SOA

3AN-06-05630CI Volume: 010
Volume 010
State of Alaska vs. Eli Lilly & Co

ELI Lilly + CO

Volume 10

CIVIL

Begun: 2-23-08
end: 2-28-08

ON APPEAL

Appeal to COA/Supreme

Please Return to Appeals Clerk

AP-475 (6/90) (TCB green-remov.)(4¼"x2")
APPEAL ID LABEL

PLAINTIFF'S ATTORNEY

DEFENDANT'S ATTORNEY

TYPE OF PROCEEDING

MASTER ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED

JUDGE ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED
Rindner	3/1/06		

FILING FEE RECEIPT# _____

INDEXED _____

OTHER _____

15764

CV-E-A

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 AMENDED PAGE/LINE DESIGNATIONS

In response to Defendant's counter designations and objections, Plaintiff hereby amends its deposition designations as follows:

BRUCE KINON
JULY 10, 2006

START PAGE/LINE	END PAGE/LINE
27:18	27:20
27:23	28:5
31:11	31:13
35:20	36:6
45:6	45:14
46:15	46:24
47:11	47:13
47:20	47:22
51:11	51:18
51:21	52:8
53:3	53:5

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53:6	53:10
53:13	53:24
61:9	61:11
61:17	61:22
62:3	62:20
64:17	65:18
65:19	65:19
69:16	69:18
69:21	70:7
71:8	71:17
71:20	72:12
72:15	72:15
72:21	72:24
73:3	73:16
76:24	78:16
81:22	82:3
82:19	83:1
83:9	84:4
84:7	84:15
84:18	84:18
84:19	84:21
85:2	85:8
89:20	90:4
92:16	92:23
101:23	102:9
102:14	104:5
104:8	104:13
104:16	104:24
134:12	134:15
134:18	134:22
135:3	137:2
137:5	139:10
139:13	139:15
139:18	140:14
235:13	235:16
235:19	236:3

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236:21	237:16
238:3	238:8
242:3	242:17
242:20	242:20
244:16	244:19
244:22	245:1
245:6	245:11
247:13	248:19
248:22	249:24
250:3	251:8
257:12	257:17
257:20	259:6
259:9	259:18
259:21	260:1
260:4	260:23
261:2	261:14
261:17	261:21
262:14	262:24
263:3	263:17
264:12	265:10
265:12	265:15
265:18	266:2
266:5	266:6

DATED this 28th day of February, 2008.

FELDMAN, ORLANSKY & SANDERS
Counsel for Plaintiff

By_____
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I hereby certify that a true and correct copy of **Plaintiff's Amended Page/Line Designations – Kinon** was served by messenger on:

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George Lehner
Hotel Captain Cook

Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By Peggy S Crowe
Date 2/28/08

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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 MEMORANDUM IN SUPPORT OF ITS NOTICE OF DEPOSITION OF JOEY ESKI

On November 21, 2007, the State of Alaska noticed the deposition of Joey Eski for December 13, 2007. Pursuant to a request of Defendant Eli Lilly and Company ("Lilly"), the deposition was re-noticed for February 28, 2008.[1] Despite the planning of the parties in preparation for this previously scheduled and noticed deposition, Lilly unilaterally canceled the deposition on the eve of it, without any motion seeking protection, unilaterally "ruling" that the Court's rulings on summary judgment somehow rendered the deposition testimony irrelevant. The State made it clear it objected to the cancellation,[2] and this morning showed up at the properly noticed deposition prepared to go forward. The witness was not present, and the State was informed that Lilly would

[1] Exhibit A, Notices of Deposition dated November 21, 2007 and February 13, 2008.

[2] Exhibit B, emails February 27, 2007, regarding State's objection to the unilateral cancellation.

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not produce her. Lilly's actions are completely inappropriate and contrary to the Rules of Civil Procedure. For that reason alone, the deposition should proceed at a place and time set by the State as soon as practicable.

Lilly's remedy, were it even conceivably correct, was not to unilaterally cancel the deposition without seeking protection from the Court. Rather, the deposition should proceed as noticed, and Lilly can seek the exclusion of the testimony by the Court if indeed the testimony is subsequently determined to be irrelevant. Whether the State is entitled to the deposition should be measured by the Rules of Civil Procedure. Those rules provide that, generally, "Parties may obtain discovery regarding any matter, not privileged which is relevant to the subject matter involved in the pending action,...."[3] They further provide that, "The information sought need not be admissible at trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence."[4] The relevance, and therefore admissibility, of this deponent's testimony can only be measured by the testimony itself. After the testimony is taken, the Court, not Lilly, will be able to decide if the testimony is admissible.

Importantly, the State will prove Ms. Eski's testimony is relevant and admissible evidence that goes to the heart of the State's claims that Lilly failed to properly warn of Zyprexa's risks. In a brief filed yesterday by Lilly in response to a pending motion in limine, Lilly itself stated that, "Whether that duty [to warn] was fulfilled depends on all

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[3] Alaska R. Civ. Pro. 26(b)(1).

[4] *Id.*

the information communicated by the manufacturer,... ."[5] As a sales representative of Lilly, Ms. Eski is a "speaking label." Sales representatives are prohibited by Lilly's Good Promotional Practices from proactively discussing, presenting or promoting any information which is not consistent with the product's label, including safety information.[6] Therefore, what Eski said and did regarding the label in the offices of Alaska physicians is highly relevant and probative on whether Lilly adequately warned of Zyprexa's risks. What she said and did regarding the label is inextricably intertwined with the labeling itself. For example, were her communications with Alaska physicians consistent with the label? Were they contrary to the label or did they vary from it? Did she communicate adverse reactions as warnings or therapeutic benefits? Did she minimize risks of adverse events as reflected in Exhibit D?[7]

For the foregoing reasons, among others which we can articulate at the hearing should the Court desire, the Court should order the deposition of Joey Eski to proceed at a place and time set by the State.

---

[5] Defendant Eli Lilly and Company's Opposition to Plaintiff's Motion to Preclude Testimony or Argument That Zyprexa's Labeling "Warned" of Diabetes, Hyperglycemia or Weight Gain, 1.

[6] Exhibit C, Lilly USA Sales Good Promotional Practices (Exhibit 8 to the Deposition of David Thomas Noesges, January 11, 2008).

[7] Exhibit D, Plaintiff's MDL Exhibit Number 1169.

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DATED this 28th day of February, 2008.

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Certificate of Service

I hereby certify that a true and correct copy of **Plaintiff's Memorandum in Support of Its Notice of Deposition of Joey Eski** were served by messenger on:

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

George Lehner
Captain Cook

Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By Peggy J. Crowe
Date 2/28/08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

NOTICE OF VIDEOTAPED DEPOSITION

PLEASE TAKE NOTICE that pursuant to Rules 26, 30 and 30.1 of the Alaska Rules of Civil Procedure, Plaintiff State of Alaska will take the deposition upon oral examination of **JOEY ESKI** at 9:00 A.M. on Thursday, December 13, 2007, at the offices of Ice Miller, LLP, One American Square, Suite 3100, Indianapolis, Indiana 46282. The deposition will be taken before a Notary Public or some other person authorized by Rule 28 of the Alaska Rules of Civil Procedure to administer oaths and it will be recorded stenographically and videotaped.

DATED this 21 day of November, 2007.

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Counsel for Plaintiff

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Joseph W. Steele
Counsel for Plaintiff

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Counsel for Plaintiff

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Notice of Videotaped Deposition – Joey Eski
was served by mail / messenger / facsimile 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 Peggy S Crowe
Date 11/26/07

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

RE-NOTICE OF VIDEOTAPED DEPOSITION

PLEASE TAKE NOTICE that pursuant to Rules 26, 30 and 30.1 of the Alaska Rules of Civil Procedure, Plaintiff State of Alaska will take the deposition upon oral examination of **JOEY ESKI** at 9:30 A.M. on Thursday, February 28, 2008, at the offices of Lane Powell, LLC, 301 West Northern Lights Boulevard, Suite 301, Anchorage, Alaska 99503. The deposition will be taken before a Notary Public or some other person authorized by Rule 28 of the Alaska Rules of Civil Procedure to administer oaths and it will be recorded stenographically and videotaped.

DATED this 13th day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

By _____
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Counsel for Plaintiff

Certificate of Service
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Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By Peggy S. Crowe
Date 5/13/08

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Mary Beth Rivers

From: Christiaan Marcum **Sent:** Thu 2/28/2008 2:34 PM
To: Mary Beth Rivers
Cc:
Subject: FW: Exhibit List
Attachments:

From: David Suggs [mailto:dsuggs@attglobal.net]
Sent: Wed 2/27/2008 9:14 PM
To: 'Lehner, George A.'
Cc: Blair Hahn; 'Tommy Fibich'; sallen@crusescott.com; Christiaan Marcum
Subject: RE: Exhibit List

George –

We will meet you in the lobby now. However, if anybody needs to go the Judge it is Lilly. We are standing on our notice of deposition and it is up to you file a motion to quash or obtain other appropriate relief.

In the future on this issue, please copy Scott Allen.

From: Lehner, George A. [mailto:lehnerg@pepperlaw.com]
Sent: Wednesday, February 27, 2008 8:05 PM
To: dsuggs@attglobal.net
Subject: Re: Exhibit List

Dave -

We have a clear disagreement about what the scope of the Judge's ruling and it's impact on the case. Can you meet at 5:15 in the lobby. Bring whomever else you like. You may need to go to the Judge if we can't get this clarified.

George.

----- Original Message -----
From: David Suggs <dsuggs@attglobal.net>
To: Lehner, George A.
Cc: TFibich@FHL-Law.com <TFibich@FHL-Law.com>; 'Eric Sanders' <sanders@frozenlaw.com>; 'Scott Allen' <sallen@crusescott.com>; bhahn@rpwb.com <bhahn@rpwb.com>; JamiesonB@LanePowell.com <JamiesonB@LanePowell.com>
Sent: Wed Feb 27 20:55:40 2008
Subject: RE: Exhibit List

P.S. If you still intend not to produce Ms. Eski, you should make arrangements for contacting Judge Rindner in advance for an emergency hearing.

From: David Suggs [mailto:dsuggs@attglobal.net]
Sent: Wednesday, February 27, 2008 7:40 PM
To: 'Lehner, George A.'
Cc: 'TFibich@FHL-Law.com'; 'Eric Sanders'; 'Scott Allen'; 'bhahn@rpwb.com'; 'JamiesonB@LanePowell.com'
Subject: RE: Exhibit List

George –

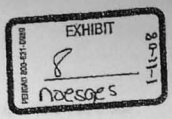
I seriously doubt that the Court's ruling will have much, if any impact, on the extent of the documentary evidence we offer at trial as much of it is relevant and admissible for more than one purpose. In any event, I am much more concerned about getting pre-admission of documents for opening statements and our first two witnesses next week as requested by the Court than I am in amending exhibit lists. Please get us the list you promised us this morning as soon as possible.

On another more time critical matter, I was just now informed that we have received a letter signed on behalf of Brewster Jamieson that Lilly will not be producing Joey Eski for her deposition tomorrow morning despite the fact that her deposition was duly noticed on that date per Lilly's request. I tried to call Brewster Jamieson about this and was listening to his voice mail tell me he was unavailable when I received your email below so I am responding to both you and Brewster in this email. Be advised that we intend to take the deposition of Ms. Eski tomorrow morning at 9:30 at Brewster's office as previously noticed because her testimony is highly relevant to the remaining causes of action. We expect and demand to take her deposition tomorrow morning and if you do not produce her we will seek appropriate sanctions from the Court.

From: Lehner, George A. [mailto:lehnerg@pepperlaw.com]
Sent: Wednesday, February 27, 2008 7:09 PM
To: dsuggs@attglobal.net; Tommy Fibich
Subject: Exhibit List

Dave/Tommy - In light of the Judge's ruling today, we will be amending our response to your exhibit list that I sent you today. I assume as well that you will be removing documents from the list.

George



LillyUSA
SALES GOOD PROMOTIONAL PRACTICES
ELI LILLY AND COMPANY
UNSOLICITED QUESTIONS ON OFF-LABEL INFORMATION OR UNAPPROVED PRODUCTS
GPP 02-004

Objective: To provide sales personnel with a policy and procedures regarding how to handle unsolicited questions for off-label information or unapproved products in order to ensure compliance with all applicable laws, regulations, and company policies.

Scope: This GPP applies to all sales personnel and sales support personnel in LillyUSA and all sales activities that take place in the United States or with US Healthcare Professionals.

Policy Statement: It is the policy of Eli Lilly and Company to comply with FDA regulations that prohibit the promotion of any unapproved new product; or indication, dosage form, and/or dosing schedule for any marketed product, with any customer by sales and marketing personnel, or other Lilly personnel or representatives in a promotional context.

Definitions:
Healthcare Professional: A Healthcare Professional is defined as any physician, physician's assistant, nurse, nurse practitioner, diabetes nurse educator, clinical investigator, pharmacist, Pharmacy and Therapeutics Committee ("P&T") member, social worker, case worker, dietitian, office staff, or any individual involved in prescribing, P&T, access, formulary, purchasing and/or reimbursement decisions.

Off-label Information: Any information about a Lilly product that is not contained in or is not consistent with the package insert labeling approved by the FDA. Examples include, but are not limited to, indications, dosage forms, dosing schedules, combination therapy, and safety information.

Procedure:

Sales Personnel *MAY NOT*:

Proactively discuss, present, or promote information concerning unapproved new products or off-label information about approved products with any customer or health care professional.

