because I had no reason to believe that treatment with Zyprexa would impact on blood glucose.
Q. Were you aware that schizophrenics are in a greater risk for the development of diabetes?
THE WITNESS: What time frame are you referring to?
MS. CONROY: When you were --
A. When I was practicing? Yes, I was aware that patients with schizophrenia are at a greater level of a number of medical co-morbidities, including diabetes.
Q. But it was not part of your practice to monitor glucose levels for diabetes?
A. Going back to earlier on in the deposition, as I indicated, if I knew that the patient was followed by a general practitioner or a medical specialist, in Canada it would be general practitioner. I

Page 229

would not be directly involved in the medical monitoring or care.
If I had reason to believe that the patient did not have adequate primary care, then I would be interested in ensuring that they did.
Q. As a psychiatrist treating schizophrenics, do you think you were in a position to know that schizophrenics were at a greater risk to develop diabetes than a primary care physician?
MR. LEHNER: Objection. Confusing.
A. I don't know. I don't know the answer.
Q. Does a primary care physician in Canada treat schizophrenia or is it generally, do they generally refer the patient to a psychiatrist?
A. For patients with schizophrenia it would be very unusual in Canada to have a general practitioner treating the patient without involvement of a psychiatrist. So at the very most it would

Page 290

yourself as having expertise in the safety of devices?
A. No.
Q. Is your expertise limited to Neuroscience products?
MR. LEHNER: In the area of safety?
MS. CONROY: Yes.
QUESTIONS BY MS. CONROY:
Q. Is your safety expertise limited to Neuroscience products?
A. Not necessarily, because the fundamental principles of product safety and product surveillance apply to any product.
Q. And by product are you talking about a drug?
A. Yes, a drug. And some of the fundamental principles also apply to devices.
Q. Do you have expertise in any other areas other than psychiatry and safety?
A. Well, I have a background in psychiatric genetics as I mentioned earlier, in clinical applications of psychiatric genetics.

Page 291

Q. Does anything that you do at Lilly today concern psychiatric genetics?
A. No.
Q. If you, if it comes to your attention that a drug manufactured by Lilly is being marketed in an unsafe manner, can you, as the senior Director of Global Product Safety, take any action?
MR. LEHNER: Objection, vague.
THE WITNESS: I don't understand what "marketing in an unsafe manner" means.
Q. If it came to your attention that a Lilly drug was being marketed in a way that did not fairly balance the risks and benefits of the product, could you take any action as the Senior Director of Global Safety?
A. I would be gravely concerned about such matter and my action would entail bringing it to the attention of those who would have direct supervision on marketing practices, as well as my superiors.

Page 292

Q. And is there a formal procedure at Lilly for doing that or is it something that you would just pick up the phone and call someone, or are there channels that you would need to go through?
A. There is no formal procedure that I'm aware of. But it's important to understand that this would be a situation that would, where, where the usual processes to ensuring that there is fair balance in marketing have not been effective. So this would be a very unusual hypothetical situation.
Q. Can you describe for me a little bit more why it would be unusual? I'm not sure I quite understood.
A. What I meant was Lilly has policies and processes in place to ensure that there is fair balance in the materials that are shared within, by the Sales and Marketing organization, shared with physicians and external parties.
Q. Have you ever been made aware of someone that marketed a product in an

Page 293

unsafe manner while you have been employed at Lilly?
MR. LEHNER: Objection. Vague.
A. Not to my recollection.
Q. And you don't know the circumstances surrounding Mr. Bandick's termination at Lilly; is that correct?
MR. LEHNER: Asked and answered.
A. As I indicated earlier, no.
Q. Would you agree with me that in Japan doctors are told that diabetes is a side effect of Zyprexa therapy?
MR. LEHNER: Objection. Overly broad.
A. I'm not aware that such communications are taking place to doctors in Japan.
Q. As the Senior Director of Global Product Safety can you tell me what the side effects of Zyprexa therapy are in the United States?
A. The side effects of Zyprexa

Page 358

presentation material if they deem that it is appropriate for what they want to convey.
Q. And if someone had a request for data or wanted some clarification is there a particular person that they would -- when Lilly gives them the grant, do they give them the names of people that they can contact or how would they know who to talk to?
A. I don't know who would be the contact.
Q. Can you recall any input that you had into any continuing education program or initiative concerning Zyprexa?
A. I recall a couple of instances.
Q. And who -- do you recall who the presenter was?
A. Not, specifically. But I do remember interacting with the presenter and providing clarification on data generated by Lilly or data generated by parties other than Lilly.
MS. CONROY: Mark as

Page 359

Exhibit 12 a two-page e-mail to Dr. Cavazzoni, Bates No. ZY200375624 and 625.
(Whereupon, Deposition Exhibit(s) 12 duly received, marked and made a part of the record.)
MS. CONROY: Take a look at that.
THE WITNESS: Thank you.
QUESTIONS BY MS. CONROY:
Q. That e-mail concerns an article that you wrote and submitted for publication; is that correct?
A. Yes. This is an article that I wrote with a number of colleagues.
Q. And what was the name of the article, or did it have a title?
A. Retrospective Analysis of Risk Factors In Patients With Treatment Emergent Diabetes During Clinical Trials of Antipsychotic Medications.
Q. And what is the date of that e-mail?

Page 360

A. It's October 16, 2003.
Q. And you submitted the article for publication, is it the American, what it is, the American Psychiatric Journal?
A. This is the Journal of Clinical Psychiatry.
Q. Did you submit the article to any other journal prior to submitting it to the Journal of Clinical Psychiatry?
A. Yes. We had previously submitted the article to Diabetes Care.
Q. And was the article published by Diabetes Care?
A. No.
Q. Was the article ever published by the Journal of Clinical Psychiatry?
A. No.
Q. Has the article ever been published in any publication?
A. Yes, it has been published.
Q. And where?
A. In the British Journal of Psychiatry.

Page 361

Q. And when was it published approximately?
A. I don't recall exactly. It would have been sometime after 2003.
Q. Do I have it right that, was it first submitted to Diabetes Care and rejected, and then submitted to the Journal of Clinical Psychiatry and rejected, and then submitted to the British Journal of Psychiatry?
A. Yes.
Q. And are you required with each submission, were you required to tell the British Journal of Psychiatry that Diabetes Care and the Journal of Clinical Psychiatry had declined to publish?
A. I don't know.
Q. Who made the decision to submit to Diabetes Care, if you know?
A. This was a recommendation by one of our nonLilly authors on the paper.
Q. And can you tell by looking at it, do you recall who it was?
A. Yes. It was Dr. John Buse.

Page 362

Q. And who made the decision to submit to the Journal of Clinical Psychiatry?
A. I don't recall. I presume it was a decision by the authoring group.
Q. And were you a part of the authoring group?
A. Yes.
Q. And the -- do you know who made the decision to submit to the British Journal of Psychiatry?
A. It would have been a decision by the authoring group, as well, of which I was part.
Q. Have you ever had with respect to a paper that you were an author and attempting to have published, have you ever had the experience of being rejected by a publication?
A. Yes. It is a very common occurrence in the peer reviewed system.
Q. And is it also common for the publication to e-mail comments about issues that it had with the article or the publication?

Page 363

A. Yes.
Q. That's standard?
A. Yes. Because the decision to publish or not to publish, which is often unfortunately related to space issue with having too many manuscripts and not enough space, also goes along with providing the authors with comments from the reviewers.
Q. And do you also receive comments nonelectronically or do they also come electronically in an e-mail?
A. It depends on the journal. Nowadays more and more they come electronically.
Q. Would you have retained comments -- if you received comments on the article from Diabetes Care would you have retained them?
A. Yes, if they had come directly to me I would have.
Q. Is it possible that if the comments may not have gone to you that you may never have received comments from Diabetes Care?

Page 364

A. The comments generally go to the primary author and I was not the primary author in the submission to Diabetes Care.
Q. So do you have a memory of whether or not you ever saw comments from Diabetes Care?
A. I have memories of discussing the comments within the authoring group.
Q. Do you get comments back when an article is accepted for publication?
A. Yes.
Q. And do you recall receiving electronic comments from the British Journal of Psychiatry with respect to this article?
A. I am aware that electronic comments or comments we received. I don't recall, you know, who received them.
Q. If you did, if you received a copy, would you have retained them in the ordinary course in your electronic folder?
A. Yes.
Q. Do you have a current CV?
A. Yes.
MS. CONROY: And, well, I

Page 365

guess, I'll just make a request for your CV through counsel. But I'm glad you have one. You don't have to create it.
QUESTIONS BY MS. CONROY:
Q. Are you familiar with Dr. Allison?
A. Yes.
Q. And how do you know him?
A. I know him in his capacity as a consultant to Lilly.
Q. And have you, have you ever written a paper with Dr. Allison?
A. Yes.
Q. And do you recall, approximately, when?
A. It was in the early 2001 time frame.
Q. And was it one paper?
A. Yes.
Q. Are you, do you have any papers in --
A. My apology. There was also a second paper, the Nizatidine paper that you

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

PLAINTIFF'S OBJECTIONS AND COUNTER-DESIGNATIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS AS OF MARCH 22, 2008

In response to Defendant's designations, Plaintiff hereby objects to the following designations:

PATRIZIA CAVAZZONI
JUNE 27, 2006

Page/Line Range	Objection
207:23-208:3	Improper opinion testimony by fact witness
208:10-208:21	Improper opinion testimony by fact witness
208:24 – 209:5	Improper opinion testimony by fact witness
209:10-209:21	Improper opinion testimony by fact witness
216:20 – 217:05	Improper opinion testimony by fact witness
217:11 – 217:23	Improper opinion testimony by fact witness
217:24-218:24	Improper opinion testimony by fact witness
221:15-221:17	Improper opinion testimony by fact witness

222:24-223:10	Improper opinion testimony by fact witness
300:3-300:15	Improper opinion testimony by fact witness; lack of foundation

Plaintiff hereby offers the following counter-designations:

Start	Stop
202:23	203:1
203:6	203:15
227:20	228:6
253:3	253:17
255:16	256:20
259:23	260:7
260:16	261:9
291:14	291:24
358:24	361:11

DATED this 22nd day of March, 2008.

FELDMAN, ORLANKSY & 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
David L. Suggs
Christiaan A. Marcum
Counsel for Plaintiff

FIBICH, HAMPTON & LEEBRON, LLP
Kenneth T. Fibich
Counsel for Plaintiff

CRUSE, SCOTT, HENDERSON & ALLEN, LLP
T. Scott Allen
Counsel for Plaintiff

Certificate of Service

I hereby certify that a true and correct copy of **PLAINTIFF'S OBJECTIONS AND COUNTER-DESIGNATIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS FOR PATRIZIA CAVAZZONI AS OF MARCH 22, 2008** was served via hand-delivery on:

George Lehner, Esq.
Pepper Hamilton LLP
Hotel Captain Cook, 19th Floor
Anchorage, Alaska 99501

By _____

Date 3-22-08

Zyprexa-Alaska new

Cavazzoni, Patrizia (Vol. 01) - 06/27/2006

1 CLIP (RUNNING 00:08:49.479)

PC PLAINTIFF COUNTERS

PCAVAZZONI COUNTERS — 9 SEGMENTS (RUNNING 00:08:49.479)

1. PAGE 202:23 TO 203:01 (RUNNING 00:00:05.187)

Q. Are you an epidemiologist?
A. No. I'm not an epidemiologist. And that's what I meant.

2. PAGE 203:06 TO 203:15 (RUNNING 00:00:19.521)

Q. Are you an endocrinologist?
A. No, I'm not.
Q. Are you a diabetologist?
A. No.
Q. Are you an expert in the treatment of diabetes?
A. No.
Q. Are you an expert in the diagnosis of diabetes?
A. No.

3. PAGE 227:20 TO 228:06 (RUNNING 00:00:23.682)

Q. You have prescribed Zyprexa to schizophrenics as well; is that correct?
A. Yes.
Q. When you prescribe Zyprexa to a schizophrenic, did you take a blood glucose reading?
A. No.
Q. And why is that?
A. Because I had no reason to believe that treatment with Zyprexa would impact on blood glucose.

4. PAGE 253:03 TO 253:17 (RUNNING 00:00:31.582)

(Whereupon, Deposition Exhibit(s) 2 duly received, marked and made a part of the record.)
MS. CONROY: The next exhibit that we marked is a standby statement dated March 5th of 2002.
QUESTIONS BY MS. CONROY:
Q. Can you tell me what a standby statement is, if you know?
A. Yes. A standby statement is a statement that is prepared to address questions from the lay press. That's, in general, what a standby statement is used for.

5. PAGE 255:16 TO 256:20 (RUNNING 00:01:34.719)

Q. Take a look at the bottom of Page 1. The last bullet point says, "Patients taking olanzapine do not require specific monitoring for diabetes and Zyprexa is not contraindicated for diabetic patients."

Do you see that?
A. Yes.
Q. Does that remain the case today that patients taking olanzapine do not require specific monitoring for diabetes?
A. Yes. If that's taken within the context of the monitoring that should be given to or to any patient if they have risk factors.
So the position is that, the position that you're referring to or you asked me to, is that no monitoring above and beyond what would be dictated by general good medical practices would be required.
Q. A psychiatrist is prescribing olanzapine, is it your position that good medical practice would require that psychiatrist to monitor their patient for diabetes?
A. Not unless that patient presented with risk factors for diabetes. And in that case, a physician would screen that patient by doing a blood glucose.

6. PAGE 259:23 TO 260:07 (RUNNING 00:00:21.188)

(Whereupon, Deposition Exhibit(s) 3 duly received, marked and made a part of the record.)
MS. CONROY: Take a look at this next exhibit. It's Draft F of a standby statement dated April 11th of 2002. This one does have an author, Andrea Smith.

7. PAGE 260:16 TO 261:09 (RUNNING 00:01:02.736)

Q. This standby statement concerns the issue Zyprexa label change in Japan. Do you see that on the top of Page 1?
A. Yes.
Q. Then also on Page 1 it says: Statement Containing Key Messages. And it says under Scenario 1 there are five bullet points. And the fourth bullet point says: "The label changes are consistent with good clinical practice." Do you see that?
A. Yes.
Q. Do you agree that the Japanese label changes are consistent with good clinical practice?
A. The Japanese label changes, if one looks at the text of the warning are, echo good principles of good medical practice for physicians.

8. PAGE 291:14 TO 291:24 (RUNNING 00:00:33.864)

Q. If it came to your attention that a Lilly drug was being marketed in a way that did not fairly balance the risks and benefits of the product, could you take any action as the Senior Director of Global Safety?
A. I would be gravely concerned about such matter and my action would entail bringing it to the attention of those who

would have direct supervision on marketing practices, as well as my superiors.

9. PAGE 358:24 TO 361:11 (RUNNING 00:03:57.000)

MS. CONROY: Mark as Exhibit 12 a two-page e-mail to Dr. Cavazzoni, Bates No. ZY200375624 and 625.

(Whereupon, Deposition Exhibit(s) 12 duly received, marked and made a part of the record.)

MS. CONROY: Take a look at that.

THE WITNESS: Thank you.

QUESTIONS BY MS. CONROY:

Q. That e-mail concerns an article that you wrote and submitted for publication; is that correct?

A. Yes. This is an article that I wrote with a number of colleagues.

Q. And what was the name of the article, or did it have a title?

A. Retrospective Analysis of Risk Factors In Patients With Treatment Emergent Diabetes During Clinical Trials of Antipsychotic Medications.

Q. And what is the date of that e-mail?

A. It's October 16, 2003.

Q. And you submitted the article for publication, is it the American, what it is, the American Psychiatric Journal?

A. This is the Journal of Clinical Psychiatry.

Q. Did you submit the article to any other journal prior to submitting it to the Journal of Clinical Psychiatry?

A. Yes. We had previously submitted the article to Diabetes Care.

Q. And was the article published by Diabetes Care?

A. No.

Q. Was the article ever published by the Journal of Clinical Psychiatry?

A. No.

Q. Has the article ever been published in any publication?

A. Yes, it has been published.

Q. And where?

A. In the British Journal of Psychiatry.

Q. And when was it published approximately?

A. I don't recall exactly. It would have been sometime after 2003.

Q. Do I have it right that, was it first submitted to Diabetes Care and rejected, and then submitted to the Journal of Clinical Psychiatry and rejected, and then submitted to the British Journal of Psychiatry?

A. Yes.

To:	CN=Virginia Stauffer/OU=AM/O=LLY@Lilly
CC:	CN=Angela L Hill/OU=AM/O=LLY@Lilly; CN=Baron J Lowe/OU=AM/O=LLY@Lilly; CN=Britton Ashley Hill/OU=AM/O=LLY@Lilly; CN=Bruce Kinon/OU=AM/O=LLY@Lilly; CN=Bryan Johnstone/OU=AM/O=LLY@Lilly; CN=Carol Lynn Gaich/OU=AM/O=LLY@Lilly; CN=David Bruhn/OU=AM/O=LLY@Lilly; CN=David L Van Brunt/OU=AM/O=LLY@Lilly; CN=Ernie Anand/OU=EMA/O=LLY@Lilly; CN=George Apostol/OU=AM/O=LLY@Lilly; CN=Hassan Jamal/OU=AM/O=LLY@Lilly; CN=Haya Ascher-Svanum/OU=AM/O=LLY@Lilly; CN=Ilya A Lipkovich/OU=AM/O=LLY@Lilly; CN=John Niewoehner/OU=AM/O=LLY@Lilly; CN=Jonna Ahl/OU=AM/O=LLY@Lilly; CN=Kristine Healey/OU=AM/O=LLY@Lilly; CN=Leslie Schuh/OU=AM/O=LLY@Lilly; CN=Lisa A Jaton/OU=AM/O=LLY@Lilly; CN=Mark Enerson/OU=AM/O=LLY@Lilly; CN=Michael E Bandick/OU=AM/O=LLY@Lilly; CN=Michael R Sale/OU=AM/O=LLY@Lilly; CN=Michael W Magdycz/OU=AM/O=LLY@Lilly; CN=Nina Barchha/OU=AM/O=LLY@Lilly; CN=Patrick A Toalson/OU=AM/O=LLY@Lilly; CN=Robert W Baker/OU=AM/O=LLY@Lilly; CN=Sara E Edwards/OU=AM/O=LLY@Lilly; CN=Sebastian Sorsaburu/OU=AM/O=LLY@Lilly; CN=Thomas A Hardy/OU=AM/O=LLY@Lilly; CN=Vicki Poole Hoffmann/OU=AM/O=LLY@Lilly; CN=Walter Deberdt/OU=AM/O=LLY@Lilly
Date:	01/14/2004 12:55:32 PM
From:	CN=Jerry D Clewell/OU=AM/O=LLY
Subject:	Re: Annals of Pharmacotherapy Recent articles of interest 2004
Attachments:	Liu cost comparison review OLZ vs RIS Ann Pharma 1-04.pdf; Sprague Selection of APDs Ann Pharm 2-04.pdf

Ginny et. al.

I too would like to offer a couple of observations from the Payer world relative to these studies and the environment.

It can not be understated that the Annals (as well as AJHP) are very widely read pharmacy journals that influence clinical pharmacists and their recommendations at the patient, and P&T Committee levels.

These reviews, especially in addition to this month's publication of the Consensus Guidelines for Schizophrenia (published in AJHP), can provide powerful arguments for P&T committee members to restrict access to olanzapine on the basis of (1) perceived parity or near parity in efficacy in light of (2) the perceived 2X cost differential between olzanzapine and risperidone.

1. **Selection of atypical antipsychotics for the management of schizophrenia- Denise Sprague**

   Payers have already expressed to me (just yesterday) that they view this information as confirming their interpretation of the data that there is very little clinical difference between olanzapine and risperidone. Never mind the author's comments that drug therapy should be individualized.

005327

What can/should we do in reaction to these perceptions?

I believe this means that we have to step up all publication and communication efforts to educate decision makers and their consultants (Thought Leaders, PBM's, etc) on the long-term effectiveness (relapse prevention, and medication persistence) of olanzapine. We were specifically criticized yesterday by a large Medicaid payer consultant for not being able to provide more peer-reviewed publications supporting an argument for long-term effectiveness.

As a company, we all need to do a much better job of proactively listening to payers (and other customers) concerns, and proactively communicating important information such as adverse effect label changes without a tone of minimizing their importance (e.g. wt gain, diabetes, CVA). Payers and clinicians have clearly articulated that this is an area where Lilly has lost its scientific integrity and therefore exposed us to great scepticism when we need to communicate the positive benefits of our products.

Best Regards,

Jerry D. Clewell, Pharm.D., MBA BCPS
Sr. Neuroscience Outcomes Liaison
Eli Lilly and Company

U.S. Medical Division
Phone 636-281-2676
Lilly VMX: 8-462-1618

Virginia Stauffer

01/12/2004 01:29 PM

To: Vicki Poole Hoffmann/AM/LLY@Lilly

cc: Jonna Ahl/AM/LLY@Lilly, Ernie Anand/EMA/LLY@Lilly, George Apostol/AM/LLY@Lilly, Haya Ascher-Svanum/AM/LLY@Lilly, Robert W Baker/AM/LLY@Lilly, Robert W Baker/AM/LLY@Lilly, Michael E Bandick/AM/LLY@Lilly, Nina Barchha/AM/LLY@Lilly, David Bruhn/AM/LLY@Lilly, Jerry D Clewell/AM/LLY@Lilly, Walter Deberdt/AM/LLY@Lilly, Sara E Edwards/AM/LLY@Lilly, Mark Enerson/AM/LLY@Lilly, Carol Lynn Gaich/AM/LLY@Lilly, Thomas A Hardy/AM/LLY@Lilly, Kristine Healey/AM/LLY@Lilly, Angela L Hill/AM/LLY@Lilly, Britton Ashley Hill/AM/LLY@Lilly, Hassan Jamal/AM/LLY@Lilly, Lisa A Jaton/AM/LLY@Lilly, Bryan Johnstone/AM/LLY@Lilly, Bruce Kinon/AM/LLY@Lilly, Ilya A Lipkovich/AM/LLY@Lilly, Baron J Lowe/AM/LLY@Lilly, Michael W Magdycz/AM/LLY@Lilly, John Niewoehner/AM/LLY@Lilly, Michael R Sale/AM/LLY@Lilly, Leslie Schuh/AM/LLY@Lilly, Sebastian Sorsaburu/AM/LLY@Lilly, Patrick A

005328

Toalson/AM/LLY@Lilly, David L Van Brunt/AM/LLY@Lilly, David L Van Brunt/AM/LLY@Lilly
Subject: Re: Annals of Pharmacotherapy Recent articles of interest 2004

Vicki et al,

Thanks for forwarding out the abstract of the review on the selection of atypical antipychotics in the treatment of schizophrenia. Attached is the PDF of this paper as well as a cost comparison review on olz vs ris that was published in the Jan issue of this journal. I think both of these reveiws are worthy of our attention and it is important for us to know that while Annals of Pharmacotherapy is not a widely distributed psych journal it is a respected, peer reviewed journal that does have a wide distribution to practicing clinical pharmacists and others involved with clinical pharmacotherapy decision making and formulary decisions. With that being said, let me make a few comment regarding the papers below:

Selection of atypical antispychotics for the management of schizophrenia- Denise Sprague, the authors are not from the US, the did do a comprehensive reveiw of the current literature and only came up with head to head comparisons of olz vs ris, as we know there are now other atypical head to head papers published but did not make this paper do to a timing issue. In addition to the head to head comparisons of olz and ris the meta anlysis papers are reviewed. I think it is important to point out that there review of the literature is consistent with what we know, "There are trends toward lower toward lower withdrawl rates, greater magnitude of improvement in PANSS scores, and greater improvement in negative symptoms with OLZ compared to RIS." I think this statement will likely be stronger when other long-term head to head comparisons with olanzapine and other atypicals are available. Also, obsevational data was not included in this literature review. Please look at the conclusions in the actually paper, very much based on the current state of the published literature and does not clearly make the statement of selecting the APD based on side effects.

Cost comparisons of olanzapine and risperidone in treating schizophrenia- Gordon Liu- This review was funded by a grant from Lilly (not sure from who) but is a comprehensive review of randomized and retrospective studies in the literature. Also reviews the literature for each of these agents vs conventionals which is very useful. I have made the HGFI core team aware of this paper and we briefly discussed at our last meeting.

Thanks and let me know if you have any comments or questions.

Sprague Selection of APDs Ann Pharm 2-0Liu cost comparison review OLZ vs RIS Ann Pharma 1-04.pdf

Vicki Poole Hoffmann
01/12/2004 08:57 AM To: Thomas A Hardy/AM/LLY@Lilly, Ilya A Lipkovich/AM/LLY@Lilly, Patrick A Toalson/AM/LLY@Lilly, John

005329

Niewoehner/AM/LLY@Lilly, Robert W Baker/AM/LLY@Lilly, David L Van Brunt/AM/LLY@Lilly, Virginia Stauffer/AM/LLY@Lilly, Michael W Magdycz/AM/LLY@Lilly, Baron J Lowe/AM/LLY@Lilly, George Apostol/AM/LLY@Lilly, Leslie Schuh/AM/LLY@Lilly, Hassan Jamal/AM/LLY@Lilly, Kristine Healey/AM/LLY@Lilly, Jonna Ahl/AM/LLY@Lilly, Nina Barchha/AM/LLY@Lilly, Sebastian Sorsaburu/AM/LLY@Lilly, David Bruhn/AM/LLY@Lilly, Michael R Sale/AM/LLY@Lilly

cc:

Subject: Ann Pharmacotherapy Table of Contents for 1 February 2004; Vol. 38, No. 2

Below is an abstract from *The Annals of Pharmacotherapy* February Issue. It appears to say that all antipsychotics have equal efficacy, so drug selection should be based on side effect profile.

If anyone has the pdf, please forward.

Thank you,

Vicki

The Annals of Pharmacotherapy: Vol. 38, No. 2, pp. 313-319. DOI 10.1345/aph.1C461

DRUG SELECTION PERSPECTIVES

Selection of Atypical Antipsychotics for the Management of Schizophrenia

Denise A Sprague, BSc(Pharm)

Clinical Pharmacist, Pharmaceutical Sciences Clinical Service Unit, Vancouver Hospital & Health Sciences Centre, Vancouver, British Columbia, Canada

Peter S Loewen, PharmD

Pharmacotherapeutic Specialist—Internal Medicine, Pharmaceutical Sciences Clinical Service Unit, Vancouver Hospital & Health

Sciences Centre; Clinical Assistant Professor of Pharmacy, Faculty of Pharmaceutical Sciences, University of British Columbia, Vancouver

Colette B Raymond, PharmD

at time of writing, Pharmacotherapeutic Specialist—Psychiatry, Pharmaceutical Sciences Clinical Service Unit, Vancouver Hospital & Health Sciences Centre; Clinical Assistant Professor of Pharmacy, Faculty of Pharmaceutical Sciences, University of British Columbia; now, Winnipeg Regional Health Authority, Winnipeg, Manitoba, Canada

Reprints: Denise A Sprague BSc(Pharm), CSU–Pharmaceutical Sciences, UBC Hospital, 2211 Wesbrook Mall, Vancouver, British Columbia V6T 2B5, Canada, fax 604/822-9742, dsprague@vanhosp.bc.ca

OBJECTIVE: To review the evidence for selecting one atypical antipsychotic agent over another for management of schizophrenia.

DATA SOURCES: A literature search of MEDLINE (1966–June 2003), EMBASE (1998–June 2003), and the Cochrane Library was conducted using the following terms: schizophrenia, quetiapine, ziprasidone, olanzapine, aripiprazole, and risperidone. Bibliographies of relevant articles were hand-searched for additional references.

STUDY SELECTION AND DATA EXTRACTION: Prospective, randomized, blinded trials and meta-analyses that directly or indirectly compared 2 atypical antipsychotic agents in the management of schizophrenia are included in this review. Studies comparing an atypical agent with clozapine are not included.

DATA SYNTHESIS: A small number of prospective, randomized, blinded trials that compare efficacy and tolerability of olanzapine and risperidone have been published. These trials did not reveal clinically meaningful differences in efficacy but did confirm that their adverse effect profiles are slightly different (more weight gain with olanzapine and more extrapyramidal reactions with risperidone). Direct comparisons between other atypical antipsychotics are not available. Systematic reviews (indirect comparisons) of placebo-controlled or traditional antipsychotic-controlled trials suggest similar efficacy for quetiapine, olanzapine, and risperidone when placebo is the comparator and inferior efficacy of quetiapine compared to olanzapine and risperidone when haloperidol is the comparator. The few available economic analyses are difficult to interpret in light of current practice.

CONCLUSIONS: Additional randomized, blinded clinical trials directly comparing efficacy, tolerability, and cost-effectiveness are needed to

confirm the proposed differences among atypical antipsychotic agents before recommendations can be made with confidence.

Vicki Poole Hoffmann, Pharm.D.
Associate Therapeutic Consultant
Eli Lilly and Company
Phone 317-433-0125
Fax 317-276-7100

NOV 1 ' 1999

NOV 2 3 1999

VCBH Ventura County
Behavioral Health Department

A Division of the Ventura County Health Care Agency

Pierre Durrand, DPA
Health Care Agency Director

November 17, 1999

John Hayes, MD
US Medical Director
Eli Lilly and Co.
Indianapolis, Indiana, 46285

Dear Dr. Hayes:

This is to inform you that we have contacted our local drug representative for Zyprexa in our county as well as the regional supervisor to let them know that we have had eight patients out of possibly thirty five patients on Zyprexa show up with high blood sugars. Two patients had to be hospitalized due to out of control diabetes and the other six, who were not diabetics prior to taking Zyprexa, ended up with blood sugars higher than 120 fasting.

We treat the monolingual Hispanic population who is already at risk for diabetes and have come to realize that Zyprexa tends to throw many of them into a hyperglucose estate. Most of the eight patients were taken off the Zyprexa with normal return to their blood sugars except for the two whose blood sugars went up to 500+ and these were controlled after discontinuing the Zyprexa.

I believe it is Lilly's responsibility to look into this delicate matter in lieu of the many reports that are coming out showing the danger of Zyprexa with weight gain and hyperglycemia. I think that it would make sense for Lilly to investigate and report on these findings rather than turn the other way and send literature on how all antipsychotics increase the probability of hyperglycemia. In this particular instance it is a very

005333

VCBH Ventura County
Behavioral Health Department

A Division of the Ventura County Health Care Agency

Pierre Durrand, DPA
Health Care Agency Director

distinct group that is watched closely with baseline blood sugars and the buck should not be passed that easily.

Right now, we have stopped using Zyprexa in our region since our Hispanic population is very high and we cannot run the risk of having these folks end up with high blood sugars. We have a staff of approximately thirty psychiatrists in the county and all are aware of this situation. Our count y serves a population of nearly 5,000 mental health patients.

Please, take this situation into consideration. I guess what we are asking is a report from Lilly in regards to Zyprexa and its potential for high blood sugar, regardless what the general antipsychotic statistics are. We certainly have never seen this with Haldol, Navane, Risperdal , and others to this extend.

If you need to reach me, please do so at your earliest convenience or our Quality Assurance, doctor of pharmacology, Dr. Patti Yoshida (805) 652-6187. We would be glad to help as much as we can. We have certainly used Zyprexa in the past with other groups to our satisfaction.

Sincerely,

Albert Marrero, M.D.

Albert Marrero, MD
Staff Psychiatrist
(bilingual)

005334

A B C D E

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-06-5630 CI

DEFENDANT ELI LILLY AND COMPANY'S AMENDED PROPOSED JURY INSTRUCTIONS AND SPECIAL VERDICT FORM

[WORKING COPY]

Defendant Eli Lilly and Company ("Lilly") respectfully requests that the Court charge the jury with the following proposed instructions and special verdict form.

DATED: March 21, 2008.

Respectfully submitted,

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac* vice
George A. Lehner, admitted *pro hac* vice
John F. Brenner, admitted *pro hac vice*
3000 Two Logan Square
Philadelphia, PA 19103-2799
(215) 981-4618

LANE POWELL LLC

By: _____
Brewster H. Jamieson,
ASBA No. 8411122
Andrea E. Girolamo-Welp,
ASBA No. 0211044

Attorneys for Defendant

TABLE OF PROPOSED CLOSING INSTRUCTIONS

No.	Subject	Source	Corresponding Pattern Instruction	Disputed
14.	General Remarks	See attached.	CPJI 2.01	Yes*[1]
15	Instructions By Court	State's Instruction No. 18[2]	CPJI 2.02	No
16.	Use of Pronouns	See attached.	CPJI 2.03	Yes
17.	Plaintiff's Claims	See attached.	CPJI 7.01	Yes
18.	Definition of Preponderance of the Evidence	State's Instruction No. 22.	CPJI 2.04	No
19.	Resort to Chance	State's Instruction No. 27.	CPJI 2.07	No
20.	Attorney's Fees and Costs	State's Instruction No. 28.	CPJI 2.06	No
21.	Credibility of Witnesses	See attached.	CPJI 2.08	Yes*
22.	Status of Witnesses in Community	See attached.	CPJI 2.09	Yes
23.	Parties Equal Before Law	See attached.	n/a	Yes
24.	Credibility of Expert Witnesses	See attached.	CPJI 2.10	Yes*
25.	Questions Asked By Court	See attached.	CPJI 2.12	Yes*
26.	Depositions Generally	State's Instruction 21.	CPJI 2.13	Yes
27.	Videotape Depositions	State's Instruction 21.	CPJI 2.14	Yes
28.	Exhibits	See attached.	CPJI 2.17	Yes*
28a.	Redactions	See attached.	n/a	New
29.	Stipulations; Binding Admissions	See attached.	CPJI 2.19	Yes
30.	Questions; Inadmissibility of Evidence; Arguments and Statements of Counsel	State's Instruction 20.	CPJI 2.22	No
31.	Failure to Present Evidence	See attached.	CPJI 2.23	Yes
32.	Unsworn Oral Admission of Party	See attached.	CPJI 2.25	Yes
33.	Evaluation of Evidence	State's Instruction 19.	CPJI 2.26	No

[1] For disputed instructions marked with an asterisk, the only dispute is whether certain boilerplate instructions given at the beginning of trial should be given again as part of closing instructions.

[2] Following the meet-and-confer process, Lilly agreed to adopt certain of the State's proposed instructions, as served on by the State on February 4, 2008, in place of its previously proposed instructions and therefore does not submit separate copies of those instructions, as set forth in this table.

No.	Subject	Source	Corres-ponding Pattern Instruction	Disp-uted
34.	FDA Approval Process	See attached.	n/a	Yes
35.	FDA Regulation of Labels	See attached.	n/a	Yes
36.	Post-Approval Monitoring	See attached.	n/a	Yes
40.	Liability For Defect In A Product	See attached.	CPJI 7.02	Yes
41.	Defectiveness Defined	See attached.	CPJI 7.03	Yes
42.	Scientific Unknowability	See attached.	CPJI 7.03A	Yes
43.	Effect of Passage Of Time On Duty To Warn	See attached.	n/a	Yes
44.	Consideration of FDA Approval	See attached.	n/a	Yes
45.	Unfair Or Deceptive Act Defined	See attached.	n/a	Yes
46.	Trade or Commerce Defined	See attached.	CPJI 10.02	Yes
48.	Identification Of Alleged UTPCPA Violations	See attached.	n/a	Yes
49.	Damages Determined Separately	See attached.	n/a	Yes
51.	Introduction To Special Verdict Form	State's Instruction No. 32	CPJI 3.09	No
52.	Special Verdict Form	See attached.	n/a	Yes
53.	General Behavior; Election of Foreperson	State's Instruction No. 29	CPJI 2.28	No
54.	Juror's Communications With Court	State's Instruction No. 30	CPJI 2.29	No
55.	Jurors' Notes	State's Instruction No. 31	CPJI 2.30	No
56.	Returning A Verdict	State's Instruction No. 32, with revisions as agreed by parties.	CPJI 2.31	No

LILLY'S INSTRUCTION NO. 14.

GENERAL REMARKS[3]

Members of the jury, you have now heard and seen all of the evidence in the case and you have heard argument about the meaning of the evidence. We have reached the stage of the trial where I instruct you about the law to be applied.

It is important that each of you listen carefully to the instructions. Your duty as jurors does not end with your fair and impartial consideration of the evidence. Your duty also includes paying careful attention to the instructions so that the law will properly and justly be applied to the parties in this case. You will have a copy of my instructions with you when you go in to the jury room to deliberate and to reach your verdict. But it is still absolutely necessary for you to pay careful attention to the instructions now. Sometimes the spoken word is clearer than the written word, and you should not miss the chance to hear the instructions. I will give them to you as clearly as I can in order to assist you as much as possible.

The order in which the instructions are given has no relation to their importance. The length of instructions also has no relation to importance. Some concepts require more explanation than others, but this does not make longer instructions more important than shorter ones. All of the instructions are important and all should be carefully considered. You should understand each instruction and see how it relates to the others given.

[3] Source: AK CPJI 2.01.

LILLY'S INSTRUCTION NO. 16.

USE OF PRONOUNS[4]

In these instructions, I have tried to use correct pronouns when referring to the parties and to use the plural form when it is appropriate. You should interpret the instructions in a reasonable way. The choice of pronouns is not important. What is important is that you follow the rules given in the instructions.

[4] Source: AK CPJI 2.03.

LILLY'S INSTRUCTION NO. 17.

PLAINTIFF'S CLAIMS[5]

In this case, the State's claims against the Defendant are based on two separate theories. These theories are:

(1) that Zyprexa is a defective product; and

(2) that the Defendant violated the Alaska Unfair Trade Practices and Consumer Protection Act.

I will instruct you separately on each of these theories and you must decide each theory separately.

[5] Source: AK CPJI 7.01 (modified).

LILLY'S INSTRUCTION NO. 21.

CREDIBILITY OF WITNESSES[6]

You have heard a number of witnesses testify in this case. You must decide how much weight to give the testimony of each witness.

In deciding whether to believe a witness and how much weight to give a witness's testimony, you may consider anything that reasonably helps you to evaluate the testimony. Among the things that you should consider are the following:

(1) the witness's appearance, attitude, and behavior on the stand and the way the witness testified;
(2) the witness's age, intelligence, and experience;
(3) the witness's opportunity and ability to see or hear the things the witness testified about;
(4) the accuracy of the witness's memory;
(5) any motive of the witness not to tell the truth;
(6) any interest that the witness has in the outcome of the case;
(7) any bias of the witness;
(8) the consistency of the witness's testimony and whether it was supported or contradicted by other evidence.

You should bear in mind that inconsistencies and contradictions in a witness' testimony, or between a witness's testimony and that of others, do not necessarily mean that you should disbelieve the witness. It is not uncommon for people to forget or to remember things incorrectly and this may explain some inconsistencies and contradictions. It is also not uncommon for two honest people to witness the same event and see or hear things differently. It may be helpful when you evaluate inconsistencies and contradictions to consider whether they relate to important or unimportant facts.

If you believe that part of a witness's testimony is false, you may also choose to distrust other parts of that witness's testimony, but you are not required to do so. You may believe all, part, or none of the testimony of any witness. You need not believe a witness even if the witness's testimony is uncontradicted. However, you should act reasonably in deciding whether you believe a witness and how much weight to give to the witness's testimony.

---

[6] Source: AK CPJI 2.08.

LILLY'S INSTRUCTION NO. 21 (CONT'D).

You are not required to accept testimony as true simply because a number of witnesses agree with each other. You may decide that even the unanimous testimony of witnesses is erroneous. However, you should act reasonably in deciding whether to reject uncontradicted testimony.

When witnesses are in conflict, you need not accept the testimony of a majority of witnesses. You may find the testimony of one witness or of a few witnesses more persuasive than the testimony of a larger number.

LILLY'S INSTRUCTION NO. 22.

STATUS OF WITNESSES IN COMMUNITY[7]

You should not assume that the testimony of a witness who holds a prominent position in the community is more likely to be correct than the testimony of other witnesses. The testimony of all witnesses should be evaluated according to the same standards.

[7] Source: AK CPJI 2.09.

LILLY'S INSTRUCTION NO. 23.

PARTIES EQUAL BEFORE LAW[8]

You should not allow your consideration of the evidence to be influenced by the status of the parties in this case. Both the Plaintiff and the Defendant are equal before the law.

The fact that the Plaintiff is the State of Alaska should not affect your decision. You should evaluate the Plaintiff's arguments and evidence according to the same standards that you would use to evaluate the arguments and evidence of any other person.

Similarly, the fact that the Defendant is a corporation should not affect your decision. You should evaluate the Defendant's arguments and evidence according to the same standards that you would use to evaluate the arguments and evidence of any other person.[9]

---

[8] Source: materials cited.

[9] *Grosjean v. American Press Co.*, 297 U.S. 233, 244 (1936) (holding that "a corporation is a 'person' within the meaning of the equal protection and due process of law clauses).

LILLY'S INSTRUCTION NO. 24.

CREDIBILITY OF EXPERT WITNESSES[10]

Several expert witnesses testified in this case. Experts have special training, education, skills or knowledge that may be helpful to you. In deciding whether to believe an expert and how much weight to give expert testimony, you should consider the same things that you would when any other witness testifies. In addition, you should consider the following things:

(1) the special qualifications of the expert;
(2) the expert's knowledge of the subject matter involved in the case;
(3) the source of the information considered by the expert; and
(4) the reasons given for the expert's opinion.

As with other witnesses, you must decide whether to believe an expert and how much weight to give to expert testimony. You may believe all, part, or none of the testimony of an expert witness. You need not believe an expert even if the testimony is uncontradicted. However, you should act reasonably in deciding whether or not you believe an expert witness and how much weight to give expert testimony.

You are not required to accept expert testimony as true simply because a number of expert witnesses agree with each other. You may decide that even the unanimous testimony of expert witnesses is erroneous. But you should act reasonably in deciding whether to reject uncontradicted testimony.

When expert witnesses are in conflict, you need not accept the testimony of a majority of the witnesses. You may find the testimony of one witness or of a few witnesses more persuasive than the testimony of a larger number.

---

[10] Source: AK CPJI 2.10.

LILLY'S INSTRUCTION NO. 25.

QUESTIONS ASKED BY COURT[11]

During the trial I asked questions of witnesses called by the parties. You should not assume that the answers to my questions were more or less correct or important than the answers to questions asked by others. Do not assume that because I asked questions I have any opinion about the case or the matters to which my questions relate. It is your job to evaluate the evidence and to decide what witnesses to believe and what weight to give the evidence.

[11] Source: AK CPJI 2.12.

LILLY'S INSTRUCTION NO. 28.

EXHIBITS[12]

During the trial, exhibits were admitted as evidence. In deciding how much weight, if any, to give an exhibit, you should examine its contents and consider how it relates to other evidence in the case. Keep in mind that exhibits are not necessarily better evidence than testimony from witnesses. You will have the exhibits with you in the jury room when you deliberate. The fact that an exhibit is available to you for your examination does not mean that it is entitled to more weight than testimony from witnesses.

[12] Source: AK CPJI 2.17.

LILLY'S INSTRUCTION NO. 28A.

REDACTIONS

You will note that on some of the exhibits admitted as evidence, certain portions have been blacked out or whited out – this is called redaction. This is done so that irrelevant information is omitted. This is entirely proper because it is often the case that documents that contain relevant data may also contain matters that are superfluous, unnecessary and not relevant. Redactions of this type are routinely utilized by the parties in litigation such as this and should not be construed as an attempt to conceal information. You are instructed not to attach any significance to any redactions made from any document introduced into evidence. You should not speculate or deliberate as to what has been redacted from any document, and you should not view any redaction as reflecting positively or negatively on any party.

LILLY'S INSTRUCTION NO. 29.

STIPULATIONS; BINDING ADMISSIONS[13]

There is no dispute in this case that the following trade names of atypical antipsychotic medications correspond to the following generic names:

Trade Name	Generic Name
Abilify®	aripiprazole
Clozaril®	clozapine
Geodon®	ziprasidone
Risperdal®	risperidone
Seroquel®	quetiapine
Zyprexa®	olanzapine

No evidence is required to prove these facts because both parties accept them as true. You must also accept them as true in this case. However, it is up to you to decide how much weight to give these facts in light of the other evidence.