However, Sales Personnel *MAY*:

Respond orally to unsolicited requests for pre-approval or off-label product information, but only if all of the conditions below are strictly observed:

- The response is made to a customer-generated, specific question. The question from the customer cannot be prompted in any manner
- If a broad, general question is posed, ask the customer to narrow the inquiry
- Do not get drawn into detailed discussions of an off-label use. Route detailed questions back to Lilly's Customer Service Group for a medical letter response
- Before you respond you must advise the customer that their question is about an OFF-LABEL or NOT APPROVED topic and if appropriate, remind them of that drug's FDA-authorized indication(s) and/or dosage and other relevant labeling information. Example: "You will note [drug name] is not indicated for _____; it is indicated for _____."
- If the HCP's specific request is covered in a Brand-approved verbatim, that response must be used. It is the responsibility of the sales force to know any specific Brand

verbatims and instructions about how to handle unsolicited questions. Any Brand verbatims and instructions will be found on KM

- If a Brand verbatim or other instructions are not available and the sales force knows the answer, a reply specific to the question asked may be given, but cannot be promotional
- The reply must be made only to the individual asking the question; others should not be able to hear the conversation
- Sales personnel must not volunteer additional information except within approved labeling
- Add fair balance (safety information) if relevant
- Sales personnel must also offer the HCP the option of a medical letter request as a supplement to the representative's verbal response.

If there is no Brand verbatim and sales personnel does not know any other information related to the question, the sales force must request a medical letter to respond to the health care professional's unsolicited question.

Medical Letters can be requested by one of the following methods:

a. Call Sales Services (1-800-222-INDY) to request that a medical letter response be sent to the requester;
b. Request a Medical Letter response be sent to the requester in the customer call section of Premier Force.

Policy Owner: Director of Compliance for Sales

Effective Date: 1/15/04

Version 3

NOTE: If you are using a printed copy of this document, check that the version number is consistent with the current version number in KM.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

Charles R. Perry Jr.
Director
Pharmaceutical Communications and Compliance
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

NOV 14 1996

RE: NDA# 20-592
Zyprexa (olanzapine)
MACMIS ID # 4682

Dear Mr. Perry:

This concerns a number of labeling pieces for Zyprexa identified as a multi-page detail aid, OL-0026; Stat-Grams identified as OL-0077 and OL-0078; a letter to the California Department of Health Sciences (assumed to be an example of similar letters to other states) with an attached backgrounder; and a "John Q. Public" letter, all submitted as required with a form FDA 2253 and also found during normal surveillance activities. This also concerns other promotional activities, such as, an interactive teleconference held on or about October 2, 1996. The Division of Drug Marketing, Advertising and Communications (DDMAC) considers these promotional labeling pieces, and promotional activities to be false or misleading, and in violation of the Federal Food, Drug, and Cosmetic Act (Act).

The promotional campaign, including the above identified labeling pieces and others submitted with the form 2253s, is lacking in appropriate balance, thereby creating a misleading message about Zyprexa. The promotional materials emphasize efficacy data but do not provide sufficient balance relating to adverse events and cautionary information. Further, they do not adequately or prominently discuss several important adverse events specifically selected for emphasis in the approved labeling. These events include orthostatic hypotension, seizures, transaminase elevations, weight gain, dizziness, and akathisia.

A. Specifically, the referenced detail aid, OL-0026, is in violation of the Act in the following particulars:

1. On page fifteen, in the summary of the Safety Profile for Zyprexa, several of the bulleted statements are considered to be misleading:

ZYP 478 414

a. "Avoids clinically significant changes in orthostatic blood pressure." This statement is misleading because the approved labeling includes a lengthy discussion of orthostatic hypotension, including syncope, caused by Zyprexa and suggests this event can be minimized by starting with a 5mg QD dose. In addition, Lilly has failed to provide information that dizziness occurs in 11% and postural hypotension occurs in 5% of patients.

b. "Transient, asymptomatic elevations in hepatic transaminases." This is misleading because the approved labeling states about 1% of patients discontinued treatment because of elevated transaminases, and states caution should be exercised in patients with hepatic impairment. While a footnote on this page mentions that periodic reassessment of transaminases is recommended in patients with hepatic disease, this footnote does not provide sufficient balance for this claim. The entire thrust of this campaign is to point out that Zyprexa is different and safer than older antipsychotic drugs. Therefore, it is necessary to properly emphasize those adverse events that do occur, that require caution when using Zyprexa.

2. On page three, the last bulleted statement reads, "Patients with intolerance to other antipsychotics because of extrapyramidal or other adverse reactions." This statement is misleading because it lacks proper balance and does not accurately reflect the information in the approved labeling. For example, the labeling reports a dose related increase in extrapyramidal symptoms, and tardive dyskinesia is listed as a Warning and as a frequent adverse event.

3. The subheadlines, "Outstanding control over the Combination...," "Outstanding Control of Positive Symptoms," and "Outstanding Control of Negative Symptoms" appear on pages four, six, and eight, respectively. These subheadlines are regarded as implications of superiority over other antipsychotic products that are unsubstantiated. While DDMAC does not question the efficacy of Zyprexa or its ability to "control symptoms," terms such as "outstanding" are usually interpreted as claims of superiority and, as such, must be adequately supported.

ZYP 478 415

4. On page twelve a discussion of adverse events appears. In the listing of other commonly observed adverse events, tardive dyskinesia is not included. The approved labeling lists tardive dyskinesia as both a Warning and as an adverse reaction occurring frequently, being defined as at least 1/100 patients (1%). It also minimizes the dose related increases in all extrapyramidal symptoms, e.g. 25% at 10mg., and 32% at 15mg. versus 16% for placebo.

5. On page 16, the bullet "No dosage adjustments for most elderly" is misleading. The approved labeling states that caution should be used in dosing the elderly, especially if there are other factors that might additively influence drug metabolism and/or pharmacodynamic sensitivity. However, the bullet suggests that dosing is simple and easy and does not convey any cautionary information.

6. On page 19, the presentation of Zyprexa's pharmacologic profile is misleading. The labeling states that the mechanism of action is unknown and provides proposed theories of the drug's activities. However, Lilly has presented Zyprexa's activity as a fact and implies that there are less adverse events, such as extrapyramidal motor function, due to the selective action. However, a low incidence of extrapyramidal effects is not due to selective modulation of pathways implicated in schizophrenia.

   Further, Lilly has selectively chosen to present Zyprexa's more beneficial proposed actions and has not included, for example, that the drug antagonizes α-adrenergic receptors, thus explaining its orthostatic hypotension effects. In addition, the claim that Zyprexa is a selective modulator in the first three bullets is inconsistent with the claim in the last bullet that Zyprexa demonstrates broad pharmacologic activity.

   It should be emphasized that the pharmacological action of Zyprexa to alleviate psychotic symptoms is unknown.

The other labeling pieces identified above contain one or more of the violations enumerated above. They all are lacking in balance relating to adverse events and precautionary information, and present a misleading impression of Zyprexa as a superior, highly effective, virtually free of side effects, easy to use product. This impression is contrary to the approved labeling.

ZYP 478 416

Charles R. Perry, Jr.
Eli Lilly & Co.
NDA 20-592

B. The Interactive Teleconference held on or about October 2, [illegible]ary D. Tollefso[illegible] Vice President of Lilly Research Laboratories, is misleading [illegible] particulars:

1. Dr. Tollefson states that the therapeutic effects of Zy[illegible] are maintained over at least one year. The approved labeling states the effectiveness of the product was only established in short-term (six week) studies. Therefore, for any use over six weeks, the physician should periodically re-evaluate the long-term effectiveness of Zyprexa. However, this cautionary information for the indication is never presented in the teleconference.

2. The possibility of tardive dyskinesia, the fact that it is in the Warnings section and its incidence as a frequent adverse event, as discussed in the approved labeling, is minimized by Dr. Tollefson's statements, such as, "...we've been able to show that there is a statistically and significantly lower incidence of this neurological side effect with Zyprexa than with conventional drugs." Thus, Dr. Tollefson's statements are misleading because he does not go on to discuss the incidence of tardive dyskinesia, which is listed both as a Warening and as a frequent adverse reaction in the approved labeling, or discuss other extrapyramidal symptoms, such as akathisia, with Zyprexa. These symptoms have an extensive discussion in the approved labeling.

3. Dr. Tollefson states, "We are very pleased that the labeling in the U.S. will show by objective rating scales that both Parkinsons-like side effects and restlessness, or akathisia, the incidence across all doses of Zyprexa was comparable to placebo." This statement is misleading because the table in the approved labeling that lists adverse effects shows that the incidence of both Parkinsonian symptoms and akathisia increase well above placebo as the dosage increases.

4. Dr. Tollefson states that, "...Zyprexa is a unique molecule in that it is a compound with very, very low risk of drug/drug interactions. And this is something that will be featured, or highlighted in the labeling.". While the labeling states there is little risk of drug interactions, and few have been observed in clinical trials, the labeling cautions that coadministration of diazapam or ethanol with olanzapine potentiates orthostatic hypotension. This drug interaction precaution is not discussed, nor is orthostatic hypotension discussed, in any form during the presentation.

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5. When asked a question about weight gain, Dr. Tollefson's response misleadingly turned an adverse event into a therapeutic benefit. He states, "So we went back and analyzed our data and saw that the vast majority of weight gain reported initially as an adverse event, in fact, was weight gain occurring in patients who had baseline before starting treatment, had been below their ideal body weight. **So we really look at this, with the majority of patients, as being part of a therapeutic recovery rather than an adverse event. And that data, I think is fairly compelling, because it was included in our labeling.** (Emphasis added)"

   The information on weight gain was indeed included in the approved labeling, but as an adverse event, not a therapeutic benefit. Since the product was approved at the time of this teleconference, Dr. Tollefson knew or should have known what information the approved labeling contained and in what section it appeared. His statements were therefore, false and misleading.

6. Dr. Tollefson states, "So the routine starting dose on day one will be ten milligrams." He made no mention of the possible need for starting at a lower dose, or what populations might need caution when initiating therapy as described in the approved labeling. He did not discuss the possible need for dosage titration in certain populations.

These promotional labeling pieces and the teleconference are considered to be false and misleading and in violation of the Act. DDMAC requests the following actions:

1. Immediately discontinue the use of all promotional labeling pieces, and cancel all advertisements containing any of the false and/or misleading statements discussed above.

2. Provide DDMAC with a complete listing of all advertisements and labeling pieces that will be canceled, and those that will continue in use. Also provide copies of these various pieces to DDMAC.

3. Provide DDMAC with a listing of all state formulary committees, health care groups' formulary or therapeutics committees, hospital therapeutics or formulary committees, or any other body engaged in the selection for inclusion or exclusion of drug products from their respective formularies or drug lists, that Lilly provided information similar to that discussed above.

ZYP 478 418

4. Provide a written statement that Lilly will agree to number 1 - 3 above, no later than November XX, 1996.

If Lilly has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Lilly that only written communications are considered official.

In all future correspondence regarding this specific issue, please refer to the MACMIS ID # 4782, in addition to the NDA number.

Sincerely,

Kenneth R. Feather

Kenneth R. Feather
Senior Advisor
Division of Drug Marketing,
Advertising and Communications

ZYP 478 419

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

REQUEST TO PROHIBIT CORRESPONDENCE TO JUDGE

At approximately 10:00 a.m. this morning, undersigned counsel received by email a copy of a letter written to this Court by George Lehner. (A copy is attached.) It is the practice in Alaska that matters presented to the Court be in the form of pleadings. Accordingly, the State of Alaska requests that the Court order that the parties not submit correspondence to the trial judge.

DATED this 28th day of February, 2008.

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Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of
Request to Prohibit Correspondence to Judge and (proposed) Order were served by messenger on:

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George Lehner
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Barry Boise, via email (boiseb@pepperlaw.com)
Pepper Hamilton

By Peggy S Crowe
Date 3/28/08

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February 28, 2007

VIA HAND DELIVERY
The Honorable Mark Rindner
Alaska Court System
825 West Fourth Avenue, Room 432
Anchorage, Alaska 99501-2004

Re: State of Alaska v. Eli Lilly and Company
Case No. 3AN-06-05630 CI

Dear Judge Rindner:

We are writing on behalf of our client Eli Lilly and Company. It is apparent that we have a substantial disagreement with the plaintiff about the scope of your summary judgment ruling and its impact on the remaining issues in this case.

Your Honor held that "acts and practices promoting off-label uses and **advertising improperly**" are prohibited by federal regulation and are therefore subject to the exemption provision of the Alaska Unfair Trade Practice Consumer Protection Act. See Rough Transcript of Hearing, February 27, 2008, page 7 (emphasis added).

In addition, as discussed at oral argument on February 26, 2008, the Code of Federal Regulations (21 CFR 202.1(e)(5)(i), among other provisions) provides that making misstatements about safety in an advertisement is unlawful and subject to penalties that may be imposed by Federal authorities. As the court noted, "advertisements" – as that term is used in the CFR – encompass a broad range of marketing and sales activities, including calls by sales representatives.[1]

Since any claimed misstatements about a drug – regarding its safety or anything else – by a sales representative would be a violation of federal law, claims based on such statements are, as the Court ruled, exempted by the UTPCPA.

Based on the Court's ruling, it is our understanding that the sole remaining issue to be tried, under both the UPTCPA and common law failure to warn theories, is whether the label that accompanies Zyprexa adequately describes the risks that may be associated with the use of the product. Under the bifurcation plan ordered by the courts, other

[1] In addition, the Court cited with favor *Pennsylvania Employees Benefit Trust Fund vs. Zeneca, Inc.* 499 F.3d 239, which held that "advertisements also come in the form of physician-directed pitches by sales representatives..." (Citing 21 C.F.R. 202.1(l)(1)).

information that doctors considered about the risks and benefits of Zyprexa, whether from the company or otherwise, will be considered in Phase II.

In light of the Court's ruling, we elected to remove a Lilly sales representative (Joey Eski) from our witness list, as the marketing conduct she would have testified about is no longer part of the case. We immediately informed plaintiff's counsel that there would be no reason to proceed with her deposition that was scheduled for February 28th. (We note that Ms. Eski did not appear on plaintiff's Preliminary, Final, Expert or Supplemental witness list). After we informed plaintiff's counsel that we were removing her as a witness, the State supplemented its list, late Tuesday evening, listing her as a trial witness, and objected to cancelling Ms. Eski's deposition.

During a brief meet and confer relating to the deposition that we initiated with plaintiff's counsel, it became clear that the State reads Your Honor's decision as permitting introduction of all manner of evidence relating to sales representatives' interactions with physicians which, as we understand, is irrelevant to the remaining claims. The State has previously asserted that it will prove label-based violations of the UTPCPA through evidence of the number of prescriptions written (a position Lilly strenuously disagrees with), not sales representatives' interactions with doctors, or advertisements. Accordingly, the testimony of sales representatives, and much other marketing-related evidence, is irrelevant to the State's remaining claims.