[13] Source: AK CPJI 2.19.

LILLY'S INSTRUCTION NO. 31.

FAILURE TO PRESENT EVIDENCE[14]

The evidence should be evaluated not only by its own intrinsic weight but also according to the evidence which is in the power of one party to produce and of the other party to contradict. If weaker and less satisfactory evidence is offered when it appears that stronger and more satisfactory evidence was within the power of one party to produce, the evidence offered should be viewed with caution.

[14] Source: AK CPJI 2.23.

LILLY'S INSTRUCTION NO. 32.

UNSWORN ORAL ADMISSIONS OF PARTY[15]

You have heard evidence about unsworn oral statements made by a party outside the courtroom. Unsworn oral statements by a party can be used as evidence against that party. However, such statements should be viewed with caution.

In evaluating such statements, you might find it helpful to consider the context in which the statement was made, including:

(1) whether the statements were detailed ones;
(2) whether they were made at a time when the party knew the facts spoken about;
(3) whether when the party made the statements, there was time to make them complete;
(4) whether the party had legal assistance in making the statements; and
(5) whether the physical or mental condition of the party or the circumstances in which the statement was made impaired the party's ability to make an accurate statement.

[15] Source: AK CPJI 2.25.

LILLY'S INSTRUCTION NO. 34 (CONT'D).

The new drug cannot be sold to patients until the FDA has approved the NDA for the drug and its labeling. The FDA must refuse approval unless substantial evidence shows that the drug is safe and effective.[23] Substantial evidence means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the medicine involved.[24] In addition, a drug may not be approved unless there are adequate tests by all methods reasonably available showing that the drug is safe for use under the conditions prescribed.[25] In deciding whether the drug is safe and effective, the FDA takes into account the fact that a drug may have some risks, including some unknown risks, and balances that fact against the beneficial uses to which the drug may be put.[26]

[23] 21 U.S.C. § 355(d).
[24] 21 U.S.C. § 355(a).
[25] 21 U.S.C. § 355(d)(1).
[26] 21 U.S.C. § 355(b)(1), 21 C.F.R. Parts 201,202, and 314.

LILLY'S INSTRUCTION NO. 35.

FDA REGULATION OF LABELS[27]

The FDA regulates and must approve the format and the content of prescription drug labeling.[28]

Under FDA regulations, the label of a prescription drug must contain several sections intended to provide information to prescribing physicians.[29] The "indications and usage" and "dosage and administration" sections of the label list the FDA-approved uses of the drug and the recommended doses for each use.[30] The "contraindications" section lists "situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit" of the drug.[31] The "warnings" section lists serious potential side effects of the drug.[32] The "precautions" section provides information regarding special care to be used by prescribing physicians or patients for the safe and effective use of the drug.[33] And the "adverse reactions" section lists the type and number of adverse events reported for patients in clinical trials (whether or not caused by the drug).[34]

Under FDA regulations, "to change labeling (except for editorial and other minor revisions), the sponsor must submit a supplemental application fully explaining the basis for the change."[35] For some label changes, advance FDA approval is required, while retroactive FDA approval is permitted for other types of label changes.[36] However, a change to a warning without prior FDA approval may only address newly discovered risks, not information that was previously available to the FDA.[37] In all cases, the final decision "whether labeling revisions are necessary" is made by the FDA, rather than by the drug manufacturer.[38]

---

[27] Source: Materials cited.
[28] 21 C.F.R. Part 201.
[29] 21 C.F.R. §201.56 & §201.80.
[30] 21 C.F.R. § 201.80(c) and (j).
[31] 21 C.F.R. § 201.80(d).
[32] 21 C.F.R. § 201.80(e).
[33] 21 C.F.R. § 201.80(f); 65 Fed. Reg. 81082, 81092 (Dec. 22, 2000).
[34] 21 C.F.R. § 201.80(g)
[35] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–36, 3934 (Jan. 24, 2006); *see also* 21 C.F.R. §§ 314.70 & 601.12.
[36] 71 Fed. Reg. 3934; *see also* 21 C.F.R. §§ 314.70 & 601.12.
[37] Brief for the United States as *Amicuc Curiae* in *Wyeth v. Levine*, at pp. 3, 14 (U.S. S.Ct., No. 06-1249).
[38] 71 Fed. Reg. 3934-35; *see also* 21 U.S.C. §§ 331, 352; 21 C.F.R. §§ 314.70, 601.12(f).

LILLY'S INSTRUCTION NO. 36.

POST-APPROVAL MONITORING[39]

After a prescription drug is approved, FDA regulations require the manufacturer to submit reports of new information about the safety and effectiveness of the drug.[40] The FDA may withdraw approval of a drug if the FDA determines that the new information indicates that the drug is not safe and effective for use under the conditions discussed in the drug's labeling,[41] or it may require the manufacturer to make changes to the drug's labeling based on the new information.[42]

---

[39] Source: Materials cited.
[40] 21 C.F.R. §§ 314.80, 314.81.
[41] *See* 21 C.F.R. § 314.150(a)(2)(i).
[42] *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 39968 (Jan. 24, 2006); 21 C.F.R. §§ 201.80(e).

LILLY'S INSTRUCTION NO. 40.

LIABILITY FOR DEFECT IN A PRODUCT[43]

Plaintiff's first theory of liability is that plaintiff was damaged by a defect in a product which the defendant made.

Under this theory, plaintiff must establish that it is more likely true than not true:

(1) that the product was defective; and

(2) that the product was defective when it left the possession of the defendant.

[43] Source: AK CPJI 7.02 (modified for Phase I to eliminate portions related to causation and damages).

LILLY'S INSTRUCTION NO. 41.

DEFECTIVENESS DEFINED[44]

I will now explain what it means for a product to be "defective."

A prescription drug is defective if the use of the product in a manner that is reasonably foreseeable by the defendant involves a substantial danger that would not be readily recognized by the prescribing physician and the manufacturer fails to give adequate warning of such danger. An adequate warning is one that is sufficient to put the prescribing physician on notice of the nature and the extent of the scientifically knowable risks or dangers inherent in the use of the drug.

In determining the adequacy of the warnings, you should keep in mind that the warnings are directed to the prescribing physician, rather than to the patient, and that there is no duty on the part of the manufacturer to warn the State or the patient directly of risks inherent in the drug.

---

[44] Source: AK CPJI 7.03 (modified pursuant to *Shanks v. Upjohn Co.*, 835 P.2d 1189 (Alaska 1992), for Phase I to eliminate portions related to causation and damages, and to reflect fact that State's claim spans multiple years).

LILLY'S INSTRUCTION NO. 43.

EFFECT OF PASSAGE OF TIME ON DUTY TO WARN[45]

The State claims that Zyprexa that was prescribed during the period between September 30, 1996 through October 1, 2007 was defective because the Zyprexa labeling did not adequately warn of the risk of weight gain. In determining whether Defendant adequately warned of the risk of weight gain, you should consider the Zyprexa labeling as a whole. You will be given a verdict form that will require you to determine whether Zyprexa was defective at any point or points during this period. If you find that Zyprexa was defective at one point between September 30, 1996 and October 1, 2007, you should not assume that Zyprexa was defective at all points during that period. It is the State's burden to prove that it is more likely true than not true that Zyprexa prescribed during this period was defective at each point in time that Zyprexa was prescribed during this period.

In determining the adequacy of the warnings given by Defendant at each point during this period, you should follow the instructions I have already given you and should take into account how the following factors may have changed over time with respect to the risk of weight gain:

(a) the content of Zyprexa's labeling regarding the risk;

(b) the extent to which physicians who prescribed Zyprexa were already on notice of the nature and the extent of the risk; and

(c) the extent to which the existence of the risk was scientifically knowable.

[45] Source: *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992) (adequacy of warning and scientific knowability of risks determined as of "the time the product was distributed").

LILLY'S INSTRUCTION NO. 44.

CONSIDERATION OF FDA APPROVAL[46]

The FDA regulates the content of labeling for a prescription drug because labeling is the FDA's principal tool for educating healthcare professionals about the risks and benefits of the approved product to help ensure safe and effective use.

In determining the adequacy of the warnings in the Zyprexa label, you may take into account the fact that the FDA approved the Zyprexa labeling and also conducted a class review of atypical antipsychotic medications from May 5, 2000 through September 11, 2003.

[46] Lilly maintains that the State's failure to warn claims are wholly preempted, for the reasons stated in its briefing previously submitted to the Court, and should not be submitted to the jury. However, Lilly acknowledges the Court's ruling on that issue, and submits this instruction in the alternative to a finding that the State's failure-to-warn claims are wholly preempted as a matter of law. *See, e.g.*, Food and Drug Administration, *Requirement on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 F.R. 3922, 3933-36 (Jan. 24, 2006) (stating that the "FDA interprets the [FDCA] to establish both a 'floor' and a 'ceiling' with respect to descriptions of potential risks of a product on the labeling" and that "FDA approval of labeling ... preempts conflicting or contrary State law" except in some circumstances); *Colacicco v. Apotex, Inc.*, 432 F. Supp.2d 514, 529-32 (E.D. Pa. 2006) (finding that "the FDA's position is entitled to significant deference" and that "based on deference alone, this Court would deem any state failure-to-warn claim impliedly preempted").

LILLY'S INSTRUCTION NO. 45.

UNFAIR OR DECEPTIVE ACT DEFINED[47]

Plaintiff's second theory of liability is that Defendant committed unfair and deceptive acts in violation of the Alaska Unfair Trade Practices and Consumer Protection Act, which is often referred to as the UTPCPA. Under Alaska law, the following acts constitute unfair or deceptive acts when they are committed in the conduct of trade or commerce in Alaska:

(1) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;[48]

(2) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;[49]

(3) Engaging in any other conduct creating a likelihood of confusion or of misunderstanding and which misleads, deceives or damages a buyer or a competitor in connection with the sale or advertisement of goods or services;[50] and

(4) Using or employing deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of goods or services whether or not a person has in fact been misled, deceived or damaged.[51]

---

[47] Source: Jury Instruction No. 11, *State of Alaska v. Anchorage-Nissan, Inc.*, CA No. 3AN-93-7761 CIV (Super. Ct., 3d Jud. Dist., 1/12/1995), *approved, State of Alaska v. Anchorage-Nissan, Inc.*, 941 P.2d 1229, 1221 (Alaska 1997) (modified to reflect differences in alleged violations).
[48] A.S. §45.50.471(b)(4).
[49] A.S. §45.50.471(b)(6).
[50] A.S. §45.50.471(b)(11).
[51] A.S. §45.50.471(b)(12).

LILLY'S INSTRUCTION NO. 46.

"TRADE OR COMMERCE" DEFINED[52]

Trade or commerce means advertising, offering for sale, selling, renting, leasing, or distributing any services, property, or any other thing of value.

[52] Source: AK CPJI 10.02.

LILLY'S INSTRUCTION NO. 48.

IDENTIFICATION OF ALLEGED UTPCPA VIOLATION.[53]

The State claims that Defendant violated the UTPCPA by failing to include an adequate disclosure of the risk of weight gain in the Zyprexa labeling between September 30, 1996 and October 1, 2007.

To decide whether Defendant violated the UTPCPA, you must decide two things. First, you must decide if it is more likely true than not true that the facts claimed by the State actually happened. Second, you must decide whether those facts constitute an unfair or deceptive act under the instructions I have given you. If you find both things – that the facts alleged by the State are more likely true than not true and that those facts constitute an unfair or deceptive act – then you must find that Defendant committed that violation. Conversely, if either the facts alleged by the State have not been proved, or if the facts do not constitute an unfair or deceptive act as defined under the instructions I have given you, then you must find that Defendant did not commit that violation

You will be given a verdict form that will require you to determine whether the Zyprexa labeling included an adequate disclosure of the risk of weight gain at any point or points between September 30, 1996 and October 1, 2007. If you find that the Zyprexa labeling did not include an adequate disclosure at one point during that period, you should not assume that the labeling lacked an adequate disclosure at other points during that period. It is the State's burden to prove that it is more likely true than not true that the Zyprexa labeling lacked an adequate disclosure of the risk of weight gain at each point in time that Zyprexa was prescribed during this period.

---

[53] Source: Jury Instructions Nos. 21-29, *State of Alaska v. Anchorage-Nissan, Inc.*, CA No. 3AN-93-7761 CIV (Super. Ct., 3d Jud. Dist., 1/12/1995), *approved, State of Alaska v. Anchorage-Nissan, Inc.*, 941 P.2d 1229, 1221 (Alaska 1997) (modified for this case).

LILLY'S INSTRUCTION NO. 49.

DAMAGES DETERMINED SEPARATELY

If you find that the Plaintiff has proved any of its claims to be more likely true than not true, the Court will determine in a separate proceeding whether the Plaintiff is entitled to any money from the Defendant. You should not speculate about whether the Plaintiff is entitled to any money from the Defendant. Your duty is to answer the questions that are presented to you in the Special Verdict form, based on the evidence that has been presented and the instructions that I have given you.

LILLY'S INSTRUCTION NO. 52.

SPECIAL VERDICT FORM

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

State of Alaska,
Plaintiff,

v.

Eli Lilly and Company,
Defendant.

Case No. 3AN-06-5630 CIV

SPECIAL VERDICT

We, the jury in the above-entitled case, find the following special verdict submitted to us in the above-captioned case:

Answer "yes" or "no" to Question No. 1. If the State failed to prove that Zyprexa was defective because the Zyprexa labeling did not adequately disclose the risk of weight gain between September 30, 1996 and October 1, 2007, you should check "No." Conversely, if the State proved that Zyprexa was defective because the Zyprexa labeling did not adequately disclose the risk of weight gain at any point or points between September 30, 1996 and October 1, 2007, you should check "Yes," and state the date or dates on which Zyprexa was defective.

(1) At any time between September 30, 1996 and October 1, 2007, was Zyprexa defective when it left the possession of Defendant? If so, when?

____ No

____ Yes. Date(s): _____

Answer "yes" or "no" to Question No. 2. If the State failed to prove that Defendant committed an unfair or deceptive act or practice, you should check "No." Conversely, if the State proved that Defendant committed an unfair or deceptive act or practice, you should check "Yes," and state the date or dates on which Defendant committed an unfair or deceptive act or practice.

(2) At any time between September 30, 1996 and October 1, 2007, did Defendant commit an unfair or deceptive act or practice by failing to include an adequate disclosure of the risk of weight gain in the Zyprexa labeling? If so, when?

____ No

____Yes. Date(s): _____

DATED at Anchorage, Alaska, this ___ day of _____, 2008.

_____
Foreperson of the Jury

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

PLAINTIFF'S OBJECTIONS AND COUNTER-DESIGNATIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS AS OF MARCH 22, 2008

In response to Defendant's designations, Plaintiff hereby objects to the following designations:

JUDGES RULING 3/24/08 Mark Rindner

PATRIZIA CAVAZZONI
JUNE 27, 2006

Page/Line Range	Objection
207:23-208:3	Improper opinion testimony by fact witness
208:10-208:21	Improper opinion testimony by fact witness
208:24 – 209:5	Improper opinion testimony by fact witness
209:10-209:21	Improper opinion testimony by fact witness
216:20 – 217:05	Improper opinion testimony by fact witness
217:11 – 217:23	Improper opinion testimony by fact witness
217:24-218:24	Improper opinion testimony by fact witness
221:15-221:17	Improper opinion testimony by fact witness

222:24-223:10	Improper opinion testimony by fact witness
300:3-300:15	Improper opinion testimony by fact witness; lack of foundation

Plaintiff hereby offers the following counter-designations:

Start	Stop
202:23	203:1
203:6	203:15
227:20	228:6
253:3	253:17
255:16	256:20
259:23	260:7
260:16	261:9
291:14	291:24
358:24	361:11

DATED this 22nd day of March, 2008.

FELDMAN, ORLANKSY & 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
David L. Suggs
Christiaan A. Marcum
Counsel for Plaintiff

FIBICH, HAMPTON & LEEBRON, LLP
Kenneth T. Fibich
Counsel for Plaintiff

CRUSE, SCOTT, HENDERSON & ALLEN, LLP
T. Scott Allen
Counsel for Plaintiff

Certificate of Service

I hereby certify that a true and correct copy of **PLAINTIFF'S OBJECTIONS AND COUNTER-DESIGNATIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS FOR PATRIZIA CAVAZZONI AS OF MARCH 22, 2008** was served via hand-delivery on:

George Lehner, Esq.
Pepper Hamilton LLP
Hotel Captain Cook, 19th Floor
Anchorage, Alaska 99501

By _____

Date 3-22-08

Lilly's testimony
Gilbertson, Courtis, Campana, Erickson

Gilbertson, Joel (Vol. 01) - 12/06/2(

Lilly Initial - Continuous

JG-INITIAL 1(

1. PAGE 5:17 TO 5:22 (RUNNING 00:00

JOEL GILBERTSON,
having been sworn, testified as follows:
EXAMINATION
Q (BY MR. ROTHSCHILD) Good morning, Mr. Gilbertson.
A Good morning.

2. PAGE 10:16 TO 11:21 (RUNNING 00:01:15.133)

Q Describe for me your work history after you received your master's degree in 2001.
A I worked in the -- well, I was employed before I finished my master's degree but after my law degree, in that time period, and that job continued past my master's degree. I was employed by the United States Senate and was the staff director and legislative director for United States Senator Frank Murkowski. That continued -- that was from 1999 until 2002.
00011:01 December of 2002 I was appointed as Commissioner of the Alaska Department of Health and Social Services, confirmed by the legislature in February of 2003. I remained in that job until the end of September of 2005. Literally the last day of September. Took from Friday, ended in that job Monday, started at Providence Health and Services.
So that would have been the first couple days of October of 2005. And I'm in that current employment now where I serve as regional director for the Alaska region.
Q And can you just tell me again when you began as Commissioner? What month?
A December of 2002, December 9th, 2002, continuing through the end of September, 2005.
Q And that was a position that you were appointed by the governor?
A Yes.
Q And who was the governor at that time?
A Frank Murkowski.

3. PAGE 12:03 TO 12:13 (RUNNING 00:00:18.611)

Q (BY MR. ROTHSCHILD) Are you represented by counsel today?
A I am.
Q And who are you represented by?
A Mr. Sniffen and Mr. Biggs.
Q Okay. And how did they become your counsel for this deposition?
A I believe from my -- I'm essentially being deposed from my role as when I was Commissioner, so it's in that function, as the State is defending my deposition.

0_P1428

4. PAGE 13:16 TO 13:20 (RUNNING 00:00:12.000)

Q Prior to speaking to Mr. Sniffen a week ago, were you aware that the State of Alaska had sued Eli Lilly regarding its prescription drug Zyprexa?
A No.

5. PAGE 15:08 TO 15:21 (RUNNING 00:00:36.667)

Q This is a pretty broad question, but tell me, what were your duties and responsibilities as the Commissioner for Health and Social Services for Alaska?
A Okay. Well, as Commissioner, you are essentially the chief executive officer of operations. The Department of Health and Social Services is the largest State agency; has a work force a little over 4,000 employees. The time I left, I managed a budget of about $2 billion, which is a combination of state, federal and other funds. Manages a collection of programs. It's sort of an umbrella agency that has divisions within it.

6. PAGE 18:21 TO 19:07 (RUNNING 00:00:34.000)

Q What were your responsibilities and the agency's responsibilities regarding the Alaska Psychiatric Institute?
A It operated it. It was a -- all employees, save for vendors, are State employees.
00019:01 It manages it, runs it. The administrator of it reports to the director of behavioral health which was -- which reported to me. It is a State facility.
Q Was the agency responsible for submitting the budget for API?
A Uh-huh. Yes.

7. PAGE 19:17 TO 20:01 (RUNNING 00:00:21.533)

Q What were the major items of expense for API?
A The major items of expense for API are similar to virtually any other health care facility, which is labor, depreciation expense and supplies.
Q And do supplies include medications?
A I'm certain they do, but the way the State budgets at that line item level, I would
00020:01 never see that.

8. PAGE 20:20 TO 21:05 (RUNNING 00:00:29.000)

Q Did any component of the agency have any responsibility for monitoring or supervising the safety of medications that were prescribed to Alaska Medicaid recipients?
A Not in the sense of doing -- no, not in the sense of doing -- vetting clinical literature
00021:01 for safety, no. It does not regulate drug products, no.
Q And why -- why not?
A It's a function of the Food and Drug Administration.

0_P1428

9. PAGE 61:24 TO 62:07 (RUNNING 00:00:27.151)

Q Are you aware of Eli Lilly making any misrepresentations about Zyprexa to the State of Alaska?
A I have no knowledge of that. I don't recall.
Q Are you aware of any -- sitting here today, do you believe that Eli Lilly omitted, failed to tell the State anything that they should have?

10. PAGE 62:10 TO 62:24 (RUNNING 00:00:53.400)

A I have no knowledge.
Q (BY MR. ROTHSCHILD) Did anybody employed by the State of Alaska ever communicate to you that Eli Lilly had made misrepresentations to them about Zyprexa?
A I don't recall.
Q In your tenure as Commissioner, did anybody employed by the Department ever communicate to you that the Department had been misled about any drug?
A I have no recollection of that.
Q And did anybody ever communicate to you that they felt that prescribers in the State of Alaska had been misled about any drug?
A I don't recall that.

11. PAGE 64:10 TO 65:20 (RUNNING 00:01:33.000)

Q If it turned out to be the case during your tenure as Commissioner that the State -- anybody employed by the State had come to the conclusion that a pharmaceutical company was misrepresenting the characteristics of a prescription drug reimbursed by Medicaid, if the State actually became aware of that, is that something you would expect you as Commissioner would be made aware of?
A I would hope I would be made aware of it. I don't know if I could expect it. I mean, at the end of the day, buried in that question is: Would I be aware of it? And I can't tell you that everyone would have made sure that I was aware of it. I would hope I would have been aware of it.
Q Why is that?
A Because I don't know what the process would have been for the State to make that evaluation. I can tell you that I would hope I would have been made aware of it, but I don't know.
Q Right. And I'm asking: Why would you hope to be? Would it be the case that you would figure that was important to your role as Commissioner?
A Well, I think for an agency head who oversees a health agency for the State, there's very little bit of -- very little information regarding health care in Alaska I wouldn't want to be aware of.
Q And potentially, depending on what the issue is, you might want to take action about it?
A I certainly would want to have deliberations around the merits or the authorities for that.