We appreciate that the Court's calendar is very tight, and we regret having to seek such clarification at this point. However, plaintiff's insistence that they will proceed to introduce evidence that goes beyond its remaining claims necessitates such clarification. Accordingly, we will file a brief today seeking guidance from the Court and a conference at the Court's earliest convenience.

Respectfully submitted,

George A. Lehner

GAL/er

cc: Eric Sanders, Esquire
David Suggs, Esquire
Joseph W. Steele, Esquire
Brewster H. Jamieson, Esquire

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 STATE OF ALASKA'S
SUPPLEMENT TO FINAL WITNESS LIST

Plaintiff, State of Alaska, hereby supplements its Final Witness List with the addition of the following witnesses. Plaintiff reserves the right to amend this witness list and the right to call additional witnesses at trial. If other witnesses to be called at the trial become known, their names, addresses, and phone numbers will be reported to opposing counsel in writing as soon as they are known; this does not apply to rebuttal or impeachment witnesses.

1. Joey Eski
c/o Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285
(317) 276-2000

2. Any corporate representative of Eli Lilly and Company appearing at trial.

3. Any witnesses identified by Eli Lilly and Company.

DATED this 21st day of February, 2008.

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Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff State of Alaska's Supplement to Final Witness List** was served by messenger on:

Brewster H. Jamieson
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301 West Northern Lights Boulevard, Suite 301
Anchorage, AK 99503-2648

George Lehner, via hand delivery

By_____

Date 2-27-08

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

MOTION FOR CLARIFICATION OF THE COURT'S FEBRUARY 27, 2008 ORDER GRANTING PARTIAL SUMMARY JUDGMENT TO LILLY

1. Yesterday, the Court granted in part Eli Lilly and Company's ("Lilly") supplemental motion seeking dismissal of the State's claims pursuant to the UTPCPA exemption and federal preemption, dismissing the State of Alaska's ("the State's") UTPCPA claims concerning Lilly's alleged marketing activity, but denying the motion as it related to Zyprexa's labeling. Lilly understands the Court's ruling to eliminate all of the State's claims that Lilly improperly promoted Zyprexa, leaving as the only question to be resolved during the first phase of trial whether Zyprexa's labeling adequately described the risks of the medication. However, the State has verbally advised Lilly that it interprets the Court's Order much more narrowly, to apply only to off-label promotional activity, preserving UTPCPA claims based on marketing activity relating to safety issues. The very terms of the Court's ruling, the rationale that the Court applied in reaching its ruling, and the federal regulatory framework concerning pharmaceutical advertising militate against parsing this Court's ruling

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this way. Lilly requests that the Court issue a written Order, clarifying that all Lilly promotional activity is exempt from the UTPCPA. This clarification is necessary to resolve the admissibility of many of the State's proposed exhibits and designated testimony, and to guide the parties' final preparation for trial.

2. The parties' conflicting interpretations became clear last night, when Lilly removed Joey Eski, a Lilly sales representative who would have testified about Lilly marketing in Alaska, from its final witness list, and cancelled her deposition. (The State had not identified Ms. Eski on its preliminary or final witness lists). This precipitated a meet and confer between counsel for Lilly and the State, during which the State argued that the Court dismissed only its claims of off-label promotion, leaving unscathed its UTPCPA claim that Lilly sales representatives improperly promoted the safety of Zyprexa.

3. Lilly's interpretation that all claims based on promotional claims are dismissed is consistent with how the State has presented its claims, with how Lilly *asked* the Court to rule, and with how the Court *did* rule. The State framed its marketing-based UTPCPA claims as follows: "it was … a separate violation of the Act for any sales call in which the sales representative minimized the hazards with weight gain and diabetes, misrepresented the facts about the drug, or improperly promoted the drug off-label."[1] When Lilly submitted its supplemental brief seeking dismissal of the State's claims pursuant to the

[1] Pl's Supp. Resp. to Def.'s Fourth Set of Interrog. No. 66, at 6, Jan. 24, 2008.

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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 . . . ."[2] Neither party ever argued that the exemption applied differently to allegedly improper marketing relating to safety and efficacy 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."[3] Having completed its discussion of the exemption's application to promotional claims, the Court then proceeded to address its application to the product's label.[4] While the Court did refer specifically to off-label promotion several times, there was no suggestion by the Court that there was some third category – non-off-label marketing – that remained unaddressed by its rulings.

4. Nor would it make sense to splice 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 yesterday's hearing that it was dismissing the State's claims involving call notes because improper advertising, including visits by sales

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

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

[4] *Id.* at 9:18.

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representatives, is regulated and prohibited by the federal government.[5] The same regulatory prohibition that prohibits promotion for non-indicated uses, 21 C.F.R. 202.1(e)(6), 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]

As the foregoing illustrates, not only do the regulations prohibit misleading safety promotion in the same way as promotion for non-indicated uses, 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 advertising as it does for advertising for non-indicated uses.

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

[6] 21 C.F.R. § 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.

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5. Application of the Court's decision to all marketing claims is also consistent with the Third Circuit's decision in *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 this Court's rationale all apply across the board to all marketing and advertising claims, not just off-label promotion.

CONCLUSION

For the foregoing reasons, Lilly requests that the Court enter an Order, confirming that its summary judgment ruling applies to all marketing conduct, including safety-related marketing.

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[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.

DATED this 28th day of February, 2008.

PEPPER HAMILTON LLP
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George A. Lehner, admitted *pro hac vice*
John F. Brenner, admitted *pro hac vice*
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and
LANE POWELL LLC
Attorneys for Defendant

By _____
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I certify that on February 28, 2008, a copy of the foregoing was served by hand on:

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

PRETRIAL HEARING
BEFORE THE HONORABLE MARK RINDNER

February 27, 2008

A-P-P-E-A-R-A-N-C-E-S

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PROCEEDINGS

THE COURT: Please be seated.

We're back on the record in State of Alaska versus Eli Lilly & Company, 3AN-06-05630 Civil.

Present in the courtroom we've got Mr. Allen, Mr. Fibich, Mr. Sniffen and Mr. Sanders with Mr. Garrison telephonic.

Can you hear us okay, Mr. Garrison?

MR. GARRISON: Yes, Your Honor.

THE COURT: And for the Defendants we've got Ms. Gussack, Mr. Lehner and Mr. Jamieson.

Before me are two motions for summary judgment or -- I guess to be more accurate an original motion and then a supplemental motion that have been filed by Eli Lilly. The original motion was based on the November 26, 2007 decision in the Rezulin products liability litigation which held that the fraud-on-the-market theory did not apply to a products liability case involving issues of drugs. That motion was opposed by the State, and argument was held on that motion.

Subsequent to the filing of that

motion, a supplemental motion was filed by Lilly. After the State disclosed the basis for its claims under the Alaska Consumer Protection Act, the State indicated that it was basing that claims and was alleging that the communications that violated the State Act involved two classes of -- of evidence. One, that product labels that had previously been approved by the FDA and which accompanied each prescription for Zyprexa that were issued in the state violated the Act. And, second, that call notes and other evidence showing the promotion of off-label uses by representatives of Lilly also violated the Consumer Protection Act. Based on that disclosure, Lilly filed a supplemental motion which, quite candidly, I'll characterize as a much more substantive, in my mind, motion and -- claiming several things.

First, Lilly claimed that the exemptions for UTP -- for the Alaska Consumer Protection Act claims that are set out in AS 45.50.481 applied to that type of claims, and that, therefore, the allegations made by Plaintiffs as to UTPA violations were exempt from a UTPA claim under the statute.

Second, Lilly argued that the UTPA claims are preempted under federal law under the doctrine of conflict preemption, and that that applied both as to the product label claims, but also to the call note and other claims, and Lilly further asserted that the common-law products liability warning claims were also preempted as a matter of federal law under conflict preemption.

Again, as I indicated yesterday, I will try to give you a decision on this in somewhat of a coherent fashion, but I think you want to know the bottom line ultimately more than you need a pretty decision from me. And I'm quite aware that these issues are not likely to -- I'm not likely to have a final decision in, and quite frankly, I doubt that even the Alaska Supreme Court will have a final decision.

I want to start with some, basically, law principles that I've applied in trying to reach a conclusion on these issues. First, whether the Alaska Consumer Protection Act exemption applies. I looked to the test of Smallwood versus Central Peninsula Hospital at 151 P. 3d. 319-329 Alaska 2006. I also recognize under the O'Neal case and the Smallwood case that

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the UTPA is to be afforded a liberal construction in light of its remedial purposes.

As to preemption and determining the laws and the rules that apply to preemption, I looked to the test enunciated in Cipollone versus Liggett which describes the various -- versus Liggett Group, Incorporated, that's 505 US 504, 1992 -- which indicates the three different types of preemption that applies that -- that this is a case not where neither field preemption or express preemption is alleged; rather, it is a case that conflict preemption applies. I note that in a preemption -- in a preemption analysis, the assumption is that state powers are not preempted unless there is clear intent and that there is a strong presumption against preemption, particularly in fields of health and safety that have traditionally been regulated by states.

I note as I went through in my questioning yesterday at oral argument on the preemption issue that there is a history which may recently be changing, but that there has been a strong history where for many, many years states regulated food and drug analysis. I note Judge Weinstein's discussion of this in his

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Zyprexa decision.

As another issue, the process and the -- by which the FDA goes about approving labeling and the applicable federal regulations and statutes that apply to that are discussed in a number of cases. They're discussed in the Solicitor's brief that was filed as a supplemental authority in this case. That brief was submitted by the Solicitor in a pending United States Supreme Court case of Wyeth versus Levine. And that discusses some of the applicable statutes and regulations and the process for approval of labelings.

There's a discussion that I found helpful in the case of Richardson versus Mylar, I think it is, maybe Miller -- it's Miller, excuse me -- at 44 Southwest 3d, page 1 which is a Tennessee Court of Appeals decision. And, again, I note Judge Weinstein's discussion of this in the case at 489 F. Supp. 2d, 230 In Re Zyprexa Products Liability Litigation, which is the multi-district litigation that raised parallel claims to many of the claims asserted in this case.

There had been issues raised as to

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what deference that I should give to the agency view of its own regulations, and its discussions of some of the issues that we're talking about today.

I agree with Judge Weinstein in his Zyprexa products liability litigation that to the extent the pre- -- what's been referred to -- a preamble to some federal regulations that discuss whether these matters are preempted or not preempted is only entitled to what we call Skidmore reference. I agree with Mr. Brenner's argument yesterday that where the agency is interpreting its own regulations that's entitled to substantial deference under Chevron.

Turning to the claims in this case, I'll first discuss the question of the call notes, and the argument, as I understand it, that these notes -- and there will be other evidence that shows that there was promotion by Lilly of off-label uses of Zyprexa.

I note that it is under federal law a crime for a drug company to promote off-label uses that -- that includes advertising. I find persuasive the discussion of this and the question of preemption in the case of

Page 9

Pennsylvania Employees Benefit and Trust Fund versus Zeneca, Z-e-n-e-c-a, at 499 F. 3d. 239, Third Circuit, 2007. I agree that advertising and stuff includes the visits by representatives of Lilly to promote the use of the drug as indicated in that case, and I believe that under the Smallwood test both parts of the test are made -- are made out that the act -- that the 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.

I, therefore, conclude -- and, again, adopting the reasoning in the Zeneca case -- that the exemption contained under state law applies, and I will grant partial summary judgment as to those claims on that basis.

The question of the products labels is a much closer question, in my mind.

Review of the substantive case law that has been cited on both sides of the issues by the parties indicates that judges have reached differing decisions on both sides of the question.

I note a couple of things. First,

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under federal law, the fact that a label is approved is not the end of the story. A manufacturer is allowed to make additional warnings and, indeed, may be required to make additional warnings, and while there is some indication that approvals need to be obtained under some circumstances, those approvals are not obtained under all circumstances. In that regard, I note and adopt Judge Weinstein's discussion at 489 F. Supp. 2d, 271 and 272 that once a label has been approved the FDA permits two types of labeling changes, major changes require the prior approval of the FDA. Manufacturers are permitted to unilaterally change warning labels in a quote, minor, unquote, without prior approval so long as the agency is notified of the changes. Such changes are specifically defined to include strengthening language regarding warnings, contraindications, precautions or adverse reactions, and he cites to section 314.70C6 small 3 capital A of the federal act labeling changes may be made without prior approval to add or strengthen a contraindication warning, precaution or adverse reaction.

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Given that a manufacturer has both an obligation and the ability to change its warnings without prior FDA approval, and given that those warnings in themselves and the failure to do that doesn't appear to be regulated by the FDA in any substantive way, I do not believe that the second prong of the Smallwood test, that the unfair acts and practices are prohibited is -- is fully met and, in light of the Smallwood case and the remedial purposes of the Act, I find that the exemption does not apply.

That requires me to turn to the question of preemption. And, as I note, cases seem to vary both ways and I have reviewed each -- each party has cited cases on both sides of the issue. It's clear to me that for a long time that preemption analysis was not accepted by the courts, but it's also clear to me that at least some courts in recent times have not accepted that.

But having reviewed virtually all of the cases, I find most persuasive Judge Weinstein's analysis on the issue.

In that regard, I note a number of things. This does not -- the preamble that has

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been discussed and which I've indicated I'm only going to give deference to if I find it persuasive as to what preemption, talks about preemption in not all cases, but in a limited number of circumstances. And Judge Weinstein discusses that in his decision, and I note that this is not a case where we're talking about a label that is -- where the violations are based on labels that are currently in use. We're not talking about claims of warnings that the FDA considered and rejected in whatever balancing they did as to what should be -- how much information should be included. They ultimately with new information added information to this, but I don't believe that even if I were to give -- even if I were to look at the deference issue, that this was one that deference should be afforded.

The label in this case was changed, and I am not being asked to find inadequate a label that would currently be in use which, in my view, would create more difficult issues of preemption.

We're aware there was proof that the FDA had basically considered the warnings

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proposed by the Plaintiffs, but actually then chose to reject them.

Rather, this is a warning that ultimately was required to be changed and allegedly was deemed to be inadequate by the federal government. And in light of that, I agree with Judge Weinstein's analysis of the preemption question both as to the UTPA claims and to the -- the common-law claims. And so for the reasons that he more eloquently expresses than I probably could if we had more time, I will deny the motion for -- as to the label aspects of this case and the common-law warning products liability claims, finding that those claims are not preempted by state -- by federal law.

In doing so, I also appreciate issues of policy as to what a contrary decision might do. It would leave the regulation of the case in many instances to the federal government that in -- after determined inadequacies of warning labels, et cetera, there would be no state law remedies, which is really what this case -- at least the allegations seem to be about.

And that historically has never

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been the case. That, historically, a state law has served as a complementary means of dealing with issues of the adequacies of drug warning and drug policy. And I believe that that policy is an important one. Again, I recognize and I'll tell everybody I probably went back and forth on this about two or three times in the last 24 hours.

Please do not take that as a suggestion that I'm going to want to get a motion for reconsideration, although I understand that people need to make their records, particularly when we're talking about these kinds of decisions.

Having attempted to then rule on the preemption supplemental brief, that leaves the original Motion for Summary Judgment on -- based on the Rezulin products liability litigation, November 26, 2007, decision. I decline to follow that decision for at least now for a number of reasons. One is I don't believe this is a fraud-on-the-market theory. This is not an allegation, although I recognize that Rezulin was broader than just paying higher prices and there is some discussion of that, but

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I don't think this is a fraud-on-the-market theory as was pointed out to me by the State in oral argument.

The claims opened under the UTPA and under Alaska state law common-law products liability claims have different elements of causation, and proof that, I believe, make the Rezulin decision inapplicable and, particularly, there's some prints versus parachutes decision dealing with issues of proximate cause in products liability case that I believe make the Rezulin decision inadequate, and to the extent that Alaska has different causes of action, I believe that at this stage there are issues of fact that would preclude summary judgment.

I also believe that the motion is somewhat premature, quite frankly. It's a causation damages kind of issue, and I continue to adhere to my previous rulings in that regard that the question of the adequacy of the State's proofs and the experts' abilities to produce evidence that ought to go to a jury are best determined down the road in Daubert hearings and other hearings where I actually know exactly what the State's evidence will be. Right now all I

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really know is the methodology, and I tend to believe that I'm not going to follow the Rezulin decision to the extent that it defines the methodologies to be appropriate to the reasons I just indicated, because I don't think Alaska law -- that would be consistent with Alaska law.

And so, in summary, I'm going to grant the Motion for Summary Judgment in part as to the claims involving the call notes and the allegations that really promoted -- unlawfully promoted off-label uses of the product. Again, I also note that there were suggestions made and -- including suggestions by the State as indicated in the New York Times article that there was some discussion of the motions in limine that Lilly may be subject to criminal investigation already for the acts that would fall within those things.

But I will deny the Motion for Summary Judgment in all other respects.

I hope that that's adequate enough for everybody to do what they're going to do on appeal.

MR. SANDERS: Thank you, Your Honor. First of all, on behalf of the State I want to thank the Court very much because I

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know that we have given you a lot of work to do, and I think you're absolutely correct that we would rather have a prompt ruling --

THE COURT: Than a pretty one.

MR. SANDERS: And, frankly, it was -- actually, it was pretty enough in many respects except for one.

All I can tell you is our attorney general, as you probably know, is back in D.C. today on the EXXON VALDEZ case, and we, of course, will have to consult with Mr. Colberg to decide, you know, what we may do in response to the Court's order today, but --

THE COURT: I assume everybody's going to make decisions based on my decision today.

Given that at least under my decision this case is going to proceed for now, I'd like to discuss a couple of hanging things. I haven't gotten any indication yet as to the motions for clarification on two of the in limine motions that I filed -- that were filed by the State. I don't know -- I know Lilly is filing a reply and that's coming today.

MR. LEHNER: I think it should be

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here. It was filed right before we came to court, so you should have it already.

THE COURT: I don't have it yet, so I'm not in a position to discuss it now. I'll read what you have and rule on the motion -- or on the two motions for clarification once I get those things.

I also don't have -- there was a pending -- a new motion in limine that I believe the State had filed that I'm not sure I have the response to either. So, I'll rule on that once I get that response. I assume I'll get that today, too.

MR. LEHNER: That was the motions on warnings and that is on its way as well. I think the first one has already been filed --

THE COURT: Right. It was a motion that sort of wanted to preclude Lilly from how you were going to refer to what the extent of the warnings might have been. That kind of grossly characterizes it.

MR. LEHNER: The only thing I was going to add, Your Honor, in light of your rulings on the first motion and motion for clarification may be impacted by your ruling

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today with respect to the off-label motion. We'll take a look at it today and if we could file a supplemental letter, if you think it's appropriate.

MR. ALLEN: Your Honor, just for the record, I anticipated that comment. The ruling today does not impact the reference to the motions for clarification. I will give you, the Court, this reference, Denise Torres in her deposition, who is the president of global marketing for Eli Lilly at the time of her deposition said that warnings affect sales, and that she knew since the day she started working at Eli Lilly that if you warned of diabetes it would affect the sales. Sales is the equivalent of money. The reason they entered the primary-care-physician market, regardless of the off-label prescription, was as their own memos say corporate performance was crucial to primary-care market's success. They further said that they were -- and this is their words, quote, betting the farm, closed quotes, on Zyprexa in the primary-care market.

We do have to prove intent as one element of the UTPA, Consumer Protection Act.

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Assuming we did not have to prove intent, motive is always relevant to conduct to the fact --

THE COURT: Mr. Allen, I really don't want to have argument on it. I'm just trying to decide if I have a motion still to decide, and I'll -- if I do, you're telling me that I do, and I quite frankly understand that I do, that both of these motions go to issues of being able to get in some evidence of motive, the extent of which is -- is probably part of the big issue here.

And I recognize that motive -- I'll tell everybody that I recognize that motive is an issue here, and it's more a question of -- I think it's going to be more a question of specifics and what I don't want to have is a mini balance sheet damages fight going on here.

MR. ALLEN: You will not have it.

THE COURT: But I want to wait for -- I don't want argument at this time on this issue. It's just clarified for me and makes sense to me that even given my rulings that we -- that motive still will be an issue in this case and that those two motions exist, and I'll wait for Lilly's response, and then I'll rule on it.

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MR. ALLEN: Thank you, Your Honor.

THE COURT: Mr. Sanders.

MR. SANDERS: Am I correct, we can file a reply on their opposition today?

THE COURT: I guess on --

MR. SANDERS: We'll get it done today, I mean --

THE COURT: You get an opposition -- well, let me read their opposition. This is -- this motion for, quote, unquote, for clarification is in many respects a motion for reconsideration. And my general practice in motions for reconsideration, a rule requires me if I might grant the motion for reconsideration to afford the other side an opportunity to respond. My general practice is I don't usually let replies come in on that basis unless I think I need it, and so I'll let you know.

MR. SANDERS: Okay. Great -- we'll have one prepared. If you want it, we'll get it right over. Okay. Thank you.

THE COURT: Those, I think, are the only three motions -- the two motions for clarification and the one new in limine motion that are hanging. Am I -- I mean, I realize

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we've got some juror stuff to talk about. We're going to talk about that in a second.
Have I missed a motion or --
MR. SANDERS: No. By the way, there is -- just so you know, your clerk knows, their opposition came in as one opposition to our two motions; so they combined theirs into one pleading.
THE COURT: Okay. Well, I assume that's going to be waiting for me sometime today. I hadn't seen it when I came on the bench.
MR. SANDERS: Yeah.
THE COURT: I want to -- I've given everybody my 16 or 17 yesterday, preevidence jury boilerplate instructions. My question -- my first question before we turn to the jury questionnaire issue is: Are there other preevidence instructions that the parties want me to give, or are there objections to the ones that I proposed to give?
MR. SANDERS: We do not have anything else to propose. I left right after court yesterday. I didn't linger around. Did you hand out a package of -- or did Mark?
THE COURT: Packets, I think, were

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given to you at the beginning of yesterday's argument.
MR. SANDERS: Okay. We don't have --
THE COURT: There was some discussion that everybody was going to look it over and let me know if there were any problems with it and let me know if there were more at issue. In looking over your proposed instructions I think I pretty much -- maybe not in the exact form cover the topics at issue except for what I call the fight about me giving the instruction to the jury about what the case is about. And as I indicated orally yesterday, my general practice, again, would be to have you give some short description to the jury, each of you, about what your case is about before we even pick the jury so that the panel can answer your questions in voir dire intelligently, and then let you go at it in opening statements as to explaining what your case is about.
I generally do not put the Court's stamp on what the case is about. I'd rather let you tell that. So I'm inclined not to give either parties' requested instruction about what

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the case is about. But I'll let you make records on that if you need to. But if -- aside from that, I'm not sure whether or not we're missing anything, but that's my question. Is there other preinstructions -- I mean, there was one instruction that talked about calling the State "the State" and Lilly, "Eli Lilly" and sometimes "Lilly" will be referred to as "Lilly" and stuff. And I don't know if I need to do that or not. I mean, names -- if somebody wants to come up with a names instruction to the jury, I'm happy to do something like that. I don't think -- that's specific to this case, I don't think I have that.
MR. LEHNER: Your Honor, I think we could -- I looked at the brief that you submitted yesterday. We could, I'm sure, spend an hour, half hour with the Plaintiffs this afternoon, if there's some objections to your proposed instructions we can let you know by the end of the day, I'm sure.
THE COURT: It's my practice when I do jury instructions, I just want to give you opportunities to make your record on those instructions or to make sure or to -- and to consider any new things you want me to give or

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any changes you want me to give to what I do. I'll tell everybody that the ones I've given you, I refer to them as boilerplate and they've been given in almost every case that I have. To the extent that somebody is going to object to my allowing jurors to ask questions or take notes, I'll let you make your record, but I'll tell you now you'll have a real uphill battle to convince me not to let me do that, it's much better practice and it keeps the jury engaged and, quite frankly, it will let you know what the jury is thinking about if you hear the questions. You can make your records if you object to that. Some lawyers, I know, do.
And I'll just -- I mean, for now I'm going to operate on the assumption that no further preliminary jury instructions will be given other than the ones that you've handed out and -- or that I handed out, and that the ones I handed out are not objected to. That's going to be the case, you'll need -- if that's not true, you're going to need to make your record at some point.
The juror questionnaire --
MS. GUSSACK: I'm sorry,

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Your Honor, before you turn to the jury questionnaire. Do you want to see the parties' proposed statement of the case before it's presented?

THE COURT: Well, I want to see -- I would like to see both parties' proposed statement of the case and have some discussion as to what's going on. Again, before anyone makes objections, the purpose of this -- this will happen -- when I bring in the jury there's a little script that I use that, basically, you know, introduces -- I'll let you introduce yourself, I'm going to make you give some information to the prospective jurors, the jury panel as to the firms and the people you practice with so they're going to be able to answer questions as to that. I'm going to ask you to identify your witnesses so that -- so that we know nobody is married to one of your witnesses or is a close relative or anything and they can answer those questions intelligently.

I go through the statutory issues, you know, whether they're citizens and whether anyone has a felony and whether they speak English and understand English and those things,

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and ask them to answer whether they have a mental infirmity. There's a list of questions that do that.

But at some point in that thing I'm going to ask each of you to describe what the case is about so that later on when they're being voir dired they can indicate whether or not they have any problems with sitting on this kind of a case. And in order for that to happen, they need to know what the case is about and I, quite frankly, think it's more engaging for them if you in more neutral terms than you might in opening statement and in a short, concise fashion, just give them some idea of that. And I'm going to let each of you do that. I'm looking for -- I would avoid a lot of adjectives and adverbs in your description because those will end up making it more objectionable. But that's what I'm looking for.

So I want to make sure somebody doesn't think that somebody else is way overstepping the lines. Again, there will be an indication to the jury that this is, you know, your description of what the case is about. You'll hear more about it in opening statements

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and that this isn't evidence and there will be -- the panel is fine, they're going to be told that lawyers' arguments and statements aren't evidence, and they'll get told that more -- they may get told that more than once. But -- so that's -- that's what that -- that's what that statement's about.

And I suspect I'd rather have a record made and have everybody make sure that to have at least me decide that I don't think it's going too far. The idea is I don't want it to go too far in terms of advocacy of what is supposed to happen in your openings statements.

And so the sooner you get those to me, we'll be able to take that up and make a record.

Let me talk about the juror questionnaire. Lilly has filed a proposed jury questionnaire. The State, basically, doesn't think a jury questionnaire is necessary and thinks that this one is intrusive and objectionable, and, I guess the words are offensive and invasive. And what -- and it was indicated in argument yesterday, I forget by whom for the State, that if I decide we're going to

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use the questionnaire, the State will have its own version that I should consider.

But let me ask -- let me ask the State what you see happening, particularly for some of the things you claim is objectionable. I mean, the questionnaire indicates that if anyone knows anyone who believes they have diabetes or related conditions, whether there's -- there's questions about, I guess, mental disabilities and stuff. But, if I don't have the jury questionnaire, why won't those questions be entirely appropriate given the subject matter of this litigation in an effort to pick a fair and impartial jury and make sure that we don't have people on this who have events in their lives that may make them biased or at least allow that inquiry be made? I mean, what I foresee happening without the questionnaire is that question is asked to all the jury panel, then everybody is raising their hands. And some people, particularly on the mental health issues, are taken out in the hall, they may not want to talk about those issues, they may want to talk about diabetes and the other things. Won't this shorten up a lot of that stuff because you've

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identified people and you can discuss things if they get called on -- into the jury box as one of the people that could sit on the jury? Isn't this going to --

MR. SANDERS: Let me answer the question. Have you ever used a jury questionnaire similar to this?

THE COURT: I have never used a jury questionnaire. But that's not a question -- that answer is not meaningful --

MR. SANDERS: I'll just tell you -- I'm answering --

THE COURT: This is the kind of case where they're frequently used.