0_P1428

12. PAGE 68:13 TO 68:16 (RUNNING 00:00:14.000)

Q I take it it's the case that you have no recollection of misrepresentations about Zyprexa being brought to your attention at any time?
A I don't recall that.

13. PAGE 72:18 TO 73:02 (RUNNING 00:00:18.633)

Q (BY MR. ROTHSCHILD) Mr. Gilbertson, you testified that if employees of the State had become aware that Lilly was misrepresenting Zyprexa, that is something you would hope you would become aware of in your role as Commissioner, correct?
A I would think so, yes.
Q But you have no recollection of that occurring?
A I don't recall it, no.

14. PAGE 73:21 TO 74:14 (RUNNING 00:00:45.600)

Q The State has also -- has alleged that Lilly misrepresented the safety and efficacy of Zyprexa, including a risk associated with diabetes. To the extent that was known in the State during the time you were Commissioner, is that something you would have hoped you would have been aware of?
A I would want to know, but I would not have been involved in any -- what the agency would have done. I mean, that's up to the clinicians and the program managers. So it would be only for information purposes, but I would want to know.
Q Okay. You would want to know?
A I'd want to know anything. I like knowledge, so I'd want to know.
Q And, again, you were not made aware of any facts of that nature during your tenure?
A Not that I recall.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:08:09.595)

0_P1428

Jackson, Karleen (Vol. 01) - 12/12/2007

1 CLIP (RUNNING 00:05:10.133)

Lilly Initial - Continuous

KJ-INITIAL — 9 SEGMENTS (RUNNING 00:05:10.133)

1. PAGE 5:14 TO 5:16 (RUNNING 00:00:03.000)

Q. (BY MR. ROGOFF) Good afternoon, Ms. Jackson.
A. Good afternoon.

2. PAGE 5:17 TO 5:22 (RUNNING 00:00:13.000)

Q. Could you state your present employment?
A. Certainly. I'm the commissioner with the Department of Health and Social Services for the State of Alaska.
Q. How long have you been the commissioner?
A. Since October of 2005.

3. PAGE 6:13 TO 7:14 (RUNNING 00:01:02.000)

Q. When did you first find out that the State of Alaska had filed a lawsuit against Eli Lilly & Company?
A. Actually, when I had a conversation with Mr. Sniffen.
Q. How long ago?
A. I spoke with him today.
Q. Is that the first time that you've learned of this lawsuit?
A. No. We had an earlier conversation, oh, a month or so ago.
Q. Was that the first time you've learned of this lawsuit?
00007:01 A. I -- yes, that is the first time I've learned of the lawsuit.
Q. What are your duties as the commissioner of the Department of Health and Social Services for the State of Alaska?
A. Basically, to serve as a member of the governor's cabinet. To -- to, to the best of my ability, fulfill the mission of the department; promote and protect the health and well-being of Alaskans; to uphold the Constitution of the United States and of the State of Alaska.
Q. How large is the budget for your department?
A. Approximately $2 billion a year.

4. PAGE 8:05 TO 8:11 (RUNNING 00:00:17.400)

How is public health related to behavioral health?
A. Public health deals with the physical health of the general population of the state of Alaska. Behavioral health specifically looks at issues of mental health, substance abuse, and those kind of more behavioral issues.

5. PAGE 8:22 TO 9:03 (RUNNING 00:00:19.900)

Q. What is the biggest component of your Department's budget?
A. The largest amount of money is involved in the Medicaid component, which includes federal

00009:01 funds as well as general funds.
02 Q. How big is the Medicaid component?
03 A. Approximately $1 billion a year.

6. PAGE 9:24 TO 10:07 (RUNNING 00:00:34.000)

24 Q. Included in the $1 billion for
25 Medicaid -- well, does that $1 billion for
00010:01 Medicaid include prescription drugs?
02 A. The $1 billion would include Medicaid
03 prescription drugs, correct.
04 Q. Does it include the payment for
05 pharmaceuticals that -- for people who are dually
06 eligible for Medicare and Medicaid?
07 A. Yes, I believe it does.

7. PAGE 23:16 TO 23:19 (RUNNING 00:00:10.000)

16 Q. What did you do, if anything, to prepare
17 for today's deposition?
18 A. I had a conversation this morning with
19 Mr. Sniffen and Mr. Steele.

8. PAGE 23:24 TO 25:03 (RUNNING 00:01:04.300)

24 Q. Is the sum total of what you know about
25 this lawsuit whatever you've learned from
00024:01 Mr. Sniffen and Mr. Steele?
02 A. That would be correct.
03 Q. Have you spoken to anyone else in the
04 Department of Health and Social Services about
05 the lawsuit?
06 A. No.
07 Q. Have you spoken to any physicians in the
08 state of Alaska about the lawsuit?
09 A. No.
10 Q. Have you spoken to anyone with any
11 advocacy groups about the lawsuit?
12 A. No.
13 Q. And by "advocacy groups," I mean a group
14 like NAMI?
15 A. No.
16 Q. Have you spoken with any legislators
17 about the lawsuit?
18 A. No.
19 Q. Have you spoken with the governor about
20 the lawsuit?
21 A. No.
22 Q. Other than Mr. Sniffen, have you spoken
23 with anyone in the Attorney General's office?
24 A. No.
25 Q. Have you gotten any information about
00025:01 this lawsuit from any other sources besides
02 Mr. Sniffen and Mr. Steele?
03 A. No.

9. PAGE 30:03 TO 31:13 (RUNNING 00:01:26.533)

03 Q. Have you ever talked with any
04 psychiatrists about Zyprexa?
05 A. No.
06 Q. Have you talked with any other
07 physicians about Zyprexa?
08 A. No.
09 Q. Have you talked with any State officials
10 about Zyprexa?
11 A. No.
12 Q. Are you aware of any statements by
13 doctors or State officials complaining about

0_P1428

misrepresentations by Eli Lilly & Company about Zyprexa?
A. No.
Q. When you were deputy commissioner or now as commissioner of the Department of Health and Social Services for the State of Alaska, did anyone ever suggest to you that the State bring a lawsuit against Eli Lilly & Company?
A. Not -- no, not that I'm aware of.
Q. Did anyone ever discuss with you the bringing -- the possibility of bringing a lawsuit against Eli Lilly & Company?
00031:01 A. Not that I can remember, no.
Q. Did you ever recommend a lawsuit be brought against Eli Lilly & Company?
A. No.
Q. Do you know of any doctors who've ever complained in the state of Alaska about being misled by any representative of Eli Lilly & Company?
A. Not that I'm aware of.
Q. And do you know of any State officials who have complained about being misrepresented by any member of Eli Lilly & Company?
A. Not that I recall, no.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:05:10.133)

Campana, David (Vol. 01) - 09/18/2007

1 CLIP (RUNNING 00:03:05.399)

Lilly Initial - Continuous

DC-INITIAL1 — 7 SEGMENTS (RUNNING 00:03:05.399)

1. PAGE 5:08 TO 5:14 (RUNNING 00:00:11.999)

DAVID CAMPANA,
deponent herein, being sworn on oath,
was examined and testified as follows:
EXAMINATION

BY MR. ROTHSCHILD:
Q. Good morning, Mr. Campana.
A. Good morning.

2. PAGE 7:15 TO 8:04 (RUNNING 00:00:41.600)

Q. Who are you employed by?
A. The State of Alaska, Department of Health and Social Services, Division of Health Care Services.
Q. How long have you been employed in that division?
A. 17-plus years.
Q. What position do you hold right now?
A. Medicaid pharmacy program manager.
Q. How long have you held that position?
A. For 17 years.
Q. What did you do before then?
A. I worked as the pharmacist for the Pay and Save chain. I was at the level of head pharmacist for the one store, the Boniface Pay and Save.
Q. How long did you do that?
A. 14 years.

3. PAGE 8:10 TO 8:14 (RUNNING 00:00:11.100)

Q. Where did you go to school?
A. University of Montana.
Q. What degree did you -- did you graduate?
A. I graduated with a bachelor of science in pharmacy.

4. PAGE 8:18 TO 8:23 (RUNNING 00:00:20.000)

Q. Can you describe what you do as the Medicaid pharmacy director?
A. I manage the program. I'm the answer man. I promote several different programs or work with several different programs as a Medicaid pharmacy program manager.

5. PAGE 12:03 TO 12:10 (RUNNING 00:00:26.100)

Q. You said you managed the program. What does that entail?
A. Oversight of the program, trying to determine what the spend for the next year is going to be as far as budgeting, looking at any avenues for cost containment or slowing cost increases, making sure that we meet the federal guidelines and the new guideline coming up.

6. PAGE 33:16 TO 33:20 (RUNNING 00:00:28.300)

Q. Have you reviewed the complaint that was filed

0_P1428

against Eli Lilly in this matter?
A. I don't believe I have seen the whole complaint.
Q. Have you seen parts of the complaint?
A. Actually, I can't say I have seen the complaint.

7. PAGE 34:04 TO 34:15 (RUNNING 00:00:46.300)

Did you participate in the decision by the State of Alaska to sue Eli Lilly?
A. No.
Q. Do you know who did?
A. No, I don't.
Q. When did you become aware that the state had sued Eli Lilly? Just to sort of put a time frame, the lawsuit was actually filed in March 2006.
A. It was in 2006 when I became aware of it.
Q. The first half of the year, second half of the year?
A. Well, let's see. Probably first quarter.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:03:05.399)

Campana, David (Vol. 01) - 09/19/2007

1 CLIP (RUNNING 00:26:09.800)

Lilly Initial - Continuous

DC-INITIAL2 — 22 SEGMENTS (RUNNING 00:26:09.800)

1. PAGE 198:19 TO 199:06 (RUNNING 00:00:54.300)

Q. Tell me about your practices as the pharmacy director for Alaska's Medicaid program. What regular efforts do you make to follow the literature regarding safety issues for the medications that Alaska reimburses?
A. I read package inserts. I read journal articles. I read the news press, get articles on list serves. I hear things at conferences, so a number of different ways.
Q. And do you consider that an important part of your responsibilities to monitor safety issues relating to the medications that Alaska reimburses?
A. Yes.

2. PAGE 199:18 TO 199:23 (RUNNING 00:00:33.000)

Q. What journals do you read?
A. American Pharmacists Journal, then reprints from different medical journals.
Q. Have you been reading American Pharmacists Journal during the entire 1996 to 2006 time period?
A. Yeah. I read parts of it on an ongoing basis.

3. PAGE 200:04 TO 200:19 (RUNNING 00:00:59.000)

Q. And every time it comes out, you look at it and see what articles interest you?
A. Correct.
Q. Is one of the things you do is look for articles about safety issues?
A. Yes.
Q. And then you say you get reprints from medical journals. How does that happen?
A. Those come from different sources. Sometimes the government affairs representatives from pharmaceutical companies.
Q. Any other source where you get these reprints?
A. Just -- I'm not sure. I just happen on them, come across them.
Q. How do you happen to come across them?
A. Let's see. Just -- I just run across them.

4. PAGE 201:17 TO 201:19 (RUNNING 00:00:09.300)

Q. Any others?
A. Then CMS issues guidance every once in a while too.

5. PAGE 239:17 TO 239:19 (RUNNING 00:00:06.400)

Q. What you told me was you became aware of the lawsuit shortly after it was filed, correct?
A. Correct.

6. PAGE 243:21 TO 244:06 (RUNNING 00:00:49.000)

Q. How did you develop your understanding that

Zyprexa caused diabetes?
A. I don't remember where I got the knowledge originally. I know we did do a drug utilization review study on the atypicals and diabetes, diabetes drugs, and
00244:01 that was back in 2004. And then we did an intervention on that also.
Q. At the time you did the drug utilization review, did you have the understanding that Zyprexa caused diabetes?
A. Yes.

7. PAGE 244:22 TO 245:17 (RUNNING 00:01:10.000)

Q. You said you did an intervention on that. What was the intervention?
A. Well, we had pulled the drug utilization review profiles, and I mentioned that yesterday, I believe, how
00245:01 the profiles come out and give you the pharmacy claims and the medical claims.
And the drug utilization review committee had reviewed those and then we produced a letter that we were going to send to providers, to the prescribing providers about monitoring for the side effects of Zyprexa that could be associated with diabetes, the metabolic side effects.
Q. Did you actually create that letter?
A. Yes.
Q. Was it sent?
A. It was sent.
Q. When was that sent?
A. In the fall of 2004.
Q. Did that letter address only Zyprexa, or other medications?
A. That I don't remember.

8. PAGE 246:14 TO 246:16 (RUNNING 00:00:11.000)

Q. So it's fair to say that by the fall of 2004, you had come to the conclusion that Zyprexa caused diabetes?
A. I had information indicating that.

9. PAGE 246:25 TO 248:02 (RUNNING 00:02:01.000)

Q. When you received this information that Zyprexa
00247:01 causes diabetes, what did you do about it?
A. Developed a drug utilization review study about that.
Q. What conclusions, if any, did you draw from the drug utilization review?
A. That it appeared that a number of the people who were taking Zyprexa had diabetes and were taking diabetic drugs.
Q. Did you, through that drug utilization review study, conclude -- reach any conclusions about whether the number of Zyprexa users taking diabetes medication was higher than would be expected?
A. I don't remember.
Q. Did you take any other actions besides the DUR study, and I think you mentioned the letter, anything else?
A. That's all we have done up to that point.
Q. Up to what point?
A. Up to this point now based on the information that or that letter from the FDA, we're looking at another intervention.
Q. Did you take any action as a result of what you found out from the DUR study?
A. Well, as far as the action we had taken was just

doing the intervention, sending out a notice to the prescribers that watch out for these metabolic effects that could happen while patients are taking Zyprexa.

10. PAGE 248:05 TO 248:07 (RUNNING 00:00:07.100)

Q. Again, you don't remember sitting here today whether it was Zyprexa specific or a class specific?
A. Correct.

11. PAGE 249:10 TO 250:17 (RUNNING 00:01:30.300)

Q. So let me just make sure I understand that. One intervention is to look at Zyprexa?
A. Well, one study or one review is to look at Zyprexa and look at whether or not diabetes drugs are being used in those who are taking Zyprexa.
Q. So one intervention that you were talking about as a result of this letter is to do another drug utilization review?
A. Correct.
Q. And another intervention that you are considering is to send another communication to prescribers?
A. Well, the intervention would grow out of the drug utilization review.
Q. So you would do a drug utilization review and then after that is completed, you might or might not send a letter to prescribers?
A. Correct.
Q. Anything else, any action you are taking as a result of --
A. We may put a study or something else with that letter.
Q. I don't understand what that means.
A. Well, as far as a study that shows, if there is another one available, that shows where diabetes may be the result of taking the Zyprexa.
Q. Are you talking about a study that Alaska would perform?
A. That's a published study.
Q. Not based on Alaska data, but what else, what's out there in the national literature?
A. Right.
Q. But that action hasn't been taken?
A. That action has not been taken.

12. PAGE 272:09 TO 272:12 (RUNNING 00:00:15.000)

Q. Did you ever recommend filing a lawsuit against Eli Lilly based on what you had learned about the safety issues with Zyprexa?
A. Not that I remember.

13. PAGE 290:22 TO 291:10 (RUNNING 00:00:59.000)

Q. Is Kevin Walters the only Lilly employee who you have met with, who you have discussed Zyprexa with?
A. To my knowledge, he is the only one that I have discussed that with. I have met with another representative out of Salt Lake, and our discussions were on the CNS product rather than the Zyprexa.
Q. When was the first -- I mean estimate for me sort of the time period in which you have been interacting with Kevin Walters by years.
A. I believe 2003 is the first time I had met with Kevin Walters.
Q. Prior to 2003, you had not met with any Lilly representative about Zyprexa?
A. I don't recall.

14. PAGE 297:11 TO 298:02 (RUNNING 00:00:57.000)

Q. In your interactions with Mr. Walters, has he ever made any representations about the safety and efficacy of Zyprexa?
A. Not that I remember.
Q. You don't remember any representations of that kind from anybody else associated with Eli Lilly, correct?
A. Correct.
Q. Have you ever asked questions to Mr. Walters or anybody else at Eli Lilly about the safety or efficacy, clinical effectiveness of Zyprexa?
A. Not that I can remember.
Q. Is it your view that anybody from Eli Lilly has made misrepresentations to the State of Alaska, and I'm referring to people like yourself in the government,
00298:01 about the safety and efficacy of Zyprexa?
02 A. Please repeat the question.

15. PAGE 298:12 TO 298:15 (RUNNING 00:00:09.000)

Q. Has Eli Lilly ever made misrepresentations about the safety, efficacy, effectiveness of Zyprexa to the State of Alaska?
A. Not that I know of.

16. PAGE 300:03 TO 300:14 (RUNNING 00:00:43.100)

Q. As of March 2006, did you have anything that you would base your contention that the package insert was a misrepresentation of -- misrepresentation to the State of Alaska that Zyprexa was safe and effective?
A. No.
Q. You were not aware of anything that would support the contention that that was a misrepresentation?
A. Correct.
Q. Do you know whether it is accurate that Eli Lilly knowingly misrepresented to the State of Alaska that Zyprexa was safe and effective?
A. I don't know.

17. PAGE 304:10 TO 304:18 (RUNNING 00:00:27.000)

Q. Alaska covers it. Okay. And you have told me that your understanding is that the package insert did not accurately represent the safety of Zyprexa, correct?
A. Correct.
Q. And you have felt that way for some period of time, correct?
A. Correct.
Q. At least since 2004, correct?
A. Correct.

18. PAGE 307:03 TO 307:11 (RUNNING 00:00:32.300)

me ask you this question: Do you know whether Zyprexa users in Alaska have developed diabetes at a greater rate than other Alaska Medicaid recipients?
A. I don't know.
Q. Do you know whether Alaska Medicaid recipients who use Zyprexa have developed diabetes at a greater rate than Alaska Medicaid recipients that use other psychotic medications?
A. I don't know that.

19. PAGE 332:05 TO 333:14 (RUNNING 00:02:27.000)

(Exhibits No. 16 and No. 17 marked.)

Q. Mr. Campana, do you recognize the two documents I have marked as Exhibits No. 16 and No. 17?
A. Yes, I do.
Q. What are they?
A. They are letters to the drug utilization review committee.
Q. Who is the drug utilization review committee comprised of?
A. It's a committee of pharmacists and physicians who are providers to the Medicaid program and sign up for a three-year term as a volunteer on the committee.
Q. Each of the letters to the committee has an attachment of meeting minutes, do you see that?
A. Yes.
Q. And it lists who was present at the meeting?
A. Yes.
Q. The first Exhibit No. 16, which has a November 2nd, 2004 letter, has meeting minutes for October 22, 2004 and it has a list of individuals present and excused. Do you see that?
00333:01 A. Yes.
Q. Is that list of names, if you include both present and excused, are those all the members of the DUR committee as of that time?
A. I believe that is.
Q. And of the individuals on the committee, and I think the list would be the same for the October 22nd meeting as the November 19th, are any of those committee members psychiatrists?
A. Yes. Alex von Hafften is a psychiatrist.
Q. And would you agree that these meeting minutes reflect some discussion and presentations regarding the issue of mental health medications and metabolic issues?
A. Yes.

20. PAGE 334:08 TO 334:18 (RUNNING 00:00:44.800)

Q. These are obviously two meetings pretty close in time, late 2004. Have there been any DUR committee meetings where -- in the last few months or anything where the issue of anti-psychotic medications and metabolic disorders have been discussed?
A. I don't know. I don't remember.
Q. Is it accurate to say that one of the things these meeting minutes report is that reports were run on anti-psychotic drug users to see whether they were also being treated for diabetes?
A. That's correct.

21. PAGE 334:25 TO 340:24 (RUNNING 00:09:59.400)

Q. Mr. Campana, is it the case that you had reports
00335:01 run that showed diabetic medication use among anti-psychotic users?
A. That's my understanding of what we did here.
Q. And what precipitated the committee reviewing this issue and running these reports at this time in late 2004?
A. I don't remember exactly, although we do get a list of items that we can run in our drug utilization review, and it may have been an item that came up in the criteria set that we could run.
Q. You always could run it, but you don't always run it, do you?
A. Well, we run based on what comes up in the criteria set. As far as what I remember, we did determine that it would be a good idea to go ahead and run the mental health drugs and look for diabetic use or

the diabetic issues coming up for mental health drugs.
Q. You don't know where that good idea came from?
A. I don't remember exactly where that came from.
Q. After this time, after this late fall 2004 period, has that report been run again by the state?
A. I don't remember us running that exact type of report again.
Q. Why not?
A. I don't remember.
Q. You didn't think it was important to run?
A. Well, I can't say I didn't think it was important to run. It's just that other issues came up and other issues took precedence over that.
Q. So you concluded sometime in the fall of 2004 that there was an issue of Zyprexa and diabetes, correct?
A. Correct.
Q. You had drug utilization reviews where that topic was focused on?
A. Correct.
Q. You ran your claims data to find out are we seeing some of this, right?
A. Right.
Q. And then just stopped?
A. Well, we did the intervention letters on that and then that continued into the next month, and sent out notice to the providers about that.
Q. But you never checked again to see if there was a problem?
A. We never ran that criteria again.
Q. At the drug review -- drug utilization review meeting on October 22nd, did Mr. von Hafften make a presentation about the issue of mental health diseases, mental health treatments and metabolic disorders?
A. Dr. von Hafften had made a presentation as noted in the minutes.
Q. And what did you understand Dr. von Hafften to be communicating?
A. Communicating about the risk of diabetes and metabolic disorders in conjunction with the ingestion of the psychotropic drugs.
Q. Did he say that there was a greater risk of metabolic disorders for those taking atypical anti-psychotics?
A. Yes, he did.
Q. Is that reflected here anywhere?
A. He also gave us a table, and that's a bad copy of it at the back of this.
And he had listed out the anti-psychotic medications and the chance for diabetes with different medications.
Q. You are referring to the page that's Bates-stamped 3351?
A. Correct.
Q. Who prepared these meeting minutes?
A. I prepared the minutes.
Q. Did you try and record everything important that Dr. von Hafften said?
A. I tried to record as much as I could while running the meeting and taking notes from the meeting.
Q. I don't see anywhere in this -- would you agree that paragraph four is your description of what Dr. von Hafften presented?
A. Yes.
Q. And I don't see anywhere in this paragraph where you record that he stated that the atypicals increased

the risk of metabolic disorders or caused metabolic disorders.
A. Well, actually in four, as I read it, he did make presentation on the mental health disease process and the effect on metabolic disorders, as indicated in the month's profiles.
Q. When we're talking that that's a reference to the mental health disease process, it doesn't refer to mental health treatments, correct?
A. That's the mental health disease process.
Q. Do you remember, did Dr. von Hafften talk about the fact that individuals with severe mental health illnesses are more prone to obesity and diabetes than the general population? Do you remember him talking about that?
A. I do remember that.
Q. If you look at that chart you are referring to on 3351, and I agree it's hard to read, this is basically
00339:01 how we received it, there is a heading that says "Medical Disorders". And it's hard to read, but it says "obesity" and then something else. Can you tell --
A. Looks like metabolic disorders, obesity, hypertension, HTN, and dyslipidemia.
Q. And so there you have -- and then the numbers there run 22 percent in the community, 31 percent psychiatric, right?
A. Right.
Q. Then it says "prior to atypical"?
A. Right.
Q. And then there is -- next it says, "General class," and it says 31 percent typical, and then it looks like, "50 percent," question mark and it's hard to read.
It says "60," but I don't know what else it says there for atypicals.
A. Yeah. I can't read that either.
Q. That's not actually for diabetes, right? That's for other sort of obesity, dyslipidemia, right?
A. Right. Diabetes is just under that.
Q. Right. That says for the community 1 to 6 percent, psychiatric 10 to 15 percent?
A. 10 to 13 percent.
Q. And then for the class it doesn't have anything,
00340:01 right?
A. That's correct.
Q. And then you have some handwriting at the bottom of the document. Is that your handwriting?
A. Yes, it is.
Q. It says, "These problems should be expected"?
A. Correct.
Q. Then below that, "Clear problem not warrant D/S meds"; is that right?
A. No. "Clear problem does not warrant discontinuing medicine." An acronym for discontinuing is D/C.
Q. So those are your notes based on what you were hearing from Dr. von Hafften?
A. That was correct.
Q. What do those notes mean?
A. The notes mean that it was his opinion that while this may be a problem about the psychotropic medication, that in his opinion it didn't warrant discontinuing those medications.
Q. When you are talking about discontinuing, was he talking about discontinuing reimbursement or was he talking about discontinuing patients on these drugs?

24 A. Discontinuing the drugs in the patients.

22. PAGE 345:22 TO 346:03 (RUNNING 00:00:25.800)

22 Q. When you came to the conclusion that Zyprexa had
23 the safety issues we have discussed, did you communicate
24 in any written form to anybody else in the department?
25 A. No, I didn't.
00346:01 Q. Did you talk with anybody else in the department
02 about the safety issues that you had determined?
03 A. I don't remember.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:26:09.800)

0_P1428

Curtiss, Lucy (Vol. 01) - 12/13/1997

1 CLIP (RUNNING 00:30:17.933)

Lilly Initial - Continuous

LC-INITIAL — 18 SEGMENTS (RUNNING 00:30:17.933)

1. PAGE 5:13 TO 5:17 (RUNNING 00:00:10.000)

Q. (BY MR. ROGOFF) Good morning, Dr. Curtiss. You heard my name is Andrew Rogoff. I represent Eli Lilly & Company in a lawsuit brought by the State of Alaska against the company.

2. PAGE 7:08 TO 8:19 (RUNNING 00:01:31.800)

Q. Dr. Curtiss, you're a psychiatrist?
A. Yes, I am.
Q. How long have you been practicing psychiatry?
A. I completed my residency in 1995.
Q. Where did you go to medical school?
A. I went to the University of Washington School of Medicine. I graduated from there in 1991. I stayed at the University of Washington for my residency, which I completed in 1995.
Q. Was your residency in psychiatry?
A. Yes.
Q. Are you board-certified?
A. Yes, I am.
Q. Did you engage -- did your residency involve any subspecialization?
A. Not formally. I informally focused on community psychiatry and geriatric psychiatry.
Q. Were those particular interests of yours?
A. Yes.
Q. Have you continued to focus on them in your practice?
A. Yes.
Q. When did you become board certified?
A. In January, 1997, I believe. It was the first opportunity.
Q. You're licensed in Alaska?
A. Yes, I am.
Q. Anywhere else?
A. I had a license in Washington during my training.
Q. Do you have to be recertified in Alaska?
A. Yes. The certification is a national, and it's every ten years. I was recertified last summer. And so my board certification expires the end of 2016.

3. PAGE 9:01 TO 13:02 (RUNNING 00:04:43.900)

Q. Where did you go to work after you completed your residency in 1995?
A. I've been here the whole time.
Q. What's here?
A. Anchorage Community Mental Health Services.
Q. Could you describe what Anchorage Community Mental Health Services does?

A. Anchorage Community Mental Health Services is a private nonprofit organization which is the largest community mental health provider in the state of Alaska. We provide services for people throughout the lifespan from toddlers to seniors. We work with people that have a range of diagnoses, but we tend to work with the people that have the most severe illness. At this time, in our adult programs, our referrals preferentially come from hospitals, psychiatric hospitals, emergency rooms, Department of Corrections. I also do psychiatric consultation for the two nursing homes in town.

Q. The description of the patient population that you gave outside of what you do in nursing homes was for the center itself or for you?

00010:01 A. For the center itself. That we work with children -- the children that we see are severely emotionally disturbed; so these are children that have been either removed from parental custody or at risk for removal due to the severity of their behavior problems.

The adults that we work with are people that have severe, persistent mental illness which has a federal definition that involves essentially anyone who has functional impairment persistently related to problems with their brain or their behavior. So it could be classic mental illness, schizophrenia, bipolar disorder. It can also be chemical dependence. We see a lot of people that have comorbid addictions, people with brain injuries, people that are developmentally disabled who have behavioral problems as a result of -- as a result of that.

We work with a lot of medically frail people, people with personality disorders.

Q. How would you characterize the population that you treat personally?

A. All of the adults that I just listed.

Q. No children?

00011:01 A. I do not work with children.

Q. You work with geriatric patients?

A. I do.

Q. What percentage of your patient population do you think is geriatric?

A. It has varied over time. At this point, 20 percent. That's an estimate.

Q. And the remainder of your patients are adults?

A. Yes.

Q. Before geriatric?

A. Before geriatric.

Q. Within the geriatric population, is there a low percentage of schizophrenia and bipolar disorder or a lower percentage than you find in the adults?

A. It depends on the setting that -- a lot of the referrals that we get for geriatrics have to do with behavioral signs and symptoms associated with dementia, and so the relative number of people that have primary mental illnesses is lower because of that. But we certainly have people that have aged through our system and are now seniors.

Q. Would you characterize the presenior adults as seriously mentally ill?
A. Severely persistently mentally ill which is its own -- it has its own definition.
Q. Legal definition?
A. Yes.
Q. And would you -- how would -- what percentage of the presenior adult population that you see would you characterize as suffering from either schizophrenia or bipolar disorder?
A. You're counting schizoaffective disorder in there as well?
Q. Yes.
A. Probably a majority.
Q. Or one or the other or both?
A. As -- as -- most of the people that come to our services have multiple diagnoses. That people don't come here unless they have failed less restrictive or less comprehensive treatment programs. You have to be very impaired to qualify for services at -- at this agency.
And so probably a majority of the people in my caseload do have a diagnosis of schizophrenia, bipolar disorder or shizoaffective disorder.
Q. Are all of your patients treated on an outpatient basis?
A. Yes.

4. PAGE 13:05 TO 18:11 (RUNNING 00:06:22.000)

Q. You said you go to two nursing homes?
A. I do.
Q. Do you practice anywhere besides the two nursing homes and the community mental health center?
A. I have a small private practice.
Q. What is the patient population of that practice?
A. The diagnoses of the people that I see are more mood and anxiety disorders.
Q. What percentage of the patients do you see in your -- break it down three ways, the private practice, the geriatric -- the nursing homes, and the mental health center?
A. Right. What percentage --
Q. Can you break it down by -- if they all added up to 100 percent, what percent of your patients do you treat here at the mental health center? What percentage do you treat at the geriatric facilities? And what percentage are in your small private practice?
A. The vast majority are here. I see a handful of patients, very small number in my private practice. And at the nursing home it's consultation. So I don't have a caseload that I consistently see. I see whoever the primary care providers ask me to see on any given visit.
Q. You're working full time?
A. Yes.
Q. Have you worked full time here since you came to the community mental health center?
A. Yes.
Q. Does this mental health center have a formulary of medications?
A. No, we do not.
Q. What percentage of your patients here

and in your private practice are Medicaid eligible?
A. No one in my private practice has Medicaid. Here, the statistics have changed over time. We are seeing fewer and fewer Medicaid-eligible patients. At this point -- I'd have to think about the breakdown. We've got -- maybe 40 percent of our patients are dual eligibles so they've got primary Medicare, secondary Medicaid; they don't use the Medicaid formulary.
25 percent are primary Medicaid here?
Q. Why are you seeing fewer Medicaid patients than previously?
A. Because the people that we are getting are sicker. They are more likely to have comorbid addictions; and less likely, as a result of their addictions, to qualify for entitlements. That if -- Social Security has gotten much harder to get over the years. It used to be that you could come in, you could apply for your benefits and within a year you would have Social Security and Medicaid. Now people can come in, it can take years, if they ever qualify at all. And my experience has been that anyone who has any sort of history of substance use, they don't get benefits, period.
Q. Do you know why?
A. Well, you would have to look into federal regulations that it's their fault that they're ill.
Q. And how do those individuals pay for their care?
A. We pay for it. We have grant -- grant dollars that we get from various sources. We have a grant from the State of Alaska. We also have a number of federal grants and Mental Health Trust Authority grants that help to offset some of the costs of providing care for unresourced patients.
Q. Does the center here have any restrictions or place any restrictions on what you may prescribe for your patients?
A. No.
Q. Do you, in your practice, use anti-psychotic medications?
A. Yes.
Q. Which ones do you use?
A. I use all of the atypicals, and some of the traditional anti-psychotics.
Q. Which of the traditional anti-psychotics do you use?
A. I use Haldol, Haldol Decanoate, Prolixin, Prolixin Decanoate and perphenazine. And occasionally some chlorpromazine.
Q. What kinds of -- we'll come back to that.
Do the psychiatrists in this community mental health center ever meet as a group?
A. Yes, we do.
Q. Do you discuss your cases?
A. Yes, we do.
Q. Why else do you meet?
A. We meet for administrative purposes.

Q. What does that mean?
A. That we have a medical team. We have at this point three psychiatrists and three advanced nurse practitioners. I am the medical director; so I'm also half-time administrative.
We meet on a weekly basis to talk about issues relating to the care of our patients, agency, news. We are -- the way that our center is organized, we are not -- we are a team; the nurses are a team; and each of us works with different clinical teams that specialize in people that may be homeless, people that may be coming out of Corrections, people that live in a certain part of town. So we each spend time with different teams.
Q. How long have you been medical director?
A. For --
THE WITNESS: How long has it been?
A. Since May, '04, I believe.
Q. (BY MR. ROGOFF) What are your responsibilities as medical director?
A. I have responsibility for the medical staff. I do the hiring, the firing. I set the standards. I write the budget. I maintain the budget. I am the lead clinician for the agency; so if there is an issue of a dispute about what ultimately can we or can we not do, I have the final say on that. I work with the directors of the different parts of the agency in determining what are our standards of care.

5. PAGE 24:20 TO 26:03 (RUNNING 00:01:33.000)

Q. What do you prescribe perphenazine for?
A. Psychosis. Occasionally, for -- now, this was in my training -- that was the primary anti-psychotic that we used in our training. And so there would be times that we would also use it for intense anxiety, for emotional flooding, we call it. People that have histories of trauma sometimes emotionally flood and cannot think. You work on getting people out of that state of mind to where they can think.
Q. Were there any second-generation anti-psychotics available to you during your training when you were using perphenazine?
A. Risperdal came out in 1994; that was toward the end of my training. That was the last year of my training that it became available.
Q. Do you prescribe as much perphenazine now as you did when you were in your training?
A. I do not.
Q. Why?
A. The older anti-psychotics have greater risk of extrapyramidal symptoms and may have greater risk of tardive dyskinesia, and oftentimes require use of a side effect medication an anticholinergic.
Q. But, given all those risks, you nevertheless prescribe perphenazine in certain circumstances?
A. Yes, I do.
Q. And why is that?
A. It typically is a matter of patient preference. Patients have been on medications for a long period of time. They know what works; they know what they trust.

6. PAGE 26:10 TO 27:10 (RUNNING 00:01:11.000)

Q. For new patients who have not used perphenazine and therefore wouldn't have a preference for it, do you, nevertheless, from time to time prescribe perphenazine for such patients?
A. At times.
Q. And what are the factors you consider in those cases?
A. The patients that come here, it is very rare that I would see a patient who has -- is treatment naive. That, by definition, the people that we take are people that are coming out of other treatment facilities, and generally have been started on an agent. And so I'm not the first one that is prescribing for somebody. They typically have experience with treatment.
00027:01 And so often people will have come here after having failed other treatments.
Q. For a treatment-naive patient, have you used perphenazine?
A. Not since my residency, no.
Q. Why is that?
A. Well, first, I don't see very many treatment-naive patients. But in terms of options that are available, I do preferentially use the newer anti-psychotics.

7. PAGE 28:20 TO 29:25 (RUNNING 00:01:32.000)

Q. Dr. Curtiss, are you ever involved in treating patients who are involuntarily committed?
A. Yes, I am.
Q. Where do you treat them?
A. I treat them here as outpatients. We do
00029:01 get patients who are on -- it's called an early release. It is an outpatient commitment that -- it starts as an inpatient commitment, and then patients can agree that they will adhere to treatment recommendations specified in the early release. We as an agency would accept responsibility for their care. And if they don't follow through with what they've agreed to, then -- well, then, it's our responsibility to seek rehospitalization. So, yes, I have treated patients like that.
Q. Are those patients coming out from API?
A. Yes.
Q. Are any --
A. There -- I'm sorry, there are also patients who are in court-ordered treatment who as conditions of their parole or probation are mandated to -- to follow treatment recommendations, in which case I would recommend to someone this is -- this is what I think you should do; if you disagree, go to your P.O. about it. That's involuntary. Coercive.
Q. The folks who are coming out of API, are any of them, when you receive them, on Zyprexa?
A. Some.

8. PAGE 33:07 TO 34:20 (RUNNING 00:02:12.000)

Q. (BY MR. ROGOFF) What are the side effects of Zyprexa with which -- of which you are aware?

A. The common side effects -- you know, I'm not going to speak to every side effect I've ever seen in every patient; that's not possible. The most common side effects are weight gain, sedation, elevated blood sugar, elevated lipids.
Q. Do you see those side effects in other second-generation anti-psychotics?
A. Yes. The frequency with which I observe it varies from agent to agent.
Q. Does it also vary from patient to patient?
A. Absolutely.
Q. You'd said earlier, Dr. Curtiss, that you prescribe all the second-generation anti-psychotics, as well as several of the typical anti-psychotics. Are you able to
00034:01 articulate a percentage, first of all, from second-generation versus first generation?
A. I would say the majority is second-generation. Beyond that, no.
Q. Can't break it down among the second-generation anti-psychotics?
A. I use all of them.
Q. Has your use of them varied over the years? And I'm talking about the atypicals.
A. Yes.
Q. For what reasons has your usage varied?
A. Availability. And they weren't all available at the same time. My experience and comfort in prescribing them. It takes probably a couple of years to really have a good feel for an agent and how to use it, when to use it, who is most likely to benefit from it. Side effect profiles. All of the concerns about metabolic effects, definitely we think more about that now than we did in the past.

9. PAGE 35:13 TO 36:23 (RUNNING 00:01:41.000)

Q. But -- I'm not asking you whether you've memorized the labels. But do you read the labels when you use medication for the first time?
A. Generally.
Q. What else do you do to familiarize yourself with new medications?
A. I tend to be a bit of a late-adopter. That -- I read about a medication. I talk with my colleagues. I hear about what their experiences have been. I talk with patients about options. I'm very straightforward with my patients about "I don't have experience with this agent yet." There are particular patients that
00036:01 they want the newest treatment the moment it becomes available, and so they're typically the first to try them. But I am more likely to hang back and see what my colleagues experience before I jump in with a medication.
Q. You also read the literature?
A. Yes.
Q. Are there publications that you regularly read in your practice?
A. There is not any publication that I regularly read. There's the Green Journal; there is Journal of Clinical Psychiatry. I get this much mail every week (indicating). I pick and choose.
Q. Do you typically read articles about

medications that you -- that are available to you to use with your patients?
A. I don't know how to answer that question. Again, I get reams and reams of material. I read some of it. I read when a particular question comes up. I read when I'm considering treatment options for a particular patient.

10. PAGE 37:06 TO 38:05 (RUNNING 00:00:57.100)

Q. Before you use a medication for the first time, do you do any research on it? Other than talking to your colleagues and --
A. Reading journal articles and reading the package insert, and I'm not sure what else you would be --
Q. Well, do you -- do you meet with pharmaceutical company sales representatives?
A. I do.
Q. Do you meet with reps from Lilly?
A. I do.
Q. And have you met with reps from other companies?
A. Yes, I do.
Q. Do you know how often you meet with them?
A. Probably each company sends a rep every couple of months.
Q. Do you meet with the reps when they come?
00038:01 A. I have -- I have over time changed my practice. I used to have a 30-minute block every other week in which reps could schedule up to 15 minutes. I am less -- much less available now. It's if they catch me between patients.

11. PAGE 39:02 TO 40:14 (RUNNING 00:01:35.400)

Q. To what extent do you rely on sales representatives for information about medications that you prescribe to your patients?
A. It's a small, small percentage.
Q. Why is that?
A. Because I assume that they are in the business of sales and that they will tell me good things about their product.
Q. And so you're skeptical of sales reps?
A. Yes.
Q. Has that always been the case?
A. Yes.
Q. When you've met with sales reps from various companies, do they take -- have they taken notes while talking to you?
A. Not often.
Q. Now, since you became medical director, can you characterize how many minutes a week or month that you would spend with a sales rep?
A. Probably less than -- less than 30 minutes a month for all reps.
Q. How many companies are you visited by?
A. Several.
Q. Are you visited by AstraZeneca?
00040:01 A. Uh-huh.
Q. That's "yes"?
A. Yes.
Q. Johnson & Johnson?
A. I don't think so.

Q. Janssen?
A. I'm sorry?
Q. Janssen?
A. Yes.
Q. Are you visited by reps from GlaxoSmithKline?
A. Yes.
Q. Wyeth?
A. Yes.

12. PAGE 40:19 TO 40:20 (RUNNING 00:00:03.833)

Q. How about Pfizer?
A. Yes.

13. PAGE 40:21 TO 41:02 (RUNNING 00:00:27.400)

Q. When you've met with sales reps from various companies, do they oftentimes talk to you about their competitors' products?
A. I discourage that.
Q. Why?
A. Again, it is negative and it's not an effective sales technique with me.

14. PAGE 42:18 TO 42:22 (RUNNING 00:00:19.000)

Q. Dr. Curtiss, you said earlier that the side effects of Zyprexa that have concerned you included weight gain and metabolic blood sugar issues and lipids. Was there anything else?
A. Sedation. Dizziness. Sure.

15. PAGE 42:23 TO 45:15 (RUNNING 00:03:31.000)

Q. How does your knowledge of those potential side effects affect your prescription habits?
A. I talk with patients and my -- my practice is that it is a collaboration. I am not particularly directive in my approach. That my philosophy is that it's about the relationship. That it's my job to try to understand my patient, who they are, what they value, what they want, and what's acceptable to them in terms of treatment. And does the treatment that I am providing help them meet their goals. I tell people that any negotiation, any result of that has to be acceptable to both of us, and that ultimately it is the patient's life, the patient's body, and they should not agree to anything that they're not prepared to -- to accept.
Q. So in each case you're making an -- you and the patient are collaboratively making an individualized judgment?
A. Most of the time. I would say the -- the exception to that is when someone is grossly psychotic or very, very demented, in which case I am less likely to talk in that detail about treatment options, potential side effects; or if someone is extremely paranoid that I tend to tailor my information where I focus more on the relationship than about immediate risks of the medication until that person has reached a degree of health where they can say, "Yeah, I feel better now."
Q. You learned in medical school that excess weight was a risk factor for diabetes?

A. I don't know where I learned that.
Q. You've known it your entire practice?
A. Yes.
Q. And, nevertheless, with the risk of weight gain and blood sugar issues with Zyprexa, you prescribe the medication?
A. Yes, I do.
Q. Why is that?
A. There are patients for whom it is the only thing that works.
Q. Are there other reasons?
A. If it works and the patient understands the potential risks and wants the treatment, I prescribe it.
Q. So then to go back to a confusing question I asked a long time ago --
A. Yes.
Q. -- which relates, really, to individual prescribing decisions, is it really possible to say that -- as a blanket matter, that any anti-psychotic medication is equally efficacious with any other anti-psychotic medications?
A. They're all different. And you don't necessarily know what will work for any given patient. You focus on desired side effects and risks. All things being equal, I preferentially will choose one of the agents with less risk for metabolic abnormalities. Ziprasidone and aripiprazole. However, their side effect profiles aren't always ideal.
Q. Is there an anti-psychotic medication that has no side effects?
A. There is no medication that has no side effects.

16. PAGE 47:14 TO 47:17 (RUNNING 00:00:12.000)

Q. How many of your severely, persistently mentally ill patients are using psychiatric medications?
A. The majority.

17. PAGE 48:01 TO 48:17 (RUNNING 00:00:53.500)

Q. For those who are taking anti-psychotic medications, do you regularly monitor any of their -- their blood levels -- the glucose levels?
A. I try to.
Q. How long have you been doing that for your patients?
A. Oh, it's been a few years.
Q. Do you know how long?
A. I don't know exactly when I started.
Q. For which patients do you test glucose levels?
A. I check for anyone who is on -- well, I try to get all my patients to have at least yearly physical health care. For people that are on anti-psychotics, I try, all of them, to get them to do it.