MR. SANDERS: I beg to differ. I would say that -- what I would say is: What possible precedent is there for something as vast as this? I don't -- I've never seen it before. So -- so I would say it's not frequently used. It's basically never been used in any case I'm aware of, and if they can contradict that, and say, "No, Judge Jones down the hall used something like this three months ago," I'll revisit this comment. My position is I want to see it, if it's ever been used before. First of

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all.

Second of all, it will not -- I'm almost certain it will not make things go faster. It will extend things. When you ask people these questions, they don't really answer the information. They give a little bit of information which then prolongs the examination. If they want to know these questions, they can ask them, because we may not want to know -- we may not feel we need to ask these questions. We may want to ask different questions. So I don't think we should be bound by what information Lilly wants, first of all.

Second of all, I can tell you that there are some questions on here which, in view of the fact that the State of Alaska is a party, as I said, are particularly offensive. I mean, these are not questions that the State of Alaska wants to be associated with because the public says, "Oh, here we are. We're summoned in for jury duty involving a case involving the State of Alaska," and they're trying to decide whether we can be jurors or not based on our race, based on our income, whether or not anybody has ever had mental problems in our family before. Because

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there are a lot of people -- I can tell you this from an informal poll in my office where people said, "It wouldn't fill this thing out. I don't think the State of Alaska has any right to this."

THE COURT: There are two questions, Mr. Sanders. One question is whether we use a jury questionnaire at all. That's a different question if I decide that a jury questionnaire will be useful as to whether I allow all of these questions or some of those questions or combine that with questions that you might want to use. And since I don't know yet what questions if we're going to use a jury questionnaire you might want to use, I can't answer that question.

I certainly can look at the question of some of these -- whether or not I should allow all or some of these things, so that kind of gets us down to -- I'd like to decide the first question first as to whether or not I'm even going to have a jury questionnaire. But if I am, then I'm quite willing and will discuss what ought to be in it.

MR. SANDERS: We are strongly opposed to it.

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THE COURT: And I'm trying to decide why you think it won't be -- this is what I'm worried about, quite frankly, that if we don't use a jury questionnaire we're going to get questions about diabetes and medical treatment and use of drugs to treat mental illness and mental illness things, which I certainly will allow in the circumstances of this case, and -- and the State may want to ask questions about -- because there's going to be testimony about API and these drugs are used at API and where these come from. That may come up; I don't know. But we're going to have a lot -- we may have a lot of hands raised and we're going to have to take those questions up, I suspect, outside, and jury picking will go on for several days.

Now, that's fine with me in order to get a fair jury in a case of this size. But I do recall that the State has already suggested that you've got some out-of-state witnesses who are only available for a short period of time at the beginning of case.

MR. SANDERS: Exactly.

THE COURT: And if jury instruction goes on unduly long that could have been avoided

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and shortened up, that's going to be too bad. And I know -- what I'm hearing is that you disagree that this is going to shorten things.

MR. SANDERS: I absolutely do. And I say that based on experience.

THE COURT: What I tell everybody, if there's a jury questionnaire that identifies some things that at least are reasonable to identify early on that will shorten this up, I'm going to be more inclined to hold people to their time limits than I am if we're getting a lot of questions that nobody has thought about and asked before and, you know, because from a jury questionnaire we might be able to get a sense of how many people we're going to be dealing with with mental health problems and what can we do about it and how we can shorten that up and --

MR. SANDERS: I'm just telling you. I mean, here's the problem: You know, from experience, it's obvious that when you ask a criminal jury, for example: Has anybody ever been a victim or had a family member be a victim of a crime? Everybody raises their hand. Okay. In this case, if you ask a jury: Do you know, have a close friend, anybody that has a mental

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health issue? Everybody is going to raise their hand. I mean -- and I don't see what the significance of that is, because if I was picking a jury, I would be asking very pointed, specific questions because, you know, the fact that my mother was depressed 40 years ago isn't really meaningful. So I would tailor the question specifically relevant to this case if I was doing it on voir dire. I wouldn't be asking a question: Has anybody ever been the victim of a crime or had a friend be a victim of crime? Because you're not going to get a helpful answer. I would say -- if it was a rape case, you would say: I want anybody who feels they've been a victim of a sexual assault to raise their hand or notify the judge privately. And so there is a way to get this information, but it's not through this questionnaire. And so -- I mean, we'll go this way if you insist. But I'm telling you, I think it's going to be a big mistake and the State has got to get their first witness on -- the first two witnesses have got to be done and out of here on the 6th or 7th. So, I mean -- and I'm not going to be in a position where somebody is going to say, "I told you so." Because we'll

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get our jury picked in one day, doing it the way we intend to pick this jury. The old-fashioned way. One day of jury selection. There's nothing particularly unusual about this case.

MR. FIBICH: Your Honor, may I weigh in just briefly on this issue?

THE COURT: Okay.

MR. FIBICH: Simply, I agree it's going to prolong the voir dire. Let me just give you an example of why I think it is. If you take one of the questions -- let's just do one: What do you think about the State of Alaska? Invariably, you're going to get a lot of people that say, "Well, I think government's too big. I think bureaucracy is too big." You know, they're going to have some political answer to that question.

As soon as I get that answer, I'm going to have to go through each and every person and examine what it is that forms the basis of that opinion. That does absolutely no good other than to create additional questions that I may have to ask.

On the other hand, if we're doing this orally, I may say: How many have had a

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circumstance with the State of Alaska that has caused you some problem with the State of Alaska? That gets to the relevance of whether there is a bias or prejudice that would prevent them from sitting as a proper jury. So my concern, and I share the Court's concern that there are some questions that may allow the jury process -- jury selection process to be shortened, but there are very few in there, Your Honor. And let me just -- while I've got your attention, and I know I'm on a point: Where have you lived in the last ten years? Why do they want to know that information? Is Eli Lilly going to go out and hire private investigators and go knock on doors overnight while we undergo this selection process?

I just think that this questionnaire is -- replete with these kind of problems.

Now, if the Court were to give each of us each ten questions that we want to ask and have a short questionnaire. I read the prior transcripts. I've heard the representations to the Court, that this is going to be a short questionnaire. And so my concern is this is

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going to create so many additional questions by the manner in which they're asked that I'm going to have to examine each and every witness by each and every answer and that will prolong it. And that is my concern because, as the Court has acknowledged, we're bringing witnesses from the Lower 48 that are coming a long way, that are high-priced, that have limited schedules that we have got to get this trial going in the manner in which we have scheduled it.

MS. GUSSACK: Your Honor, Nina Gussack. May I speak briefly? Because I think the absurdity of -- of the State's position is evident in the comment that, you know, is Lilly going to hire investigators overnight to go investigate based on where these people live? I think the Court readily understands that there are a series of questions here that have to do with medical conditions, serious mental illness and related issues that the State is well aware of that they are charged with the oversight of the seriously mentally ill and seem to want to distance themselves from asking the citizens of the state what their status is. Questions that are directly relevant to the issues presented by

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their allegations here. This questionnaire is designed to elicit in a confidential way, designed to minimize embarrassment and intrusion, those -- those subjects. To allow the kind of targeted follow-up in voir dire that would be appropriate and not embarrassing to members of the panel.

This kind of questionnaire is designed to facilitate jury selection of a fair and impartial group; not to in any way delay or extend the kind of questioning that's necessary. But, certainly, to the extent that Mr. Fibich has questions that he wants to put to the panel, he can do that in voir dire without any limitations as to whether they -- assuming that they are appropriate. No one is telling him how he needs to ask those questions.

But I think most fundamentally, from the Court's perspective, we have invited the Plaintiff's questions, we have invited their comments on this questionnaire. We can't do anything more than say, "Please, you know, let us know what it is that you find objectionable and let us work towards a joint process here that will facilitate the jury selection."

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I do want to point out that I am very sensitive to the difficulties of witness availability. But I can't say that there's any guarantee that two experts showing up here are going to get in and out of court based on whether this questionnaire is used or not. That's going to be a direct relationship to what the scope of their testimony is.

And this questionnaire, I think, is designed to insure that the jury selection process is more expedient, not less so. And I would still invite the State to advise us which questions specifically they find objectionable, and which ones they would like to supplement here.

THE COURT: I'm going to agree with that. I'm not deciding this question yet. I'll tell everybody, there's a lot of personal information -- there's a lot of things on this questionnaire the jurors are going to ask anyway.

One of the processes that I probably should have done, but I figured that local counsel would be quite aware of it, is that at one point there's a board -- I don't know where we have it -- with ten questions or eight

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questions that jurors are asked to -- is it around that everybody can see real quickly?

All the jurors will be asked before you even start questioning them in voir dire for their name, the neighborhood in town that they live in, occupation -- there it is -- occupation and brief work history, spouse's name and occupation, number of children and their ages, where they were raised, hobbies, fraternities, whether they've been involved in litigation, whether they've ever served on the jury, are there any reasons they shouldn't serve on the jury.

There are a number of questions in this questionnaire that are totally unnecessary other than to give it to the parties ahead of time, I suppose, which -- and to the extent you're asking people about race, marital status, ten years worth of addresses and stuff, I'm not sure why that helps move this along in any particular way.

Family income is another question I don't see -- those are questions that can be asked individually if you want to or not individually if you want to.

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On the other hand, there's a number of questions that I consider perhaps case-specific in identifying that people may want to talk about ultimately individually, and I'm getting some sense of how much -- many people we're talking about may be useful.

MR. JAMIESON: Your Honor, Brewster Jamieson, for the record.

The reason that we've included many of the same questions as on the board in this questionnaire is, again, related to moving things along. I've been involved with Judge Gleason in issuing a juror questionnaire within a couple of years, I've been involved with Judge Link down in Kenai, I've been with Judge Weeks down in Juneau. And each of the questionnaires contain this basic information so that the night before the parties can look at it and make decisions as to whether there's followup needed as opposed to scramble around and taking notes of the answers that are given very hastily on the first day of trial.

The proceeding that I understood and we talked about in the last month, at least on a couple of occasions, was that we would have the jury panel come in on Monday, fill this

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questionnaire out, which includes basic things as well as case-specific things. And then we would -- the parties would have equal opportunity to look them over and so forth. That would allow us to target and focus our -- our questioning of the panel in what I now understand to be a two-hour-each process which we've agreed to and which insures we get a jury selected in this pretty high-profile case in one trial day.

And so we're -- we're willing to adhere to that process. We think that this questionnaire, including some of these basic questions, really enhances and simplifies that.

THE COURT: What I would like -- the question to how fast we're going to get this done depends, quite frankly, on my willingness, which I am willing to do to impose limits on everybody as to what kinds of questions they're going to get. Now, I'm a little bit worried about all of these -- it takes longer to do voir dire if we have to take a lot of questions up in chambers individually rather than in front of a panel. There may well be a few things here. To be quite honest, I'd like to get a sense of whether that's going to be a big problem sooner

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rather than later to figure out what to do about that.

But everybody should know, I'm going to hold -- once I figure -- you know, absent logistical problems of the Court's making, which sometimes happen, we're going to get to the evidence on Thursday, and so that's -- I'm not really worried about this going longer one way or the other, quite frankly. I'm not convinced that this will shorten up and give some people more information that they wouldn't otherwise get because they're not going to ask questions because we're shortening things up. But they'll have the information because of the questionnaire.

So, I am going to ask the State by first thing tomorrow morning to give me, A, the specific objections to the questions that they think are totally inappropriate, understanding that if they're not going to be inappropriate to ask when people are in the courtroom that they're not inappropriate in my mind to ask on paper. And give me the list of questions that they think are appropriate to ask if there's going to be a jury questionnaire.

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MR. SANDERS: Well, I just want to be heard, because, you're right, they have lots of questions here that you could ask a juror. But it would take you about four days of jury selection to ask all these questions, so there is -- you're getting all this information and --

THE COURT: What's wrong with that, Mr. Sanders? Why -- why shouldn't I give both of you an opportunity to get extra information if we're going to shorten up selection, give you an opportunity to get more information about jurors. I'll let you exercise all your preempts and challenges better.

MR. SANDERS: Okay. Can I have just a moment? I want to think this through. So you're going to ask me, for example, if Eli -- Eli Lilly can ask lots of questions that they want to. So they can ask juror No. 1, "Mrs. Hernandez, are you from Mexico?" They can ask that, if they want to. I'm not going to ask it. Certainly, nobody on our side is going to ask that. Or they can say, "Mrs. Smith, how much money did your family earn last year?" They can ask that if they want to, but I'm not going to ask it.

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THE COURT: I get your point.
MR. SANDERS: They can ask, "Do you have any opinions about personal injury lawsuits?" I mean, we're not going to ask that, this isn't a personal injury lawsuit. So they can ask all kinds of questions if they want to. And that's what they're trying to do in this questionnaire: Ask all kinds of questions that we don't feel are appropriate or they would have the time to do in jury selection. So I -- I fundamentally oppose virtually the whole process -- that's my position. And if you expect me to go through and say to every one of these questions, "Do you have any children? What are their ages and occupations?" the Court has already decided what kind of information that should be. The reason that board is used --
THE COURT: Those questions don't shorten this up at all. Because we're still going to go through that process.
MR. SANDERS: You want the jurors to kind of get a chance to talk a little bit, to loosen them up. So -- I mean, I don't know where to begin. If you want me to go through and object to this, you want to explain why I object

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to all of these questions? I'll do that, but I'm not happy about it because I think that there are lots of reasons in here for objections, and -- and I've been working night and day trying to get this case teed up for trial, and they dropped this on us the last minute. And now I have to go through and object to all these questions. I mean --
THE COURT: I guess I'm going to say, we've been talking about a jury questionnaire for some time in this case. And we've been waiting -- I've been waiting to get it and see what the positions were, and the State didn't -- when the topic was broached, which I recall was not this week, but maybe a hearing or two ago, the State didn't stand up and say, "We don't like any jury questionnaires period," the end.
MR. SANDERS: No, no, no, no. I was here. I'm the one that spoke to it. And I know what I said. And I've got a transcript that says what I said. What I said was: We would be objecting to a jury questionnaire, but I really can't do that until I see it. And Mr. Jamieson said, "We will be getting them one, Your Honor."