18. PAGE 49:05 TO 50:13 (RUNNING 00:01:22.000)

Q. Dr. Curtiss, do you know whether you have in your possession any promotional or marketing materials from my pharmaceutical company?

0_P1428

A. In my personal possession or in the clinic?
Q. In your office.
A. I try to throw it all away. There probably is something in there that I haven't thrown away.
Q. But you can't identify it as you sit here; is that right?
A. If I went and looked, I could find things, but, no, I don't hang on to materials from drug companies.
Q. And I may have asked this before, and I apologize if I did, but do you recall receiving any written communications from any arm of the State of Alaska regarding anti-psychotic medications?
A. I don't know.
00050:01 Q. Nothing comes to mind?
A. Nothing specifically, no.
Q. Doctor, thank you. I have no more questions.
A. I do have one more comment on that last question, though.
Q. Okay. I'm sorry.
A. That the Drug Utilization Review Committee is another pharmacy committee that is part of the State. And so I have received communications from them. And I receive communications from the P & T in my role on that committee.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:30:17.933)

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-06-5630 CI **MEMORANDUM REGARDING PROPOSED JURY INSTRUCTIONS**

The Court granted summary judgment concerning the State's UTPCPA claims related to alleged illegal promotional activity of Lilly, which includes the allegations that Lilly's sales representatives delivered improper messages such as the use of a "comparable rates" message, to physicians regarding Zyprexa's safety. Despite the Court's ruling, the State has insisted that these claims are still alive and well—and now the Court appears to have changed its mind regarding its summary judgment ruling to endorse the State's position. Lilly maintains that the federal regulatory framework and logic that the Court applied in dismissing the State's off-label UTPCPA claims require that *all* UTPCPA claims premised on marketing activity of Lilly be dismissed.

However, if the Court considers that the State has viable claims based on marketing activity, Lilly needs clarification before it submits jury instructions as to precisely what the State claims is a violation of the UTPCPA and precisely which of these claims still remain at issue in this case.

Lilly also submits this short memorandum to explain its instructions concerning weight gain.

A. Lilly Understood the Court's Ruling on Summary Judgment To Have Excluded All of the State's Promotion-Based UTPCPA Claims

That *all* claims based on the State's promotional claims are dismissed is consistent with how the State has presented its claims, with how Lilly asked the Court to rule on its summary judgment motion, and with how the Court *did* rule. The State's plain attempt to bootstrap its safety related promotional claims to its labeling-related UTPCPA claims is baseless—the nature of Lilly's alleged conduct is, in fact, and always has been, promotionally related.

When Lilly submitted its supplemental brief seeking dismissal of the State's claims pursuant to the UTPCPA exemption, it sought dismissal of *all* claims related to Lilly's promotional activity, including "Lilly's alleged efforts to downplay Zyprexa's risks of weight gain and diabetes . . . ."[1] Neither party ever argued that the exemption applied differently to allegedly improper promotional activity relating to safety than to alleged off-label promotion. In its ruling from the bench, the Court stated that "the unfair acts and practices at issue are both regulated elsewhere by the federal government and that the unfair acts and practices promoting off-label uses and advertising improperly are prohibited."[2] The Court's clarifying comments, moreover, confirmed that all promotional-based UTPA claims were dismissed by the summary judgment ruling, noting that the State's only remaining claims were the "common-law warning claims" and "the UTPA . . . based on evidence of the product labels."[3]

---

[1] Def.'s Supp. Br. Seeking Dismissal of the State's Claims Pursuant to the UTPCPA Exemption and Federal Preemption 9, Feb. 5, 2008.

[2] Hr'g Tr. 9:9 to 9:12, Feb. 27, 2008.

[3] Hr'g Tr. 13:19 to 14:2, Feb. 28, 2008.

Nor would it make sense to divide Lilly's alleged promotional activity, as the State advocates, into off-label promotional activity and safety related promotional activity. The Court explained several times during its ruling on summary judgment that it was dismissing the State's UTPCPA promotional claims because improper advertising, including visits by sales representatives, is regulated and prohibited by the federal government.[4] The **same** regulatory prohibition that prohibits promotion for non-indicated uses[5] applies to misleading safety information. A pharmaceutical company violates Section 502(n) of the FDCA if it:

- "Advertises conditions of drug use that are not approved or permitted in the drug package label;"[6]

or

- "Makes representations not approved for use in the labeling, that the drug is safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience."[7]

Not only do the regulations prohibit misleading safety promotion in the **same way** as promotion for non-indicated uses, but misleading safety promotion can actually be a form of off-label promotion.[8] Accordingly, the rationale that the Court used to grant partial summary judgment—"the acts or practices at issue are both regulated elsewhere . . . and advertising improperly [is] prohibited,"[9]—requires the same conclusion concerning safety related promotional activities

---

[4] *See id.* at 9:3 to 9:12; 16:7 to 16:9.

[5] 21 C.F.R. § 202.1(e)(6).

[6] *Id.* § 202.1(e)(6)(xi).

[7] *Id.* § 202.1(e)(6)(i).

[8] *See id.* (prohibiting "representations not approved for use in the labeling, that the drug is safer . . . .").

[9] Hr'g Tr. 9:8 to 9:12, Feb. 27, 2008.

(e.g., claims based on sales representatives alleged use of a "comparable rates" message) as it does for off-label advertising.

Application of the Court's decision to all claims based on allegedly false promotional activity is also consistent with *Pennsylvania Employees Benefit Trust Fund v. Zeneca*,[10] which the Court relied upon in its decision.[11] In *Zeneca*, the Third Circuit dismissed the plaintiff's state consumer fraud claims, based on advertising materials related to safety and efficacy of the medication at issue, because of the "high level of specificity in federal law and regulations with respect to prescription drug advertising . . . ."[12] In *Zeneca,* the Court invoked regulations relating to advertising about safety and efficacy, because there was no off-label component to the plaintiff's claim.[13] The federal regulations, the *Zeneca* decision, and the Court's rationale all apply across the board to all marketing, promotion, and advertising claims, not just off-label promotion.

To now deny the dismissal of the State's safety related promotional UTPCPA claims after having granting summary judgment would deny Lilly its constitutional right to due process. Lilly prepared its affirmative case, prepared its cross-examination material, and presented its defense in reliance on the Court's ruling that all promotional-based UTPCPA claims were dismissed. Lilly's evidence dealt with the adequacy of Zyprexa's labeling, the scientifically knowable risks of Zyprexa, and Lilly's cooperation with the FDA concerning

---

[10] *Id* at 8:21 to 9:17 499 F.3d 239 (3d Cir. 2007).

[11] Hr'g Tr. 8:21 to 9:17, Feb. 27, 2008.

[12] 499 F.3d 239, 242, 252 (3d Cir. 2007); *see also Bober v. Glaxco Wellcome PLC*, 246 F.3d 934, 942 (7th Cir. 2001) ("recognizing primacy of federal law in this field, the Illinois Statute itself protects companies from liability if their actions are authorized by federal law").

[13] *See, e.g.,* 499 F.3d at 248-49.

Zyprexa's potential risks. Because Lilly has not been given proper notice after the Court's ruling on summary judgment that certain of the State's promotional-based UTPA claims are again viable, Lilly has been deprived of its constitutional right to a meaningful opportunity to present a full defense to the State's claims.[14] The Court, therefore, should issue an Order dismissing all of the State's non-labeling UTPCPA claims.

If the Court determines that some or all of the State's safety related promotional UTPCPA claims may remain at issue, before Lilly can submit to the Court proposed jury instructions on such claims, Lilly requests that the Court (1) order the State to define precisely what it claims are the remaining UTPCPA violation, and (2) rule as to which of these purported violations will be submitted to the jury. As per *Anchorage Nissan*, Lilly would expect that the jury be instructed as to exactly which conduct the State alleges constituted UTPCPA violations.

B. The State's Labeling Claims Are Confined to Zyprexa's Risk of Weight Gain

Although the State has alleged that Zyprexa causes diabetes, hyperlipidemia, and weight gain, the only proof that the State has offered is that Zyprexa causes weight gain, which, in turn, induces the other conditions. The State's experts all testified that diabetes and hyperlipidemia are consequences of the weight gain that Zyprexa causes.[15] Indeed, the State's experts confirmed that this association is fundamental medical knowledge taught to every medical student.[16] Because it is undisputed that all physicians are aware of the sequellae of

---

[14] *See Philip Morris USA v. Williams*, 127 S. Ct. 1057, 1063 (2007) (noting that due process guarantees that a party may put forth all of its defenses); *see also Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 429 (1981); *Johnson v. Celotex Corp.*, 899 F.2d 1281, 1284-85 (2d Cir. 1990); *Windham v. Am. Brands, Inc.*, 565 F.2d 59, 71 (4th Cir. 1977).

[15] Vol. 4, Hr'g Tr. 223-26, 228-29 (Dr. Brancati); Vol. 10, Hr'g Tr. 111, 162-63 (Dr. Wirshing).

[16] Vol. 4, Hr'g Tr. 185-86 (Dr. Brancati); Vol. 10, Hr'g Tr. 161-62 (Dr. Wirshing).

weight gain, Lilly has no duty under state law to warn about diabetes and hyperlipidemia.[17] Lilly's only duty was to warn physicians about weight gain, and Lilly has tailored its proposed jury instructions accordingly.

DATED this 21st day of March, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac* vice
George A. Lehner, admitted *pro hac* vice
John F. Brenner, admitted *pro hac vice*
3000 Two Logan Square
Philadelphia, PA 19103-2799
(215) 981-4618

LANE POWELL LLC

By: _____
Brewster H. Jamieson,
ASBA No. 8411122
Andrea E. Girolamo-Welp,
ASBA No. 0211044

[17] *See, e.g., In re: Meridia Prod. Liab. Litig.*, 447 F.3d 861, 866 (6th Cir. 2006) (affirming, in case involving pharmaceutical manufacturer's alleged failure to warn about cardiovascular and cerebrovascular sequellae of increased blood pressure, label containing specific warning of increased blood pressure was adequate because "physicians are well aware of the scope of the risks associated with increased blood pressures and do not need specifics regarding the possible consequences of blood pressure increases.").

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 OPPOSITION TO BLOOMBERG, LLC D/B/A/ BLOOMBERG NEWS' MOTION TO INTERVENE AND TO UNSEAL RECORDS

Bloomberg's Motion to Intervene and to Unseal Records should be denied because summarily vacating the protective order without an analysis of the individual documents would be an extreme measure unsupported by case law. The Court should maintain the confidentiality of all documents filed under seal that have not been admitted into evidence.

I. INTRODUCTION

"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," this Court entered a Protective Order on July 31, 2007, pursuant to Rule 26(c) of the Alaska Rules of Civil Procedure.[1] By its terms, this Order extended to all "information that the producing party in good faith believes is properly protected under Alaska Rule of Civil Procedure 26(c)(7); under any Federal or state statutes, regulations or court rules; or under Federal or state constitutions."[2] Relying upon

[1] Exhibit A, Protective Order at 1.

[2] *Id.* at 2.

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

this Protective Order, the parties have filed under seal numerous motions and exhibits containing confidential information, including internal Lilly documents and confidential communications with the FDA. The parties have also filed several iterations of confidential deposition designations discussing trade secrets and other confidential business information.

Bloomberg demands that the Court immediately release these confidential documents, preventing Lilly from demonstrating, on a document-by-document basis, the reasons for maintaining the confidentiality of each document,[3] and preventing this Court from making informed determinations of confidentiality.[4] Due process concerns, as well as those of judicial economy, dictate that these time-intensive confidentiality determinations should not be made while the trial is unfolding. With each day of trial, the confidentiality of some evidence is lost as it is admitted into evidence; at the same time, eleventh hour decisions are made to not seek admission of certain documents, preserving the existing confidentiality of those documents. Making confidentiality determinations now would force the Court and the parties to operate against a moving background, spending unnecessary time and resources on ever-changing confidentiality challenges. Accordingly, any proceedings regarding the documents filed under seal should be held after the conclusion of trial, so that the Court and the parties may accurately assess which documents should remain confidential under the blanket protective order.

[3] *See Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1122 (3d Cir. 1986) (if confidentiality of document produced pursuant to blanket or umbrella protective order is challenged, party seeking protection may then offer good cause showing); *see also* Manual for Complex Litigation (Fourth) § 11.432 (2004) (blanket or umbrella protective orders expedite production, reduce costs, and avoid the burden of document-by-document adjudication by delaying necessity of such a document-by-document adjudication until a challenge to confidentiality arises).

[4] *See, e.g., Phillips ex. rel. Estates of Byrd v. General Motors Corp.*, 307 F.3d 1206, 1212 (9th Cir. 2002) (remanding to district court for further proceedings to "identify and discuss the factors it considered in its 'good cause' examination to allow appellate review of the exercise of its discretion").

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

To the extent that this Court decides to make confidentiality determinations before the close of trial, however, the documents at issue here should retain their confidentiality. First, those documents filed with non-dispositive motions meet the requisite "good cause" standard of Alaska Rule of Civil Procedure 26(c), and Bloomberg cannot justify their release to the public. Second, those few documents not admitted at trial, but filed with dispositive motions, meet the requisite "compelling reasons" standard and their confidentiality should likewise be maintained. Regardless of the applicable standard, the Court should deny Bloomberg's motion as to the documents at issue.

II. THIS COURT ENTERED THE PROTECTIVE ORDER TO FACILITATE DISCOVERY.

Bloomberg's demand that the Court lift the Protective Order entered in this case ignores the value and necessity of protective orders, which allow parties to freely conduct discovery and exchange information without risking irreparable harm through a breach of confidentiality. "[P]rotective orders issued under Rule 26(c) serve the vital function of securing the just, speedy, and inexpensive determination of civil disputes by encouraging full disclosure of all evidence that might conceivably be relevant."[5]

Bloomberg argues that the Protective Order should be lifted for all documents filed with the Court. This argument is flawed because it contemplates releasing Lilly's documents without first allowing Lilly to demonstrate why each document should be kept confidential, thereby incurring the very harm that the Protective Order seeks to avoid. Lilly designated these documents as confidential because of its good faith belief that they contain valuable trade secret information as well as other highly confidential information, the disclosure of

[5] *S.E.C. v. TheStreet.com*, 273 F.3d 222, 229 (2d Cir. 2001) (internal quotation omitted).

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

which would place Lilly at a severe competitive disadvantage.[6] Bloomberg's challenge to the documents' confidentiality does not merit the dissolution of the Protective Order, but requires that Lilly demonstrate, as it does here, the importance of keeping these documents confidential and the harm that would come to Lilly if this confidentiality were breached.

III. RULE 26(c) PROTECTS CONFIDENTIAL LILLY DOCUMENTS ATTACHED TO NON-DISPOSITIVE FILINGS UNDER THE GOOD CAUSE STANDARD.

Bloomberg's motion fails to distinguish between the legal standards applicable to 1) judicial documents attached to dispositive pleadings or admitted into evidence, and 2) documents attached to non-dispositive pleadings. In doing so, Bloomberg urges this Court to apply the wrong standard to the great majority of documents at issue.

There is a strong presumption against the disclosure of confidential documents attached to non-dispositive motions.[7] Where documents attached to non-dispositive motions are at issue, a party seeking their protection need show "good cause" as defined by Alaska Rule of Civil Procedure 26(c).[8] Rule 26(c) authorizes a court to enter, "on such terms and conditions as are just," any order "which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." The court may enter

[6] The pharmaceutical industry is highly competitive, and the value of commercially sensitive information to competitors is high. *See, e.g.*, Exhibit B, Declaration of Gerald Hoffman filed in connection with confidentiality challenges currently pending in the Zyprexa MDL ("Hoffman Decl.") at ¶¶ 10-11, 18; Exhibit C, Declaration of Timothy Franson at ¶¶ 16-17 ("Franson Decl.").

[7] *See Gambale v. Deutsche Bank AG*, 377 F.3d 133, 143 (2d Cir. 2004); *TheStreet.com*, 273 F.3d at 233.

[8] *See Phillips*, 307 F.3d at 1210 (where good cause is shown the court must balance the public and private interests to decide whether a protective order is necessary); *see also In re Zyprexa Injunction*, 474 F. Supp. 2d 385, 415 (E.D.N.Y. 2007) ("The balance struck should incorporate consideration of the overarching purpose of the discovery process: Discovery involves the use of compulsory process to facilitate orderly preparation for trial, not to educate or titillate the public.") (internal quotation marks omitted).

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

such an order to protect, *inter alia*, Lilly's "trade secret[s] or other confidential research, development, or commercial information."[9] Given the "potential for abuse" attendant to liberal discovery rules,[10] Rule 26(c), like its federal counterpart, permits a party to seek a protective order prohibiting dissemination of information produced in discovery upon a showing of "good cause." "This provision . . . applies primarily to commercially sensitive information that might cause the defendant some competitive harm."[11]

Good cause can be demonstrated by showing that particularized harm will result from the disclosure of information.[12] Among the factors considered for confidentiality protection under Fed. R. Civ. P. 26(c)(7) are (1) the extent to which information is known to those outside the business; (2) the extent to which the information is known to those inside the business; (3) the measures taken to guard the secrecy of the information; and (4) the value of the information to the business and its competitors.[13] As demonstrated herein, the sealed

[9] *Phillips*, 307 F.3d at 1211 (courts have "broad latitude to grant protective orders to prevent disclosure of materials for many types of information, including, *but not limited to*, trade secrets or other confidential research, development, or commercial information.") (italics in original).

[10] *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 34-35 (1984).

[11] Jack B. Weinstein, *Secrecy in Civil Trials: Some Tentative Views*, 9 J.L. & Pol'y 53, 57 (2000) ("This provision does not specifically refer to the public interest. Rather, it applies primarily to commercially sensitive information that might cause the defendant some competitive harm.").

[12] *Phillips*, 307 F.3d at 1211.

[13] *Sullivan Mktg. v. Valassis Commc'n*, No. 93 Civ. 6350 (PKL), 1994 WL 177795 at *2 (S.D.N.Y. May 5, 1994); *see Wilcock v. Equidev Capital L.L.C.* No. 99 Civ. 10781LTSDFE, 2001 WL 913957, at *1 (S.D.N.Y. Aug. 14, 2001). Courts in the Ninth Circuit have focused primarily on the potential for irreparable harm to the party seeking a protective order. *See Phillips*, 307 F.3d at 1210-11 (focusing on harm if no protective order is entered); *Nutratech, Inc. v. Syntech (SSPF) Intern., Inc.* 242 F.R.D. 552, 555 (C.D. Cal. 2007) (entering protective order to protect against competitive harm); *In re Worlds of Wonder Sec. Litig.*, 147 F.R.D. 214, 216 (N.D. Cal. 1992) (entering a protective order covering "closely-guarded" documents because "their disclosure to competitors probably would be harmful").

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

Lilly documents attached to non-dispositive pleadings meet the Rule 26 "good cause" standard, and should be kept confidential:

- Plaintiff's Ex. Nos. 10105, 10106, 10107, and 10111. These recent regulatory responses, as Lilly has previously noted,[14] are not publicly available and not widely disseminated within the company. Both Lilly and the FDA take numerous steps, including exempting these documents from the Freedom of Information Act ("FOIA"), to protect their confidentiality. Moreover, as set forth in the Declaration of Timothy Franson, "the 2007 submissions and communications are so current that companies with products in competition with Zyprexa and Symbyax could use this information to gain unfair insight to their benefit, as well as to exploit this information to harm Lilly in the marketplace today."[15]

- Document Bates Numbered FDACDER 2154-2168. This document was produced by the FDA to the Plaintiffs' Liaison Committee in the Zyprexa Multidistrict Litigation pending before Judge Jack B. Weinstein, pursuant to the protective order in the MDL.[16] The confidentiality rights to this document are held by FDA, and this Court should not disclose it to the public without permitting FDA the opportunity to assert its document's confidentiality.[17]

- Plaintiff's Ex. No. 4121. This document contains Lilly market research and strategic marketing discussions. Lilly has taken steps to keep this document from being disclosed to the public or widely circulated within the company because competitors would use the information contained within the document to Lilly's competitive disadvantage. Additionally, Lilly expended time, money, and effort

[14] *See* Motion Requesting Confidential Protections of Regulatory Communications Not Subject to Public Disclosure filed under seal February 28, 2008.

[15] Exhibit C, Franson Decl. at ¶ 17.

[16] Exhibit D, Letter from J. Zellner to M. Miller (Nov. 20, 2006).

[17] Exhibit E, *In re Zyprexa Prods. Liab. Litig.*, MDL No. 1596, Case Management Order No. 3 at ¶¶ 7, 9.

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

to conduct the market research reflected in this document. Permitting competitors to have the benefits of that research without the attendant costs would harm Lilly's competitive edge.

- Plaintiff's Ex. No. 10097. This document is an internal Lilly policy regarding interactions with health care professionals. Lilly has taken steps to keep this document from being disclosed to the public or widely circulated within the company because competitors could use it determine how Lilly trains its employees and Lilly's strategies for interacting with its customers. Competitor access to Lilly's training materials would adversely impact Lilly's position in the pharmaceutical marketplace.

- Plaintiff's Ex. No. 8262. This internal Lilly email was disseminated only to the recipients listed therein – it was neither widely circulated in the company nor released to the public. This email reflects internal Lilly discussion about its products and plans for further medical and regulatory development. Permitting Lilly's competitors access to this email could give them insight into Lilly's development plans for Zyprexa and other medications, allowing them to counter-detail Lilly products in the marketplace.

- Plaintiff's Ex. No. 3909. This draft letter to healthcare professionals was not available outside of the company, not widely disseminated within the company, and Lilly takes steps to ensure the security of its document and computer systems.[18] Lilly would be at a severe competitive disadvantage if this document were released because draft documents give competitors insight into Lilly's clinical analysis and thought processes.