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From the very first time jury questionnaire was mentioned, I said I'm opposed to it. There is a fundamental reason.
THE COURT: Well, as I understand the reason, they're going to ask some of these questions, you would rather have them take the heat for it than have a neutral --
MR. SANDERS: Let them -- there's nothing unusual about this case. They should be -- Rule 47 talks about jury selection. It doesn't say you need to submit 100 questions that you would like to ask if you had two weeks to ask them. And so, I mean, why don't you do this in every case? You can say the same thing about literally every case that gets tried here with a jury. Wouldn't we speed things up if we had a questionnaire?
THE COURT: Mr. Sanders, we both know that in every case I don't have seven lawyers on each and a floor at the Cook being devoted for each of the parties. This is a different -- this is not -- when this case started, it was -- everybody said, "Oh, no, this is not a usual case." And it's not. So the question is that doesn't mean one way or the

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other whether or not a jury questionnaire is appropriate or not. But it certainly means I ought to think about it a little bit more than I think I would in a $12,000 --
MR. SANDERS: I'm going to do what you want, obviously, and so what I'm going to do is I'm going to go through -- for example, I'm going to say, name, we don't need to ask their name, because they're going to tell us their name. Age, as far as I know, that's not an appropriate question. Number of children and their ages -- fine, you know, okay. I'll go through and answer all these.
My question -- my next question is: Is there any reason why if you give a jury questionnaire it has to be coded so their jury consultant can interpret it?
MS. GUSSACK: Your Honor, let me speak. Mr. Sanders, your memory is a little bit limited, Mr. Fibich spoke to the jury questionnaire at the hearing, and he said, "I am opposed, but if we're going to do it, I have lots of questions to add." So if we have lots of questions to add, let's see those questions.
No. 2, we have told the State --

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not that it's particularly any of your business, but we don't have a jury consultant working with us on this questionnaire. What we're trying to do is facilitate the selection of a fair and impartial jury. So, if we could, we invite, again, the State to give us any questions that they would like so that we can have a joint submission.

THE COURT: I don't care if you've invited them or not. I've invited the State to do that by close of business tomorrow as well as tell me what questions that they want to object to. I am not going to be giving questions that the jurors would have to answer anyway. I mean, name will be given. It's obvious that a jury questionnaire is meaningless if you don't know who the person is. But, if they're going to have to tell you they're 47, I don't think they should tell you on the questionnaire that they're 47. It doesn't shorten things up. That's what I'm trying to do here is shorten things up or at least have the ability to plan and shorten things up.

MR. SANDERS: How many jurors are you going to summon in for this panel?

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THE COURT: That's -- I haven't thought about that yet, but more than I usually would because I'm a little bit worried about some of the mental health issues. I'm worried about the State -- whether there's issues with the State employees and how that will play out. And, most importantly, this is at least a three-week trial, from what I understand, just on the evidence, so we're probably talking about four weeks. And spring break is going to be in the middle of that. And so we're going to have a lot of people -- when they say, "Who can't be on this case," we're going to have a ton of people that are going to raise their hand and say, "Spring break, we've got tickets to go to Hawaii," and I'm going to let those people off. And that's what I -- so I need a bigger panel, I'm sure. How big? I haven't figured out.

MR. SANDERS: One request. I know this may be impossible because of your calendar. Is there any chance we can bring in whatever that panel is, 80 people, on Monday, have them at least prescreen for the spring break issue? Because there's no reason for those people to come back if they're going to be excused for

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spring break.

THE COURT: Let me look at my calendar, but I don't think it's possible. But that's -- hopefully, a lot of people -- that's the problem, we're starting March 3rd and the people are on jury duty for this week, and so a lot of people may not have requested a -- you know, there's a process where you can request a different week if it's going to conflict with something. I'm more worried that people would have expected to be on this long --

MR. SANDERS: This group will be for the March 3rd trial. Spring break starts the following, so they will think, "I'm just on jury duty for a week," and that --

THE COURT: They may. That's going to be the concern, but that's going to be a problem. And if I can figure out a way to deal with that, I'll try to, but I don't know if I can.

MR. JAMIESON: Your Honor, just on the issue of questions that the people are going to -- potential jurors are going to be asked in any event. I think it's quite helpful to both sides and along the lines of prescreening, we're

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going to get a lot of information the night before, and we're going to realize, probably, from what's written on the jury questionnaire that we've prepared and certainly if the State adds into it, we're going to get a lot of indications as to who really should be sitting on this jury. We're going to have that the night before so we can go in --

THE COURT: I don't think you're going to get that information by asking people their neighborhood and their length of time that they're in Alaska and stuff. There's nothing -- other than the last question: Is there any reason you shouldn't be on this jury, there's nothing in those first number of things that would let anyone know -- it's just kind of general background information, but it's not going to form -- other than the last question, you know -- I suppose if somebody says, "We work for Feldman Orlansky & Sanders" -- I hope I've got you in the right order -- then that will make it pretty clear they should not be on the jury. But, other than that -- and I don't think getting that information ahead of time shortens this up since they're going to be asked to answer those

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questions anyway.
MR. JAMIESON: Well, we also have a list of potential witnesses which we'll ask the State to go ahead and add to that that will help the jurors go down and see if they recognize any names and circle them if they do. That's another reason for shortening things up. Because we're going to rattle off a bunch of names, and we should do it in open court again just to be on the safe side. But we're going to rattle off a bunch of names that people won't necessarily have seen before and that will just give us a better -- better shot at making -- because there are a lot of people that are going to be on everybody's list of potential witnesses and lawyers and so forth. I think it just helps shorten the process.
And, again, that's what we're trying to do with this, and we think that's what this accomplishes.
THE COURT: I understand why you want to use it, and I understand some of the State's objections to it. Again, I would like to see what the objections are. I'm going to try to shorten it up considerably, because, quite

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frankly, we've got, you know, right now you've got a 15-page jury questionnaire, and maybe the State has their own 15 pages. And then we've got a 30-page questionnaire. And pretty soon it's a lot more than a questionnaire, it's an exam. And to the extent we're going to have a lot of people doing their best to get off of the panel, I'm not sure that a 30-page exam is going to be helpful.
But I am not convinced that some jury questionnaire won't be helpful. I'm going to let you file your objections as well as the additional questions that if I do have a jury questionnaire I would include.
And to be quite honest, I'm going to ask a couple of other judges. I know Judge Michalski has used a jury questionnaire in some of his bigger cases that he's done. I think there's a few more. I'll probably consult some of my colleagues, as to whether or not Mr. Sanders is correct that it's just going to double the work, or whether it's going to have --
MR. JAMIESON: And Judge Gleason as well, Your Honor, very recently administered one not all that different from this in a fairly large high-profile case involving large

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companies.
THE COURT: So tomorrow morning, then, for the State to do this, and I'll try to give you a prompt ruling on this.
If I find there's a way to do something that we can figure out how many people we're losing because of spring break and other kinds of hardships, I'll probably get a few single moms or one-person businesses that will say they can't be away for a month from their work, we'll look at -- we'll look at that.
So that's how we'll proceed on that.
Are there any other issues that are left hanging other than we've got some motions that I'm going to rule on?
MR. FIBICH: Your Honor, there is one other issue that we need the Court's guidance on. We telescoped out on a trial and we're certainly doing that. We have opening statement being prepared and there will be documents that are going to be used in the opening statement.
The opening statement is going to be substantially disrupted or, alternatively, we're going to get bogged down before we start

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with the jury here unless we can get these documents preadmitted. And we have a need for the Court to ask -- to act as an umpire for those documents that they're not going to agree to.
THE COURT: These are documents that are going to be used in opening statement as opposed to all documents?
MR. FIBICH: Well, we'd like to start with those, Your Honor. Clearly, I think, it would expedite the trial to have them all admitted, but --
THE COURT: Give me a packet that I can review over the weekend before we get to opening statements on -- well, which will be Wednesday, is what we're planning on.
Give me a packet saying, "These are the documents Plaintiff wants to use in opening statement; these are the documents Defendant wants to use in opening statement, all of which are objected to by the other side." So don't give me the documents that are admitted, because as to those documents, you should give me a stipulation. And -- but the ones that are objected to, refer me to what your objections are. You can just refer their objections are

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already set forth in your objections to exhibits, you don't have to repeat it in some fashion. I don't know if you want to make my life easier, you can do that, too. And I'll rule on those before the opening statement.

MR. FIBICH: Your Honor, we appreciate -- I speak for, I'm sure, all the lawyers that are in here, with the effort that we're putting before the Court in ruling on matters that we need to have resolved. And I'm almost too timid to ask this, but I'm going to anyway. The documents that we anticipate using in opening are a pretty limited group. It's 30 or 40, probably, at the most.

We would like for you not to spend your weekend doing it if you can avoid that by doing it early so that we would have it before this weekend to prepare the opening. If that's not possible, given the pressing matters before this Court, then we appreciate that.

THE COURT: My problem is that I don't think it's going to be possible. I mean, I've got hearings virtually full-time this -- subject to things falling off the calendar tomorrow and Friday and this afternoon. And I've

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fallen behind on a bunch of the other cases.

MR. FIBICH: As I say, we've witnessed the pressing matters before the Court and the manner in which you've dealt with us. We appreciate you doing what you can -- I was hesitant to ask, and we're certainly willing to accept your rulings.

THE COURT: What I'll try to do is get it done this weekend. And let me just ask, because -- I don't believe I'm going to volunteer this.

Are there objections about the first two days of exhibits, witnesses? Are there some problems with those exhibits that I'm going to have to rule on, or that it will be useful to know about?

MR. FIBICH: Yes, sir, the short answer is, yes, there will be.

THE COURT: So if I've got 30ish exhibits to rule on for openings, how much are we talking about for those first two days?

MR. LEHNER: Your Honor, the Plaintiffs gave us a list that I don't remember how many exhibits were on that. It was 15 pages or so, with a lot of exhibits. But what we've

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done is we've tried to go through and identify those to which we have no objection. And I think it's about at least 50 percent of which we have no objection. There are a number that we will recognize that are going to be admitted over our objection, because they relate to certain motions in limine, and we've tried to put those in a packet of -- so you can sort of rule on them en masse --

THE COURT: You're going to make your objection so that you can keep a record --

MR. LEHNER: Exactly.

THE COURT: -- and let you know that I've ruled on it in the motion.

MR. LEHNER: But there are some, and I don't know whether they relate to their opening or whether they relate to the first day that we are going to present to you for a ruling, and I think we're pretty close to sort of identifying that. I think we have, because we have identified those. I don't really know the number of them right now, because I didn't count them up.

MR. SUGGS: Mr. Lehner and I spoke this morning about this, Your Honor. We gave

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them at least I think about 125, 130 documents that we would seek additional preadmission for. They then sent us back a list listing those which they are willing to admit without objection. Another list where they're objecting on the grounds of hearsay, but it's admissible. And there's some -- another category where they will, I guess, stipulate -- maybe stipulate is not the right word -- but you don't object to their admission over your objection. We will not require a separate hearing on those. And then you're going to get to us, hopefully, today, a listing of those where we are going to need to have Your Honor take a look at the documents.

THE COURT: Get me -- again, if you can get me a list of these -- for the openings, a list of the exhibits that you would like to refer to and what the objections are and stuff, I'll rule as to what I'm going to be admitting.

Again, these rulings are going to be based kind of in a little bit of an abstract, because I may have different rulings as evidence comes in down the road and I see what people say and people may do things that open doors and stuff. So these rulings are kind of prerulings

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for the purpose of allowing an exhibit to be shown to the jury. It can be instructions if it turns out that later on down the road I may -- well, it's not going to matter if later on down the road I admit an exhibit that I wouldn't allow to be shown in opening. It may matter later down the road if I change my mind because some things happen. But that's less likely, I think.

You'll get me a second packet for the first two days of trial?

MR. SUGGS: Yes, Your Honor. I don't want to get your hopes up, but it may -- I haven't had the opportunity to go through -- I just got their list this morning. It may well be that the number that is in dispute as to opening is even much less than 30 --

THE COURT: That will be great. Like I said, if I get -- if I can get this by close of business Friday -- it has to be in chambers close of business Friday, then I'll work on it during the weekend.

MR. SUGGS: We'll get that to Your Honor.

THE COURT: I'll get your rulings Monday morning.

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MR. SUGGS: Very good.

MR. LEHNER: No problem.

MR. SUGGS: Thank you, Your Honor.

THE COURT: Two other things that occur to me. I do have settlement conferences on Monday morning. As I'd indicated, if there's a way to prescreen people as to get a real handle on what a problem for spring break is likely to be, I'll try to do that. But I just don't know if it will -- I'm also going to see if I'm able to do that, we'll be having everybody come in on Monday morning at least to discuss some of these things and deal with any final pretrial things, and I think people are trying to do things with the courtroom.

I hope I'm not mucking up the works by suggesting this in any way. I recognize I've sort of ruled against the State on some issues and for the State and against Lilly on some issues and for Lilly, and it certainly would be in anybody's realm given the nature of these motions and the case law and what I perceive as being hard issues to petition me on the case.

I'll tell everybody now, if you both are going to do that and you're going to ask

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the Supreme Court to do that and both want me to do it, only if both of you want me to do it -- there was a time in one case when Mr. Sanders, who was then a judge issued a ruling on a hard issue of law and I issued a contrary on the same issue of law and we both, basically, put something in our decisions that suggested that the Supreme Court ought to take up the issue; which they did.

If you both want that to happen, which obviously would mean that you're going to put off your trial, I would be happy to say something if the parties want me to say something, because I do consider these hard issues. But I won't do that unless both sides want to proceed.

MR. SANDERS: First of all, Your Honor, who was right in that decision that we both disagreed on?

THE COURT: I believe I was.

MR. SANDERS: That's why he tells the story, because he was the one who was right and I was wrong.

THE COURT: I specifically did not reveal that fact.

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MR. SANDERS: Obviously, I think we would need to talk to the client about this decision --

THE COURT: I understand that.

MR. SANDERS: I think it's unlikely that we're going to try to do anything to stop the trial.

THE COURT: Yeah, I don't know if anybody is going to want to do it or anybody wants to do it. I'm just saying, I'm not going to say anything to do that that will give somebody -- one side an edge that somebody doesn't want. If you would rather get these issues decided by the Alaska Supreme Court before you go to trial, I certainly would not be averse to that happening, because I realize that we may be having -- I mean, the choice is that we would be having a trial that we shouldn't be having or that we should be having a trial that we -- that we're going to have a trial that maybe we shouldn't have. And it may be that I don't want you to have to spend the money to do this over again because I was wrong today. And I totally recognize that I could be.

Anyway, with that being said, then,

I'll wait for the filings on the motions that are outstanding and the jury questionnaire issue.

MR. JAMIESON: Housekeeping matter, Your Honor. We did deliver some things this morning to your chambers. Here's an extra chambers copy just for your -- your own use.

THE COURT: Thank you, Mr. Jamieson. Let me just state, Lilly has been filing chambers copies of almost everything, and while I appreciated that up until now, I'd rather you didn't do that anymore because there's too much paper floating around and it's getting a little bit hard just to keep track of things in my office. The file is probably in disarray right now. And the -- the original is sufficient, just file it in chambers and, quite frankly, it gets to me -- if you file it, the original in chambers, it's almost the best way to do it.

If there's nothing else, then we'll be off record.

(Hearing adjourned at 12:30 p.m.)

TRANSCRIBER'S CERTIFICATE

I, SANDRA M. MIEROP, hereby certify that the foregoing pages numbered 1 through 66 are a true, accurate, and complete transcript of the requested proceedings in Case No. 3AN-06-5630 Civil, State of Alaska v. Eli Lilly and Company, transcribed via realtime transcription to the best of my knowledge and ability.

February 27, 2008 _____

SANDRA M. MIEROP

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

ELI LILLY AND COMPANY'S RESPONSE TO PRE-EVIDENCE "BOILERPLATE INSTRUCTIONS"

Defendant Eli Lilly and Company has no objection to the court's "boilerplate" instructions, but would make the following addition and correction to them:

The proposed instructions contain no admonition that jurors should not watch, read or listen to news accounts about the case, which has has a high profile in the media. Accordingly, we suggest adding the following sentences, extracted from the State's proposed (and undisputed) instruction No. 2, as follows:

> Do not read newspaper articles about the case or watch or listen to television or radio news stories about this case until the trial is over. Do not read about this case or any matters related to this case on the internet.

Two logical places to add these sentences would be in the penultimate paragraph of the Court's proposed instruction No. 5, and in the last paragraph of the Court's proposed instruction No. 14.

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Lilly also notes that proposed instruction No. 14 advises the panel that this case "will probably take about one week." We presume the court will edit this statement in accordance with the probable length of this trial.

DATED this 28th day of February, 2008.

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

STATE OF ALASKA'S OBJECTIONS TO ELI LILLY'S PROPOSED JUROR QUESTIONNAIRE

As stated in previous pleadings and at the February 27, 2008 hearing, the State of Alaska is strongly opposed to Lilly's juror questionnaire. It is the State's position that using the questionnaire will prolong the jury selection process and, accordingly, the State will not present additional questions to compound the problem. It is the State's position that if the Court decides to use any part of the proposed questionnaire, the questionnaire should be clearly identified as "ELI LILLY'S JUROR QUESTIONNAIRE."

As requested by the Court, these are the objections to the questions posed in Lilly's juror questionnaire.

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QUESTION NOS. 1, 2, 3, 4, 5, 8, 11, 14, 29, 30, 33, 34, 42 AND 43.

These questions are not necessary because the information is disclosed on the standard forms used by the jury clerk in Anchorage or are answered by each juror in the courtroom. (*See* attached jury questionnaires.)

The Lilly questionnaire asks people to list "your prior residence over the past 10 years." This information is not useful and will be confusing for people who are unable to provide accurate answers.

QUESTION NO. 6.

This question is invasive, offensive, and perhaps illegal. If Lilly believes race is relevant to a juror's fairness, it can ask this question in open court.

QUESTION NO. 9.

Asking someone if they live alone and, if not, whom they reside with is unnecessary and invasive. Jurors are required to disclose their marital status, spouse's name, number and ages of children and other relevant information.

QUESTION NO. 10.

Inquiring about annual family income is not relevant and is invasive. Lilly is welcome to ask jurors this question in the courtroom.

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QUESTION NO. 12.

Prospective jurors do identify their occupation, and their spouse's occupation. Lilly is welcome to ask jurors to describe their employment duties, as well as what the juror likes least or most about their job. Having prospective jurors attempt to furnish all this information on one line will not be helpful.

QUESTION NOS. 17, 18, 19, 20, 21 AND 22.

All these questions ask about "a mental illness." A dictionary definition of mental illness is: "A health condition that changes a person's thinking, feelings or behavior and that causes the person distress and difficulty in functioning." This trial is not about mental health generally, but specific, narrow psychiatric disorders such as schizophrenia and bipolar disorder. Any juror questionnaire should be specific to information relevant to the instant case.

QUESTION NO. 25.

This question is overbroad insofar as it asks: "Do you know **anyone** who **believes** they have had diabetes **or a related condition**?"

QUESTION NO. 26.

This question is overbroad. If asked, the question should be limited to prospective jurors receiving Medicaid, not any and all aid or assistance.

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QUESTION NO. 28.

Whether or not someone smokes is not relevant to determini
prospective juror will be fair. Lilly is welcome to ask this question in t

QUESTION NO. 31.

This question is unnecessary because this is not a personal inju
should not be suggested that the jurors will be sitting in a personal injury case.

QUESTION NOS. 37, 38, 39 AND 40.

These questions are unnecessary and meaningless because every prospecti
will either have a positive or negative opinion about state government or governm
agencies.

QUESTION NOS. 41 AND 42.

These questions ask whether the juror has read anything about this lawsuit in which the State has "sued a pharmaceutical company to recover monies paid for medicines?" There is no reason for this question to be asked because phase one will not concern damages.

QUESTION NO. 44.

This question should not be asked because it invites people to attempt to avoid service as a juror in this case.

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QUESTION NOS. 45, 46, 47, 48, 49, 50, 51 AND 52.

Lilly is welcome to ask these questions of jurors in the courtroom.

DATED this 28 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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Counsel for Plaintiff

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IN THE

Certificate of Service
I hereby certify that a true and correct copy of **State of Alaska's Objections to Eli Lilly's Proposed Juror Questionnaire** 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 Peggy J. Crowe
Date 3/28/08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

Case No. 3AN-06-5630 CIV

NOTICE OF FILING EXHIBIT TO STATE OF ALASKA'S OBJECTIONS TO LILLY'S PROPOSED JUROR QUESTIONNAIRE

Attached are the standard juror questionnaires which were inadvertently omitted from the State of Alaska's Objections to Eli Lilly's Proposed Juror Questionnaire.

DATED this 28th day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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Counsel for Plaintiff

Certificate of Service
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Date 2/28/08

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JUROR QUESTIONNAIRE

LEASE PRINT

Name: _____

Date of Birth: _____ Place of Birth: _____

Marital Status: _____ Spouse's Name: _____

Number of Children: _____ Ages of Children: _____

Occupation: _____ Employer: _____

Spouse's Occupation: _____ Employer: _____

Education: _____

Have you ever served as a juror? _____ When? _____

Are you related to or close friends with any law enforcement officer or prosecutor? _____

****

The above information is true and correct to the best of my knowledge.

_____ _____

Signature Date

J-145 (7/88) (st.3)
JUROR QUESTIONNAIRE (Short Form)

002811

JUROR QUESTIONNAIRE

1. Name _____

2. Date of birth, birthplace, and where raised _____

_____

3. Marital status, occupation & brief work history _____

_____

4. Spouse's name & occupation _____

5. Number of children & ages _____ _____

6. Hobbies & interests _____

_____

7. Name all organizations of which you are a member _____

_____

_____

8. Have you or any member of your family been involved in litigation (lawsuits)?
☐ Yes ☐ No

9. Have you ever served on a jury? ☐ Yes ☐ No If so, when? _____

10. Are you related to or close friends with any law enforcement officer or prosecutor? ☐ Yes ☐ No

11. Have you or a family member ever been a victim of a crime? ☐ Yes ☐ No
If so, when and what kind of crime? _____

_____

12. Is there any reason why you cannot or will not follow the instruction on the law as given to you by the court?

_____

_____

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 NOTICE OF FILING UNDER SEAL

Defendant Eli Lilly and Company, by and through counsel of record, hereby files its Motion Requesting Confidential Protections of Regulatory Communications Not Subject to Public Disclosure, and accompanying Affidavit of Timothy R. Franson, under seal, attached to this notice. Portions of the content of the Motion and the Affidavit have been deemed confidential.

DATED this 28th day of February, 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

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Pepper Hamilton LLP
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215.981.4000
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February 28, 2007

VIA HAND DELIVERY
The Honorable Mark Rindner
Alaska Court System
825 West Fourth Avenue, Room 432
Anchorage, Alaska 99501-2004

Re: State of Alaska v. Eli Lilly and Company
Case No. 3AN-06-05630 CI

Dear Judge Rindner:

We are writing on behalf of our client Eli Lilly and Company. It is apparent that we have a substantial disagreement with the plaintiff about the scope of your summary judgment ruling and its impact on the remaining issues in this case.

Your Honor held that "acts and practices promoting off-label uses and **advertising improperly**" are prohibited by federal regulation and are therefore subject to the exemption provision of the Alaska Unfair Trade Practice Consumer Protection Act. See Rough Transcript of Hearing, February 27, 2008, page 7 (emphasis added).

In addition, as discussed at oral argument on February 26, 2008, the Code of Federal Regulations (21 CFR 202.1(e)(5)(i), among other provisions) provides that making misstatements about safety in an advertisement is unlawful and subject to penalties that may be imposed by Federal authorities. As the court noted, "advertisements" – as that term is used in the CFR – encompass a broad range of marketing and sales activities, including calls by sales representatives.[1]

Since any claimed misstatements about a drug – regarding its safety or anything else – by a sales representative would be a violation of federal law, claims based on such statements are, as the Court ruled, exempted by the UTPCPA.

Based on the Court's ruling, it is our understanding that the sole remaining issue to be tried, under both the UPTCPA and common law failure to warn theories, is whether the label that accompanies Zyprexa adequately describes the risks that may be associated with the use of the product. Under the bifurcation plan ordered by the courts, other

[1] In addition, the Court cited with favor *Pennsylvania Employees Benefit Trust Fund vs. Zeneca, Inc.* 499 F.3d 239, which held that "advertisements also come in the form of physician-directed pitches by sales representatives..." (Citing 21 C.F.R. 202.1(l)(1)).

information that doctors considered about the risks and benefits of Zyprexa, whether from the company or otherwise, will be considered in Phase II.

In light of the Court's ruling, we elected to remove a Lilly sales representative (Joey Eski) from our witness list, as the marketing conduct she would have testified about is no longer part of the case. We immediately informed plaintiff's counsel that there would be no reason to proceed with her deposition that was scheduled for February 28th. (We note that Ms. Eski did not appear on plaintiff's Preliminary, Final, Expert or Supplemental witness list). After we informed plaintiff's counsel that we were removing her as a witness, the State supplemented its list, late Tuesday evening, listing her as a trial witness, and objected to cancelling Ms. Eski's deposition.

During a brief meet and confer relating to the deposition that we initiated with plaintiff's counsel, it became clear that the State reads Your Honor's decision as permitting introduction of all manner of evidence relating to sales representatives' interactions with physicians which, as we understand, is irrelevant to the remaining claims. The State has previously asserted that it will prove label-based violations of the UTPCPA through evidence of the number of prescriptions written (a position Lilly strenuously disagrees with), not sales representatives' interactions with doctors, or advertisements. Accordingly, the testimony of sales representatives, and much other marketing-related evidence, is irrelevant to the State's remaining claims.

We appreciate that the Court's calendar is very tight, and we regret having to seek such clarification at this point. However, plaintiff's insistence that they will proceed to introduce evidence that goes beyond its remaining claims necessitates such clarification. Accordingly, we will file a brief today seeking guidance from the Court and a conference at the Court's earliest convenience.

Respectfully submitted,

George A. Lehner

GAL/er
cc: Eric Sanders, Esquire
David Suggs, Esquire
Joseph W. Steele, Esquire
Brewster H. Jamieson, Esquire

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

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant Eli Lilly and Company's Motion in Limine to Exclude Adverse Event Reports for any Purpose Other Than Establishing Lilly Knew About the Specific Adverse Event, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that Lilly's motion is GRANTED. The State of Alaska is prohibited from introducing at trial any evidence referring or relating to adverse event reports for any purpose other than establishing Lilly knew about the specific adverse event.

ORDERED this 27 day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 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

609867.0038/163327.1

I certify that on 2-27-08 a copy of the above was mailed to each of the following at their addresses of record:
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Jamieson

Administrative Assistant

002816

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant Eli Lilly and Company's Motion to Accept Late Filing of its Motion in Limine to Exclude Adverse Event Reports for Any Purpose Other than Establishing Lilly Knew About the Specific Adverse Event, and any response thereto:

IT IS HEREBY ORDERED that Defendant Lilly's Motion to Accept Late Filing is GRANTED.

ORDERED this 27 day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 25, 2008, a copy of the foregoing was served by hand on:

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT ELI LILLY AND COMPANY'S OPPOSITION TO PLAINTIFF'S MOTION TO PRECLUDE TESTIMONY OR ARGUMENT THAT ZYPREXA'S® LABELING "WARNED" OF DIABETES, HYPERGLYCEMIA OR WEIGHT GAIN

I. INTRODUCTION

Prescription drug manufacturers fulfill their duty to warn if their warnings and directions provide doctors reasonable notice of the adverse events of their products.[1] Whether that duty was fulfilled depends on all the information communicated by the manufacturer, as well as information otherwise known to the doctor, not, as the State argues, just the contents of the "Warnings" section of the medication's FDA-approved label.[2] In

[1] *Shanks v. Upjohn Co.*, 835 P.2d 1189 (Alaska 1992).