- Plaintiff's Ex. No. 10052. This document contains a presentation to Lilly's Global Management Team, setting forth priorities and business strategies. This document is not publicly available and was not widely disseminated within the company because competitors could use this information to Lilly's competitive disadvantage.

[18] *See* Exhibit B, Hoffman Decl. at ¶¶ 12-15.

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

- Plaintiff's Ex. No. 10025. This internal presentation to certain Lilly employees was not widely circulated and not released to the public. Dissemination to Lilly competitors could harm Lilly in the marketplace.

- Also attached to these motions are excerpts of confidential deposition designations. These deposition designations contain discussions of trade secrets and other confidential business information, not all of which have been or will be disclosed in court, or even be relevant to the case. Until this trial concludes, it is impossible to know whether these designations will be played in open court. It is an inefficient use of judicial time and resources to attempt to separate that which has already played from that which may be played or will not be played. These determinations are better made after the completion of trial.

IV. DOCUMENTS ATTACHED TO DISPOSITIVE MOTIONS ARE PROTECTED UNDER THE "COMPELLING REASONS" STANDARD.

When evaluating the confidentiality of documents attached to dispositive motions,[19] courts employ a "compelling reasons" standard to balance the public's interest in accessing the court with a litigant's interest in protecting confidential commercial information.[20] Under this standard, a "court must weigh relevant factors, base its decision on a compelling reason, and articulate the factual basis for its ruling . . . without relying on hypothesis or conjecture."[21] "Relevant factors include the public interest in understanding

[19] The public's interest in accessing the courts is confined to the trial setting, and does not bear on documents disclosed during the course of pre-trial hearings. *See, e.g., In re Zyprexa Injunction*, 474 F. Supp. 2d at 412-13 (public interest is to monitor the courts, documents exchanged during pre-trial do not implicate this interest).

[20] *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 664 (D.N.J. 2004).

[21] *Pintos v. Pacific Creditors Assoc.*, 504 F.3d 792, 802 (9th Cir. 2007) (alteration in original, internal quotation marks and footnote omitted).

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

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

the judicial process and whether disclosure of the material could result in improper use of the material for scandalous or libelous purposes or infringement upon trade secrets."[22] "A well-settled exception to the right of access is the protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm."[23] "[C]ourts may deny access to judicial records . . . where they are sources of business information that might harm a litigant's competitive standing."[24] As demonstrated herein, the sealed Lilly documents attached to dispositive pleadings meet the "compelling reasons" standard, and should be kept confidential:

- Plaintiff's Ex. Nos. 10098, 10099, and 10100. These documents are excerpted "call notes" from Lilly sales representatives. Call notes are rough notes concerning sales representatives' discussions with physicians. Lilly takes numerous steps to ensure that call notes are not available to the public and are not widely disseminated within the company. Call notes vary in length, style, and use of idiosyncratic shorthand, and it is often impossible to determine whether a physician or a Lilly sales representative raised a given topic or the extent to which any topic was covered or what was actually said. Nevertheless, these call notes would be very useful to Lilly's competitors. Competitors could use the call notes to roughly determine what concerns Lilly's customers – doctors – share with Lilly about its products as well as its competitors' products. In this way, call notes could be used like market research, costing Lilly the time, expense, and good will it has expended to compile this information.[25]

---

[22] *Id.* at 802 n.9 (internal quotation marks omitted).

[23] *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d at 664 (internal quotation marks omitted).

[24] *Republic of the Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 662 (3d Cir. 1991) (internal quotation marks omitted).

[25] *See* Exhibit B, Hoffman Decl. at ¶¶ 17-18 (explaining "competitive intelligence gathering" in the pharmaceutical industry).

- As above, the dispositive motions also attach excerpts of confidential deposition designations, which may or may not be played in open court or even be relevant to the case. Until the conclusion of this trial, it is unknown whether these designations will be played. It is an inefficient use of time and resources to attempt to separate that which has already been played from that which may or may not be played. These determinations are better made after the completion of trial.

V. CONCLUSION

For the foregoing reasons, Lilly requests that this Court protect from disclosure confidential Lilly documents filed under seal with dispositive and non-dispositive pleadings, and deny Bloomberg's Motion to Intervene and to Unseal Records. In the alternative, Lilly requests that this Court defer ruling on specific challenges to the confidentiality of Lilly's sealed documents until the conclusion of the trial. This will promote judicial efficiency by narrowing the universe of documents at issue and will enable this Court to make an informed determination of the applicable legal standard as well as the sufficiency of Lilly's bases for its confidential designations.

DATED this 20th day of March, 2008.

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac vice*
George A. Lehner, admitted *pro hac vice*
John F. Brenner, admitted *pro hac vice*
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
and
LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

I certify that on March 20, 2008, 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

Jon S. Dawson, Esq.
Davis Wright Tremaine, LLP
701 West Eighth Avenue, Suite 800
Anchorage, Alaska 99501

_____
00586/00038/163934.1

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

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 have become publicly available without a breach of the terms of this Order, all documents, information or other

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

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 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 Alaska Rule of Civil Procedure 26(c)(7); under any Federal or state statutes, regulations or court rules; or under Federal or state constitutions. Federal and state regulations may preclude the parties under certain circumstances from producing personal identifying information. In such cases, the parties may produce redacted or de-identified information for use in this litigation and under the protection of this Order, provided, however, that the Court nevertheless retains the authority to review any such action by any party.

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; or (c) as

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

required by Federal or state law. If information is redacted for any reason, the redacting party shall produce a separate log that identifies the document subject to redaction by bates number, the reason for such redaction, and describes the nature of the information redacted so that other parties may assess the applicability of any privilege or production. Nothing in this Order shall be interpreted to require Lilly to prepare new privilege logs for the MDL production or supplement the privilege logs produced in the MDL.

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 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

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

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.

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

6. Permissible Disclosures of Confidential Discovery Material

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.

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

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

f. 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;

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

h. 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;

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

j. 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;

k. Any individual to whom disclosure is to be made under subparagraphs (d) through (j) 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

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

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 (j) 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 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 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 fact or circumstances of the inadvertent production.

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

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 Alaska Rules of Civil Procedure and/this Order, provided that such motion is made within forty-five

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

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 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 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 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 they represent unless they sign the form described, and otherwise comply

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

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 as 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

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

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 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

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

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 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

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

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 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 above. Any copy provided to a person listed in paragraph 6 shall be returned to counsel of

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

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.

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

ORDERED this 30 day of July, 2007.

The Honorable Mark Rindner
Judge of the Superior Court

#8685996 v2

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

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

Administrative Assistant

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

---x

In re: ZYPREXA
PRODUCTS LIABILITY LITIGATION

MDL No. 1596 (JBW) (RLM)

---x

THIS DOCUMENT RELATES TO:
UCFW LOCAL 1776 AND PARTICIPATING
EMPLOYERS HEALTH AND WELFARE FUND,
ERIC TAYAG and MID-WEST NATIONAL
LIFE INSURANCE COMPANY OF TENNESSEE
on behalf of themselves and other similarly situated

---x

DECLARATION OF GERALD HOFFMANN

GERALD HOFFMANN declares, under penalty of perjury, pursuant to the provisions of 28 U.S.C., Section 1746, as follows:

1. I am employed by Eli Lilly and Company ("Lilly") as Manager of Global Competitive Intelligence Strategy.

2. I have been employed by Lilly since November 1998.

3. I have held a management position in Competitive Intelligence since November 1998, and have worked in the field of competitive intelligence since 1989. Prior to my employment at Lilly, I was the Director of Competitive Intelligence for SBC Communications.

4. The field of competitive intelligence is well established, and the methods described below are well recognized in industry and academia, and are the subject of textbooks and published literature, including: LIAM FAHEY, COMPETITORS: OUTWITTING, OUTMANEUVERING, AND OUTPERFORMING (1999); LEONARD M. FULD, COMPETITIVE INTELLIGENCE: HOW TO GET IT;

HOW TO USE IT (1985); BENJAMIN GILAD, THE BUSINESS INTELLIGENCE SYSTEM: A NEW TOOL FOR COMPETITIVE ADVANTAGE (1988); BENJAMIN GILAD, BUSINESS BLINDSPOTS: REPLACING YOUR COMPANY'S ENTRENCHED AND OUTDATED MYTHS, BELIEFS AND ASSUMPTIONS WITH THE REALITIES OF TODAY'S MARKETS (1994); MICHAEL E. PORTER, COMPETITIVE STRATEGY: TECHNIQUES FOR ANALYZING INDUSTRIES AND COMPETITORS (1980); as well as numerous articles by Jan Herring, under whom I also trained. I have also been a member of the Society of Competitive Intelligence Professionals since 1989.

5. Part of my responsibilities, as well as the responsibilities of the Competitive Intelligence Group generally, is to educate employees as to the importance of maintaining the confidentiality of internal information and documents ("intelligence data") and as to the dangers of competitive harm from the failure to keep intelligence data – even seemingly innocuous documents – confidential. I also assist global product teams on how to gather competitive data from the public domain for use in gaining advantage in the marketplace.

6. From this experience and training, I understand the value to Lilly's competitors of internal Lilly documents, including those at issue in this case, if they were permitted to be released in the public domain.

7. I have reviewed the Amended Complaint, and each of the documents referenced therein as listed on the attached Schedule "A."

8. Each of the documents listed in the Amended Complaint and Schedule "A" contains information of the type that Lilly treats and protects as confidential, and is subject to Lilly's confidentiality polices and procedures described below.

9. Each of the documents listed in the Amended Complaint and Schedule "A" contains information related to: confidential research and development information;

strategic plans; marketing plans, strategies; competitive analyses; market research; clinical trials and non-clinical trials; or interactions with key regulators or publishers. Each document reveals something about Lilly's internal organization and structure, qualifies as intelligence data, and if disseminated would be useful to Lilly's competitors in the atypical antipsychotic marketplace, and Lilly generally.

10. The pharmaceutical industry operates in an intensely competitive market generating revenues in the hundreds of billions of dollars per year.

11. Lilly dedicates a substantial amount of time, money, and resources to research and development of medicines; strategic plans; marketing plans, competitive analyses; market research; clinical trials and non-clinical trials; and interactions with regulators and publishers. Lilly recognizes the competitive threats within the pharmaceutical industry and has implemented elaborate safety precautions to prevent its confidential information from falling into a competitors' hands.

12. Every Lilly-operated facility employs private security guards and utilizes private security systems. All employees and guests must possess an individually assigned and distributed security badge to enter any Lilly-operated facility. Lilly's computer systems are protected by state-of-the-art security software. To gain access to Lilly's computer system requires a Lilly-controlled and monitored username, as well as a user-specific password. Separate security clearance is necessary to obtain a username. Within Lilly's computer system, each employee is given a personal email account with limited access by others within the company. Lilly's document management system also provides limited employee access to Lilly's documents.

13. In addition to the physical security and electronic security Lilly utilizes, every employee is bound by the provisions of The Red Book – Code of Business Conduct, as well as Global Lilly Policies, each of which delineates employees' responsibilities to maintain the confidentiality of all Lilly information assets, and includes:

a. All information developed by employees relating to company business, such as research and development plans, organizational charts, compounds and processes, manufacturing methods, clinical trial data and marketing, advertising, and business development studies and plans must be safeguarded by all employees.

b. Employees must keep the information in secure locations and limit access to information to those employees who have a need to know in order to perform the duties of their employment.

c. An employee must not disclose information to third parties unless information-specific approval is obtained by the employee's supervisor, and only after considering the need for a confidentiality agreement approved by Lilly's Law Division and signed by the third party.

d. Violations of The Red Book – Code of Business Conduct, or any other physical or electronic policy, are disciplined up to and including termination of employment.

14. Lilly extends its requirements for protection for confidential material to consultants, vendors, and clinical investigators, as well. Every person receiving Lilly confidential materials or data is bound by confidentiality agreements, which protects negotiations, conversations, correspondence with Lilly.

15. Lilly also devotes substantial resources both to monitoring competitor data in the public domain to assist its strategic planning for its products, and to protecting its own data from public dissemination.

16. Lilly currently markets over fifty medications, each with a different market base, as well as many compounds moving toward the market, while developing new indications or line extensions for existing products.

17. Zyprexa® is indicated for use by patients with bipolar disorder and schizophrenia. Like the pharmaceutical industry, the bipolar and schizophrenia markets are fiercely competitive, and Lilly must compete with pharmaceutical companies such as AstraZeneca, Bristol-Myers Squibb, Janssen, Merck, Novartis, and Pfizer, as well as with companies manufacturing generic medications, and potential competitors who may be deciding whether to enter these markets. It is standard practice in the pharmaceutical industry to engage in competitive intelligence and monitor competitor intelligence data.

18. Competitive intelligence requires the gathering of data bit-by-bit; leveraging prior gained intelligence data. The more pieces of information about a competitor that are gathered, the more complete the picture of the competitor that can be gained. With access to the documents at issue here, a competitor could obtain considerable insight into Lilly's structure, decision tree, internal workings, strategies for development, and its processes for deliberation and strategy-implementation. Public dissemination would reveal the manner in which the company considered or developed research information, strategic plans, marketing plans, strategies, competitive analyses, market research, clinical trials and non-clinical trials, and interactions with regulators or publishers. If Lilly's internal documents were to be publicly disseminated, every pharmaceutical company in the world, including competitors to all of Lilly's

marketed medications, including Zyprexa®, would have access to a treasure trove of competitive intelligence, in an organized and assembled manner.

19. Public dissemination of Lilly's internal documents would work serious competitive harm to Lilly and the Zyprexa® brand.

20. With the benefit of not only the inferences that can be drawn from individual pieces of information, but also by what can be learned by comparing individual documents with other documents – both documents that are publicly available as well as other documents that are subject to this challenge – pharmaceutical companies worldwide would be able to copy Lilly's actions, draw from Lilly's actions, or anticipate Lilly's future actions to plan countermeasures.

21. The documents would also permit competitors to generate lists of current and former Lilly employees and consultants as potential contact people to gather competitive information. Showing Lilly's deliberative processes can also be used by competitors to evaluate whether the Zyprexa® team has weaknesses that can be competitively exploited.

22. In addition to the immediate harm that Lilly would face as a result of public dissemination of its documents, companies with products that compete with Zyprexa® may utilize the Zyprexa®'s documents in counter-detailing presentations to Lilly's customers, showing customers documents and information taken out of context with the aim of damaging Lilly's reputation and bolstering competitors' market shares.

I declare under penalty of perjury and under the laws of the United States of America that the foregoing is true and correct

GERALD HOFFMANN
Executed on January 16, 2006 at
Chesterfield, Missouri

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

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

AFFIDAVIT OF TIMOTHY R. FRANSON IN SUPPORT OF DEFENDANT ELI LILLY AND COMPANY'S MOTION REQUESTING PROTECTION OF REGULATORY COMMUNICATIONS NOT SUBJECT TO PUBLIC DISCLOSURE

I, TIMOTHY R. FRANSON, being duly sworn, state as follows:

1. I am currently employed by Eli Lilly and Company ("Lilly") as Vice President, Global Regulatory Affairs.

2. Since 1996, I have had regulatory management responsibility in the United States for all products within the neuroscience therapeutic area. I have worked closely with the regulatory scientists who have primary responsibility for Zyprexa®.

3. During my tenure, I have participated in meetings and discussions with the Food and Drug Administration ("FDA") regarding changes to the United States label for Zyprexa in 2003 and 2007.

4. On January 12, 2007, the FDA sent Lilly a letter requesting certain information in response to articles published in *The New York Times*. On February 20, 2007, Lilly submitted to the FDA the solicited response, in three parts. Part one of this response, structured in direct reply to allegations in *The Times* articles, offers Lilly's views regarding the allegations. The second part contains literature requested by the FDA, and the third part contains data requested by the FDA.

5. In March 2007, in the context of an approvable letter for a new indication for Symbyax® (combination of olanzapine and fluoxetine), the FDA requested certain analyses of Zyprexa clinical trial data with the intent of updating the United States label. The FDA made a similar request in April 2007, in an approvable letter for a new indication for Zyprexa.

6. In August and September 2007, Lilly submitted the requested analyses to the FDA.

7. During this time, Lilly and the FDA also exchanged communications regarding draft labeling. Lilly revised the Zyprexa label on October 5, 2007.

8. Pharmaceutical companies and regulatory bodies regularly exchange confidential information to facilitate the drug approval and compliance process in an efficient and fair manner. These protections encourage full and frank communications, and both parties maintain these communications in confidence.

9. Regulatory submissions and communications between Lilly and the FDA are private and confidential, not subject to public disclosure. They contain confidential proprietary information, confidential commercial information, confidential trade secret information, and other confidential information. These submissions and communications are exchanged between Lilly and the FDA with an expectation and understanding that they will not be disclosed or disseminated.

10. Such regulatory submissions and communications are not widely disseminated within Lilly, but instead are restricted to those employees with responsibility for regulatory affairs. Lilly employees, in general, do not have access to these documents.

11. Within Lilly, measures are taken to guard the secrecy of these documents. In addition to the measures Lilly takes to guard its computer systems from external disclosures and its physical plant facilities with security personnel, Lilly employees are bound by The Red Book – Code of Business Conduct, and by Global Lilly Policies, each of which delineates confidentiality measures for Lilly Information Assets.

12. Such regulatory submissions and communications are not publicly available, nor have they been disclosed to the public.

13. These types of documents would not be subject to disclosure under the Freedom of Information Act ("FOIA"), even if requested.

14. Documents such as the New Drug Applications for Zyprexa and for Symbyax, which typically contain such submissions and communications, also are not publicly available, nor have they been disclosed to the public. Such documents contain a cover sheet typically reflecting the following statement:

> THIS DOCUMENT CONTAINS TRADE SECRETS, OR COMMERCIAL OR FINANCIAL INFORMATION, PRIVILEGED OR CONFIDENTIAL, DELIVERED IN CONFIDENCE AND RELIANCE THAT SUCH INFORMATION WILL NOT BE MADE AVAILABLE TO THE PUBLIC WITHOUT EXPRESS WRITTEN CONSENT OF ELI LILLY AND COMPANY.

15. Clinical data discussed in such submissions and communications is owned by Lilly. Lilly dedicates a substantial amount of resources to clinical trials and data analysis. The data is proprietary because it has definable value to Lilly, and that value could be transferred to Lilly's competitors if disclosed. With access to such information, competitors could gain

considerable insight into Lilly's strategies, plans, processes, goals, and actions. This type of information is useful as a guide for competitors' own drug development and research efforts.

16. Dissemination of the data and of these strategies could cause commercial hardship to Lilly and would benefit its competitors in the marketplace.

17. In particular, the 2007 submissions and communications are so current that companies with products in competition with Zyprexa and Symbyax could use this information to gain unfair insight to their benefit, as well as to exploit this information to harm Lilly in the marketplace today.

Timothy R. Franson

SWORN TO AND SUBSCRIBED
BEFORE ME, NOTARY, this
27th day of February, 2008
Lana L Dishman
Notary Public

Lana Dishman
My Commission Expires:
February 8, 2015
Resident of Johnson County

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

November 20, 2006

Michael Miller, Esq.
Miller & Associates
105 North Alfred Street
Alexandria, VA 22314

Re: Zyprexa Plaintiff's Steering Committee v. FDA
Multi District Litigation No. MDL-1596 (JBW)

Dear Mr. Miller:

Please find enclosed a CD containing documents that are responsive to the PSC's subpoena issued to the FDA in the above-captioned case, as narrowed by letter from Michael Goldberger, Esq. to you dated July 18, 2006, and a corresponding privilege log. FDA considers these documents, along with the withheld pages, as indicated on the privilege log, to be a full response to the above-referenced subpoena.

It is further FDA's understanding that, pursuant to agreement between the parties and the FDA, as set forth in the letter from Andrew Rogoff, Esq. to AUSA Goldberger dated July 26, 2006, we are producing documents pursuant to the terms of Case Management Order No. 3 ("Protective Order") dated August 3, 2004, entered by the magistrate judge in the underlying case in the Eastern District of New York.

Please note that certain information within the documents contained on the enclosed CD has been withheld. These withholdings, detailed on the privilege log, include third-party confidential commercial information, personal privacy information, information about which the government will assert the deliberative process privilege, and information outside the scope of discovery as agreed to by the parties.

005438

EXHIBIT D
PAGE 1 OF 2

E

Please feel free to contact me with any questions you may have.

Very truly yours,

Jessica L. Zeller /HKP

Jessica L. Zeller
Assistant Chief Counsel

Enclosures (2)
CD

cc: Michael Goldberger, Esq. (without attachments)
Andrew Rogoff, Esq.

005439

EXHIBIT D
PAGE 2 OF 2

E

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

005440

EXHIBIT E
PAGE 1 OF 15

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 3, 2004
Brooklyn, New York

SO ORDERED as opposing act of magistrate judge and parties no objections having been received.

Hon. Jack B. Weinstein
Senior District Judge

Dated: 8/3, 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: _____

Jon S. Dawson
Davis Wright Tremaine LLP
701 W. 8th Avenue, Suite 800
Anchorage, Alaska 99501-3468
(907) 257-5300, telephone
(907) 257-5399, facsimile
jondawson@dwt.com

Attorneys for Bloomberg, LLC,
d/b/a Bloomberg News

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-06-05630 CI
	)	

ERRATA TO CERTIFICATES OF SERVICE

Bloomberg, LLC d/b/a Bloomberg News, through its attorneys Davis Wright Tremaine LLP, hereby notifies the Court of an error that occurred in the certificates of service contained on its motion to intervene and supporting papers filed Friday, March 7, 2008. Counsel intended service to be completed on that same date by hand delivery but due to a misunderstanding, service of the motion and related documents was not completed until Monday, March 10, 2008. The certificates mistakenly stated that service

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

was accomplished on March 7, 2008. By this Errata, counsel gives notice that service actually took place on March 10, 2008.

DATED this 10th day of March, 2008.

DAVIS WRIGHT TREMAINE LLP
Attorneys for Bloomberg, LLC,
d/b/a Bloomberg News

By: _____
Jon S. Dawson,
Alaska Bar Assoc. # 8406022

Certificate of Service:

I certify that on March 10 2008, and a true and correct copy of the foregoing document was sent to the following attorneys or parties of record by:

(X) Mail
( ) Facsimile and Mail
( ) Hand Delivery

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

Brewster H. Jamieson, Esq.
Lane Powell LLC
301 W. Northern Lights Blvd., Ste. 301
Anchorage, AK 99503

Janet Eastman

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

005456

Jon S. Dawson
Davis Wright Tremaine LLP
701 W. 8th Avenue, Suite 800
Anchorage, Alaska 99501-3468
(907) 257-5300, telephone
(907) 257-5399, facsimile
jondawson@dwt.com

Attorneys for Bloomberg, LLC,
d/b/a Bloomberg News

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-06-05630 CI

MOTION TO INTERVENE AND TO UNSEAL RECORDS

Bloomberg, LLC d/b/a Bloomberg News, through its attorneys Davis Wright Tremaine LLP, moves (1) to intervene in this matter for the limited purpose of seeking to unseal documents filed under seal in this matter and to assert the public's right of access to any documents which any party may hereafter attempt to seal or file under seal; (2) for an order directing that all documents previously filed with the Court under seal be unsealed and made available to the public; and (3) for an order vacating those portions of

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

Motion to unseal

the Protective Order dated July 30, 2007 which permit the parties to file documents under seal without motion or hearing. This motion is supported by the Memorandum in Support filed herewith, and by the record and pleadings herein.

DATED this 7th day of March, 2008.

DAVIS WRIGHT TREMAINE LLP
Attorneys for Bloomberg, LLC,
d/b/a Bloomberg News

By: _____
Jon S. Dawson,
Alaska Bar Assoc. # 8406022

Certificate of Service:

I certify that on 3/10, 2008, and a true and correct copy of the foregoing document was sent to the following attorneys or parties of record by:

( ) Mail
( ) Facsimile and Mail
(X) Hand Delivery

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

Brewster H. Jamieson, Esq.
Lane Powell LLC
301 W. Northern Lights Blvd., Ste. 301
Anchorage, AK 99503

Janet Eastman

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

Jon S. Dawson
Davis Wright Tremaine LLP
701 W. 8th Avenue, Suite 800
Anchorage, Alaska 99501-3468
(907) 257-5300, telephone
(907) 257-5399, facsimile
jondawson@dwt.com

Attorneys for Bloomberg, LLC,
d/b/a Bloomberg News

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-06-05630 CI

MEMORANDUM IN SUPPORT OF MOTION TO INTERVENE AND TO UNSEAL RECORDS

Bloomberg, LLC d/b/a Bloomberg News submits this memorandum in support of its Motion to Intervene and to Unseal Records.

I. INTRODUCTION

Pursuant to a stipulated Protective Order, the Court has permitted the parties to file under seal a host of pleadings and documents in a matter of significant public concern. Under the First Amendment, the common law, and Alaska's statutes and rules, court

records cannot be sealed absent specific findings that there is a compelling interest that overcomes the right of public access to the records; that sealing is necessary to preserve that interest; and that there are no less restrictive alternatives to sealing. In this case, pleadings and documents were sealed without any such findings. Those records must therefore be unsealed.

II. FACTS

This litigation involves matters of paramount concern to the public. The State of Alaska's complaint in this matter alleges that Defendant Eli Lilly and Company knowingly misrepresented the risks associated with the drug Zyprexa, advertised and sold Zyprexa for a number of non-approved uses despite the lack of any FDA approved testing demonstrating the effectiveness of Zyprexa for such uses, and knowingly withheld reports of severe and harmful health conditions experienced by users of Zyprexa. Complaint at paras. 12-24. If the State of Alaska is correct, then a substantial number of persons have experienced, and will in the future experience, severe medical problems after taking Zyprexa. The citizens of Alaska and of other states, and particularly persons who have taken, are now taking, or may in the future take Zyprexa, are entitled to know to extent Zyprexa has, and continues to, harm patients, and to have access to documents filed in the course of this matter.

In conjunction with proceedings in this matter, the Court approved a stipulated Protective Order that allows the parties to unilaterally designate materials as

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

"Confidential Discovery Materials." See Protective Order dated July 30, 2007. The Protective Order does not provide for judicial review of a party's decision to designate any such materials as confidential. If documents that a party designates as confidential are filed with the Court, the Protective Order requires that such documents be filed and kept under seal. Protective Order at § 12. Under the current scheme, the Court is not required to make any findings that compelling reasons exist for removing such documents from the public record of this case.

Acting under the authority granted by the Protective Order, the parties filed over two dozen pleadings and related exhibits under seal in this matter. The sealed documents are reflected in the following docket entries:

02/29/2008 Notice of Filing Under Seal Attorney: Jamieson, Brewster H. (8411122)

02/28/2008 Defendant Eli Lilly and Company's Notice of Filing Under Seal Attorney: Jamieson, Brewster H. (8411122)

02/25/2008 Notice of Filing Under Seal a pleading titled "State of Alaska's Request for Clarification of the Court's Order Excluding Evidence of the Defendant's Profits, Net Worth, and the Price of Zyprexa." Attorney: Sanders, Eric T. (7510085)

02/25/2008 Notice of Filing Under Seal a pleading titled "Request for Clarification of the Court's Order Excluding Testimony or Argument Regarding Other Drugs Manufactured by Defendant Eli Lilly and Company." Attorney: Sanders, Eric T. (7510085)

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

02/20/2008 Notice of: Reply re: Mtn Exclude Evidence New York Times Articles, Filed Under Seal Attorney: Jamieson, Brewster H. (8411122) Eli Lilly & Co (Defendant)

02/20/2008 Reply: Motion in Limine Exclude Regulatory Communications, file under seal Attorney: Jamieson, Brewster H. (8411122) Eli Lilly & Co (Defendant); Case Motion #66: Standard Motion

02/20/2008 Eli Lilly and Company's Notice of Filing its Reply in Further Support of its Motion in Limine to Exclude Evidence Relating to New York Times Articles Under Seal

02/19/2008 Notice of Filing Under Seal - Objection to the State's Motions in Limine to Exclude Evidence Eli Lilly & Co (Defendant); Case Motion #60: Standard Motion

02/14/2008 Plaintiff's Response to Defendant's Motion in Limine to Exclude References to Foreign Regulatory Action (FILED UNDER SEAL) Attorney: Sanders, Eric T (7510085) State of Alaska (Plaintiff); Case Motion #63: Standard Motion

02/14/2008 Plaintiff's Response to Defendant's Motion in Limine to Exclude Testimony and Call Notes of Non-Alaska Based Sales Representatives (FILED UNDER SEAL) Attorney: Sanders, Eric T (7510085) State of Alaska (Plaintiff); Case Motion #64: Standard Motion

02/14/2008 Plaintiff's Response to Defendant's Motion in Limine to Exclude References to Recent Regulatory Communications and Developments (FILED UNDER SEAL) Attorney: Sanders, Eric T (7510085) State of Alaska (Plaintiff); Case Motion #66: Standard Motion

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

02/11/2008 Notice of Filing Plaintiff's Objections to Defendant's Page/Line Counter Designations Under Seal

02/11/2008 Eli Lilly's Notice of Filing Deposition Designations Under Seal Attorney: Jamieson, Brewster H. (8411122) Attorney: Girolamo, Andrea E (0211044)

02/04/2008 Notice of Filing Counter-Designations and Excerpts of Depositions Under Seal Brewster H Jamieson (Attorney) on behalf of Eli Lilly & Co (Defendant)

02/04/2008 Notice of Filing Motion in Limine to Exclude Certain Testimony of the State's Experts Under Seal Brewster H. Jamieson (Attorney) on behalf of Eli Lilly & Co (Defendant)

02/04/2008 Notice of Filing Motion in Limine to Exclude Evidence Relating to New Yor Time Articles Under Seal Brewster H. Jamieson (Attorney) on behalf of Eli Lilly & Co (Defendant)

02/04/2008 Notice of Filing Plaintiff's Amended Trial Deposition Designations Under Seal Eric T Sanders (Attorney) on behalf of State of Alaska (Plaintiff)

01/28/2008 Notice of Filing Plaintiff's Objections to Defendant's Page/Line Designations and Exhibits Under Seal Eric T Sanders (Attorney) on behalf of State of Alaska (Plaintiff)

01/28/2008 Notice of Filing Plaintiff's Counter Designations to Defendant's Deposition Designations and Exhibits Under Seal Eric T Sanders (Attorney) on behalf of State of Alaska (Plaintiff)

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

01/25/2008 Notice of Filing Supplemental Exhibits in Opposition to Lilly's Motion for Summary Judgment Under Seal

01/25/2008 Notice of Filing Supplemental Page 77 Under Seal Eric T Sanders (Attorney) on behalf of State of Alaska (Plaintiff)

01/23/2008 Notice of Filing Deposition Designations Under Seal Brewster H Jamieson (Attorney) on behalf of Eli Lilly & Co (Defendant)

01/22/2008 Notice of Filing Pleading and Exhibits Under Seal Eric T Sanders (Attorney) on behalf of State of Alaska (Plaintiff)

01/08/2008 Notice of Filing Pleadings Under seal Attorney: Orlansky, Susan C (8106042)

12/20/2007 Notice of Filing Pleading and Exhibits Under Seal, Re: Defendant's Motion to Compel Discovery Eric T Sanders (Attorney) on behalf of State of Alaska (Plaintiff) Case Motion #42: Standard Motion

Included among the sealed documents are exhibits to dispositive motions, deposition designations, and various motions and pleadings—a number of which cannot be identified from the docket. All of these documents were filed under seal pursuant to the Protective Order and without any finding by the Court that compelling reasons exist for removing such documents from the public record of this case.

Bloomberg News is a 24-hour global news service that supplies real time business, financial, and legal news to more than 200,000 subscribers world-wide. Bloomberg also operates eleven 24-hour cable news television outlets which cover important legal,

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

medical, and other matters. As a wire service, Bloomberg provides news to hundreds of newspapers around the world. See http://about.bloomberg.com/news/news.html. Bloomberg has provided extensive coverage of the problems that have surfaced regarding Zyprexa, including related litigation across the country.[1] Bloomberg's ability to discharge its obligations to its readers and the public, and to report on matters of substantial public importance, is substantially curtailed when court documents are improperly or unnecessarily placed off limits to the public. As such, Bloomberg has a fundamental interest in the issue of access to court documents that it seeks to bring before the Court.

III. ARGUMENT

A. Bloomberg Is Entitled to Intervene.

There can be no dispute that the media serves "as a representative or agent of the public" with respect to the public's "right of access to news or information concerning the operations and activities of government." Cable New Service, Inc. v. American Broadcasting Companies, Inc., 518 F.Supp. 1238, 1240 (N.D.Ga. 1981). It is well

[1] Bloomberg's recent articles on Zyprexa include, without limitation:
(1) Elizabeth Amon, "New Century, Lilly, Verizon, Samsung in Court News" (February 1, 2008), available at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a07I9vXBTOOk;
(2)Elizabeth Lopatto, "Lilly Gets U.S. Subpoena Related to Zyprexa Marketing" (January 30, 2008), available at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=axuM76vX68J4;
(3) Catherine Larkin, "Lilly Will Take New Zyprexa Formula to Advisory Panel" (December 18, 2007), available at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=abpTipzTkYpA;
(4) Shannon Pettypiece, "Lilly Adds New Weight-Gain Warnings for Zyprexa" (October 5, 2007), available at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=apS97DoNOi9I;
(5) Bob van Voris, "Lilly Settles Case Over Zyprexa Documents With Doctor" (September 7, 2007), available at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aeTr21YD7iQ0.

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

established as a matter of federal constitutional law that the press has standing to assert the public's—and its own—constitutional right of access to court records and proceedings. See, e.g., Globe Newspaper Co. v. Superior Court, 457 U.S. 596, 609 n.25 (1982) ("representatives of the press and general public must be given an opportunity to be heard on the question of their exclusion"). The Ninth Circuit has held that non-parties must be permitted to intervene for the purpose of challenging any restrictions on the First Amendment right of access. See Beckman Industries, Inc. v. Int'l Ins. Co., 966 F.2d 470, 473 (9th Cir. 1992). The Ninth Circuit has also recognized that non-parties seeking to intervene to challenge restrictions on public access to court records and proceedings should not be required to file a formal complaint or seek permission to join as a party. See id. at 473-474. See also In re Associated Press, 162 F.3d 503, 508 (7th Cir. 1998) (reversing district court and instructing that "the Press ought to have been able to intervene in order to present arguments against limitations on the constitutional or common law right of access"); In re Knight Publishing Co., 743 F.2d 231, 234 (4th Cir. 1984) (same).

B. The U.S. Constitution, the Common Law, and Alaska's Statutes and Rules Create a Right of Access to Judicial Records.

The U.S. Supreme Court has firmly established that under the First and Fourteenth Amendments to the U.S. Constitution, the press and general public have a constitutional right of access to court proceedings. See, e.g., Globe Newspaper Co. v. Superior Court,

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

457 U.S. 596, 603 (1982); see also NBC Subsidiary, Inc. v. Superior Court, 20 Cal. 4th 1178, 980 P.2d 337, 86 Cal. Rptr. 2d 778 (Cal. 1999) (First Amendment right of access applies to civil proceedings); Globe Newspaper Co. v. Pokaski, 868 F.2d 497 (1st Cir. 1989) (First Amendment right of access to records of closed criminal cases); accord Richmond Newspapers, Inc. v. Virginia, 448 U.S. 555 (1980). The constitutional right of access applies regardless of whether the proceedings are criminal or civil in nature. See Richmond Newspapers, 448 U.S. at 580 n.17 (Stewart, J., concurring) ("the First and Fourteenth Amendments clearly give the press and public a right of access to trial themselves, civil as well as criminal"); Publicker Industries v. Cohen, 733 F.2d 1059, 1066 (3rd Cir. 1984) (concluding that Richmond Newspapers analysis applies equally to civil cases). The right is based on the public's fundamental interest in the fair and open administration of justice and extends to all court documents and records, and not just courtroom proceedings. Seattle Times Co. v. United States Dist. Court, 845 F.2d 1513, 1516 (9th Cir. 1988) (pretrial detention documents); Brown & Williamson Tobacco Corp. v. F.C.C., 710 F.2d 1165, 1179 (6th Cir. 1983) (vacating sealing order on documents filed with court).

Beyond the Constitutional mandate of openness to all court proceedings, there is also a common law right of access. As the Supreme Court has stated: "It is clear that the courts of this country recognize a general right to inspect and copy public records and documents, including judicial records and documents." Nixon v. Warner

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

Communications, Inc., 435 U.S. at 597 (1978) (footnotes omitted). This common law creates a "strong presumption in favor of access." San Jose Mercury News v. United States Dist. Court, 187 F.3d 1096, 1102 (9th Cir. 1999). "[A]ccess is particularly appropriate when the subject matter of the litigation is of especial public interest." Welsh v. City and County of San Francisco, 887 F.Supp. 1293, 1297 (N.D.Cal. 1995); see also Doe v. Marsalis, 202 F.R.D. 233, 239 (N.D. Ill. 2001) (court documents presumed public "especially when they concern matters of general concern to the workings of our democratic society"). In Richmond Newspapers v. Virginia, 448 U.S. 555 (1980), the Court noted that the presumption of openness that traditionally has attached to court proceedings in this country "is no quirk of history; rather it has long been recognized as an indispensable attribute of an Anglo-American trial." Id. at 569 (plurality opinion). This time-honored practice is also supported by sound policy considerations. Open judicial proceedings are essential to self-government. As the Court emphasized in Globe Newspaper, access "enhances the quality and safeguards the integrity of the fact-finding process, with benefit to [the litigants] and society as a whole." 457 U.S. at 606 (footnote omitted). Furthermore, access promotes public confidence in our judicial system by assuring the public "that established procedures are being followed and that deviations will become known." See Press-Enterprise Co. v. Superior Court, 464 U.S. 501, 508 (1984) ("Press-Enterprise I").

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

While in some circumstances compelling interests may outweigh the right of access and the interests of the public, the public's right "is not lightly to be deflected." Federal Trade Comm'n v. Standard Fin. Mgmt. Corp., 830 F.2d 404, 410 (1st Cir. 1987). As stated by the U.S. Supreme Court:

> The presumption of openness may be overcome only by an overriding interest based on findings that closure is essential to preserve higher values and is narrowly tailored to serve that interest.

Press-Enterprise Co. v. Superior Court ("Press-Enterprise I"), 464 U.S. 501, 510 (1984). Sealing of records must be rare and only for cause shown that outweighs the value of openness. Press-Enterprise I, 464 U.S. at 509. As the Ninth Circuit held only days ago, the public's constitutional right of access can be overcome only if

> (1) closure serves a compelling interest; (2) there is a substantial probability that, in the absence of closure, this compelling interest would be harmed; and (3) there are no alternatives to closure that would adequately protect the compelling interest.

United States of America v. Ismail Higuera-Guerrero, __ F.3d __ (9th Cir. March 4, 2008), quoting Oregonian Publ'ng Co. v. U.S. Dist. Court, 920 F.2d 1462, 1466 (9th Cir. 1990).

Alaska law evidences an equally strong commitment to ensuring broad public access to judicial records. See Johnson v. State, 50, P.3d 404 (Alaska App. 2002). This strong presumption derives from at least three sources: (1) an open records policy dating

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

back to the case of City of Kenai v. Kenai Peninsula Newspapers, Inc., 642 P.2d 1316 (Alaska 1982); (2) Alaska's open records statute, AS 40.25.110 et seq.; and (3) Alaska Administrative Rule 37.5, which provides that "All public records within the Alaska Court System shall be open to inspection by any member of the public" and which defines such records to include any "document or item filed with the Alaska Court System which contains information relating to the conduct of the public's business." As stated in the legislative findings to the 1990 amendments to the Alaska Public Records Act, public access serves as an important "check and balance" that allows citizens to maintain "control of government." And the Supreme Court's decisions have characterized public access to records as a "fundamental right." Fuller v. City of Homer, 75 P.3d 1059, 1061-1062 (Alaska 2003).

A party wishing to seal documents under Civil Rule 26 has the heavy burden of demonstrating a *compelling* need for doing so. See Foltz v. State Farm Mut. Aut. Ins. Co., 331 F.3d 1122 (9th Cir. 2003) (applying identical Federal R. Civ. P. 26(c)). Indeed, documents should not be kept from the public unless "the disclosure of the documents would cause a clearly defined and very serious injury." Welsh, 887 F.Supp. at 1297 (internal citations omitted). The party must show "specific harm or prejudice that it expects will arise from disclosure" of the particular document, and must support its request by affidavits and concrete examples; unsubstantiated allegations or speculation will not establish prejudice. Id. at 1130, 1131. The fact that the case file may contain

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

unsubstantiated allegations, or may subject a litigant to embarrassment or potential liability is not in itself sufficient to justify placing the documents off-limits to the public. Id. at 1137. Entire documents should not be sealed where mere redaction of sensitive items will satisfy the need for secrecy. Id. Finally, the trial court must make particularized factual findings. These must be sufficiently specific to support meaningful appellate review, and may not rely on hypothesis or conjecture. Id. at 1135.

C. The Sealing of Records Pursuant to the Stipulated Protective Order Violated the Right of Access.

As shown above, the public's right to inspect court records can be overcome only by an overriding, compelling interest as shown by specific, detailed findings—on a document by document basis—of a particular harm that would accompany openness. In assessing whether there exists an overriding, compelling interest, the court must take into account the fact that the subject matter of the litigation raises serious public safety issues and is a matter of intense public interest. The stipulated Protective Order does not include any findings as to particular documents, because it does not relate to specific documents at all, but rather permits the parties to seal any documents the parties deem to be confidential. By allowing the parties to determine what should be sealed or not, the Protective Order turned the right of public access on its head. Furthermore, the Protective Order does not give any consideration to whether means less restrictive than sealing might be sufficient. Even if there may be a compelling, overriding interest in

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

favor of restricting access to certain documents, any such restriction must be narrowly tailored to serve that interest. Redaction and other more limited options may be sufficient to prevent any claimed harm to the litigants or third parties without interfering so drastically with the public's right to know.

IV. CONCLUSION

This is an important case to the public, and the Court should uphold the public's rights of access under the First Amendment, the common law, and Alaska's statutes and rules. The Protective Order does not meet the rigorous requirements for sealing judicial records. Bloomberg News therefore respectfully requests that all records previously filed under seal in this matter be unsealed, and that the provisions of the Protective Order that heretofore permitted the parties to file matters under seal be vacated.

Dated this 7th day of March, 2008.

DAVIS WRIGHT TREMAINE LLP
Attorneys for Bloomberg, LLC,
d/b/a Bloomberg News

By: _____
Jon S. Dawson,
Alaska Bar Assoc. # 8406022

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

Certificate of Service:

I certify that on March 7, 2008, and a true and correct copy of the foregoing document was sent to the following attorneys or parties of record by:

( ) Mail
( ) Facsimile and Mail
(X) Hand Delivery

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

Brewster H. Jamieson, Esq.
Lane Powell LLC
301 W. Northern Lights Blvd., Ste. 301
Anchorage, AK 99503

Janet Eastman

Davis Wright Tremaine LLP
LAW OFFICES
Suite 800 · 701 West 8th Avenue
Anchorage, Alaska 99501
(907) 257-5300 · Fax: (907) 257-5399

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

Filed in the Trial Courts
STATE OF ALASKA, THIRD DISTRICT
JAN 25 2008
Clerk of the Trial Courts
By _____ Deputy

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

NOTICE OF FILING SUPPLEMENTAL EXHIBITS IN OPPOSITION TO LILLY'S MOTION FOR SUMMARY JUDGMENT UNDER SEAL

On this date the State of Alaska is filing a pleading titled "Notice of Filing Supplemental Exhibits in Opposition to Lilly's Motion for Summary Judgment." Because the exhibits filed with these pleadings may be confidential documents under the Court's April 6, 2007 oral ruling, the State of Alaska is submitting the attached exhibits under seal.

/

/

/

Sealed envelope / Separate

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

005474

DATED this 25 day of January, 2008.

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
David L. Suggs
Christiaan A Marcum
Counsel for Plaintiff

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 **Notice of Filing Supplemental Exhibits In Opposition to Lily's Motion For Summary Judgment Under Seal** was served by messenger on:

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

Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By Annette R. Carter
Date 1-25-08

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