[2] Throughout the body of the State's Motion in Limine, its primary regulatory citations are to revised FDA regulations, which, as the State notes, did not become effective until June 30, 2006. The State's secondary, or "cf" citations, are to the superseded regulations, which were in effect through June 29, 2006. While the distinctions are not material to the determination of the State's Motion, it is these earlier regulations that are relevant to the pre-2003 Zyprexa label and to the 2003 label change. Upon request, Lilly will provide the Court with a complete explanation of the changes effected by the 2006 rule changes. *See generally* Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922 (Jan. 24, 2006).

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arguing that Lilly's arguments regarding its warnings to doctors is limited to the contents of the "Warnings" section of the label, the State confuses the narrow and specific definition of "Warnings," as used in the FDA's labeling format regulations, with the broader concept of "warnings" addressed in the common law of products liability. The State has not identified a single case suggesting that a manufacturer's duty to warn must be confined to a specific section of a prescription drug label. To the contrary, cases in Alaska and elsewhere compel denial of the motion.

II. ARGUMENT

The State argues in its motion that, because weight gain and related information was listed in the "Adverse Reactions" section of Zyprexa's label, rather than the "Warnings" section, not only will the State claim that Lilly's labeling did not adequately warn of the risks of diabetes, hyperglycemia, and weight gain, but Lilly should be precluded from arguing otherwise. The State cites no authority for this radical position; in fact, the State's argument is refuted by Alaska products liability law and by relevant decisions from other jurisdictions.

In *Shanks v. Upjohn Co.*,[3] the leading Alaska case on prescription drug liability, the Court established that, "[i]n most cases, for a warning to be adequate, it should: 1) clearly indicate the scope of the risk or danger posed by the product; 2) reasonably communicate the extent or seriousness of harm that could result from the risk or danger; and 3) be conveyed in

[3] 835 P.2d 1189 (Alaska 1992).

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such a manner as to alert the reasonably prudent person."[4] *Shanks* made clear that clear that all of the "warnings and directions" accompanying a medication were to be considered in determining the adequacy of a warning,[5] without specifying where the warnings were specifically placed within the drug label.

In fact, courts have never adopted any such requirement, routinely finding warnings to be adequate when included in sections of labels other than the "Warnings" section.[6] For example, in *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566 (D. MD. 2006), a federal court rejected a claim that the labeling of an antibiotic Trimox was inadequate because it appeared – as here – in the Adverse Reactions section, instead of the Warnings section. The prescribing physician testified that "it made no difference to him whether the [relevant] warning appeared in the Warnings or the Adverse Reaction section."[7] The Court found that the package insert was not defective, explaining that, while "[o]ne might prefer to have [the reaction] listed in the Warnings section, . . . the present structure cannot be said to

[4] *Id.* at 1200 (citation omitted).

[5] *Id.* at 1200.

[6] *See, e.g., Ames v. Apothecon, Inc.,* 431 F. Supp. 2d 566 (D. MD. 2006); *Saraney v. TAP Pharmaceutical Products, Inc.,* 2007 WL 148845, 5-6 (N.D. Ohio 2007) (warnings of loss of bone density associated with drug Lupron were adequate when included in "Precautions" and "Adverse Reactions" sections of labeling); *In re Rezulin Products Liability Litigation*, 331 F. Supp. 2d 196, 199-200 (S.D.N.Y. 2004) (warnings of nausea, peripheral edema, and pain associated with Rezulin use were adequate as a matter of law when they appeared in Adverse Reactions section of package insert).

[7] *Ames*, 431 F. Supp. 2d. at 570.

be unreasonable merely because it requires the reader to make a cross-reference."[8] As these cases suggest, the FDA's determination of where safety information should appear in the label are regulatory determinations, balancing the need to inform physicians of relevant risks while not discouraging use of efficacious medications,[9] not guidelines for common law product liability.

Ames also demonstrates that the adequacy of a warning is not determined simply by its placement in the body of a label, but, as Lilly has consistently argued, must rest on whether *a given doctor,* prescribing for a *given patient,* received adequate information. It is impossible for the State to argue that Alaska physicians were not adequately warned by the Adverse Reactions section of Zyprexa's label in the absence of testimony by those physicians. As the *Ames* Court pointed out, "[o]ne must . . . bear in mind that the warnings are intended to be read by learned intermediaries who are presumed to have considerable medical training as well as the ability to access the medical literature if they require further

[8] *Id.* at 573.

[9] *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate.").

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information."[10] In addition to finding that the label was not defective, the Court held that the plaintiff, as a matter of law, would be unable to prove causation. Noting that the prescribing physician testified that "the warnings advocated by the plaintiff would not have altered his decision to prescribe Amoxycillin . . . ,"[11] the Court concluded that "[a] product defect claim based on inadequate warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician."[12]

III. CONCLUSION

There is no conceivable basis for the State's argument that Lilly may not claim that it "warned" of diabetes, hyperglycemia, and weight gain when those risks were in the Adverse Reactions section of Zyprexa's label. Accordingly, Lilly requests that the State's Motion in Limine be denied.

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[10] *Ames,* 431 F. Supp. 2d at 573; *see also Taylor v. Danek Medical, Inc.*, 1998 WL 962062, *13 (E.D. Pa. 1998) ("Whether the warning was adequate depends on whether a learned intermediary, having considered the 'the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient,' would use his independent judgment to prescribe a medical device.") (citation omitted).

[11] *Ames*, 431 F. Supp. 2d at 573.

[12] *Id.*

DATED this 27th day of February, 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*
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and
LANE POWELL LLC
Attorneys for Defendant

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

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ELI LILLY'S RESPONSE TO THE STATE'S OBJECTION TO LILLY'S PROPOSED JUROR QUESTIONNAIRE.

In its Objection to Lilly's Proposed Juror Questionnaire, the State advances several arguments, all of which lack merit and should be overruled. The State claims a written questionnaire is unnecessary and "unprecedented," even though the State's lead trial counsel claimed at the oral argument of February 26 that the State had prepared its own, equally lengthy questionnaire. Such questionnaires are commonplace in Alaska jury trials involving technical or potentially sensitive issues, as this case certainly does. Questionnaires similar to that proposed by Lilly have been administered by the Superior Courts in Anchorage, Juneau and Kenai, and in each such case, jury selection has been streamlined and made more, not less, efficient.

The State also complains that administering this questionnaire will "prolong the jury selection process and prejudice" the State. The State has it backwards. The plan discussed in detail during the hearing on January 29, and again at the final pretrial conference on February 22, was that the jury panel would arrive on Monday, March 3, fill out the questionnaire, and then return on the morning of March 4 for voir dire. The court has allotted 2 hours per side for voir dire, or less than one trial day, and the jury will be empanelled and sworn on March 4. The State supposedly fears "follow-up examination to obtain

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meaningless information" about certain subjects. Lilly does not plan to waste its allotted 2 hours in this manner, and presumes the State will not either.

Third, the State claims that the juror questionnaire is "offensive and invasive." At the core of this case, Medicaid patients are being treated for the most extreme and debilitating forms of mental illness at public expense, and the State claims that this expense has been increased because some of these patients allegedly later developed problems such as significant weight gain and diabetes. It would be hard to find more sensitive and private issues for many people than their mental and physical condition, yet knowing each potential juror's experience with these issues is crucial to selecting a fair and impartial jury. Asking these questions in an open forum would either expose each potential juror to the embarrassment of discussing private issues in public, or would instead require numerous trips to the hallway to conduct a private examination. Both of these options are unacceptable, and both issues are alleviated, either completely or mostly, through the use of a written and privately administered confidential questionnaire.

The State takes issue with a number of other questions, all of which are designed to elicit important information about the attitudes and interests of prospective jurors. This is the standard stuff of jury selection, and eliciting this information in a written questionnaire only serves to streamline the process.

Finally, the State claims, without basis, that the questionnaire is designed to favor Lilly, even though the State will be completely free to use the information obtained through its administration. The State is also free to seek the inclusion of additional questions. The State apparently finds something sinister about a defendant employing a tool that is common in litigation throughout this country. The State of Alaska's extensive trial team is evidence of the unlimited resources available to it. The State has already volunteered that it retained

"jury consultants from many different states" who have already arrived in Anchorage. The State is hardly disadvantaged by the use of this jury questionnaire.[1]

The questionnaire will aid the court, the parties, and the prospective jurors in the jury selection process allowing a jury to be seated in this high-profile case in just one trial day. Eli Lilly respectfully requests that the Court administer the jury questionnaire as proposed.

DATED this 27th day of February, 2008.

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John F. Brenner, admitted *pro hac vice*
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Attorneys for Defendant

By _____
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Nancy L. Biggerstaff, CPS, PLS
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[1] *See,* State's Opposition to Motion for Reconsideration and Response to Court's Order, dated February 21, 2008, at p. 17.

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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 STATE OF ALASKA'S
SUPPLEMENT TO FINAL WITNESS LIST

Plaintiff, State of Alaska, and hereby supplements its Final Witness List with the addition of:

1. Robin Pitts Wojcieszek
   c/o Eli Lilly and Company
   Lilly Corporate Center
   Indianapolis, IN 46285
   (317) 276-2000

DATED this 27 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff State of Alaska's Supplement to Final Witness List** was served by messenger on:

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ELI LILLY AND COMPANY'S OPPOSITION TO PLAINTIFF'S REQUESTS FOR CLARIFICATION OF THE COURT'S ORDERS EXCLUDING EVIDENCE OF OTHER DRUGS MANUFACTURED BY DEFENDANT AND DEFENDANT'S PROFITS, NET WORTH AND THE PRICE OF ZYPREXA®

From the beginning of this case, the State has emphasized time and again that Eli Lilly and Company's ("Lilly") motive and intent play no role in the consumer protection claim. On the eve of trial – and in the form of a request for clarification – the State seeks to introduce unduly prejudicial evidence under the guise of motive and intent. The State of Alaska wants to introduce evidence regarding the expiration of Lilly's Prozac patent, and its alleged financial consequences, to demonstrate a profit motive for the way Zyprexa was marketed. The State should not be permitted to expand the scope of Phase I of this trial by introducing irrelevant and misleading evidence that will prolong and confuse this trial.

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I. BOTH REQUESTS FOR CLARIFICATION SEEK TO INTRODUCE IRRELEVANT EVIDENCE.

The basis for the State's clarification requests is that evidence of Lilly's profits and other products is relevant to Lilly's marketing motivation.[1] In particular, the State seeks to persuade the jury that the loss of the Prozac patent caused Lilly to engage in off-label promotion to expand the market for Zyprexa. The State long ago conceded the irrelevance of Lilly's motive to any of the State's allegations in Phase I of this trial. In its first filing that discussed its theory of the case, the State said that "neither intent to deceive nor actual injury is required . . ." for its UTPCPA claim.[2] Similarly, evidence of motive is irrelevant to the State's strict liability claim.[3] The State has acknowledged, and in fact seeks to instruct the jury, that "intent to deceive need not be proved."[4] As the State has recognized, evidence is

[1] *See, e.g.*, State of Alaska's Request for Clarification of the Court's Order Excluding Testimony or Argument Regarding Other Drugs Manufactured by Defendant Eli Lilly and Company at 7 ("Evidence related to the loss of the Prozac patent and what it meant to Lilly is also specifically relevant to Lilly's *intent and motive* to launch Zyprexa into the primary care physician (PCP) market in 2000 and to Lilly's *motive and efforts* to promote Zyprexa for off-label uses.") (emphasis added); 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 at 2.

[2] Pl. Mem. Proofs and Claims at 21.

[3] *Id.* at 18-19 (noting that focus of strict liability claim is on the objective adequacy of the warning, not the subjective process of the label's creation).

[4] State's Proposed Jury Instruction No. 25.

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only relevant, and admissible, if it has a "tendency to make the existence of any fact that is *of consequence* to the determination of the action more probable or less probable."[5] Since Lilly's state of mind is not an element of either of the State's claims, any alleged financial motive for its marketing activity is simply irrelevant to the decision the jury must make at this stage of the case. Lilly's sales representatives' communications with Alaska doctors either were or were not deceptive, as defined by the statute; they do not become more so if Lilly had a particular financial objective, nor less so if it did not.

This rationale also applies to the State's effort to introduce evidence relating to Lilly's diabetes product line. To the extent that the 2001 Hyperglycemia Sell Sheet for Zyprexa, with references to Lilly's position in "Diabetes Care,"[6] is introduced to demonstrate the content of Lilly's sales messages for Zyprexa, Lilly does not object (provided, of course, that the State can prove these messages were actually communicated by Lilly sales representatives to physicians in Alaska). However, general reference to Lilly's status as a

[5] State of Alaska's Request for Clarification of the Court's Order Excluding Testimony or Argument Regarding Other Drugs Manufactured by Defendant Eli Lilly and Company at 3 (citing Alaska Rule of Evidence 401 *Definition of Relevant Evidence*) (emphasis added).

[6] State's Request for Clarification Regarding Other Drugs at 10.

"Diabetes Care Company," unrelated to Zyprexa marketing, has no relevance to the disputed issues in the case and could lead to prejudicial inferences by the jury.[7]

II. THE EVIDENCE THAT THE STATE SEEKS TO INTRODUCE REGARDING LILLY'S ALLEGED PROFIT MOTIVE IS DESIGNED TO DISTRACT THE JURY FROM THE ABSENCE OF EVIDENCE OF ACTIONABLE CONDUCT.

Put simply, the profit motive evidence the State seeks to offer serves its intended purpose of playing on prejudices some jurors have about large companies, including pharmaceutical companies. The State cannot have this both ways, however. If this evidence of Lilly's "bad character" were admitted, the Court would also have to reconsider its exclusion of evidence of Lilly's long history of developing life-saving and life-enhancing medications as evidence of its valuable corporate citizenship, including its investment of company revenues in research and development of the next generation of medications. And Lilly would also need the opportunity to rebut the State's assertions, *e.g.*, that the Prozac patent expiration had been accounted and planned for, that Lilly's financial forecasts were based on multiple products in development, and the like. This would improperly divert the

[7] The State also seeks to introduce evidence relating to Symbyax, a Lilly product that includes olanzapine (Zyprexa). Lilly understands the Court's Order Denying Lilly's Motion *In Limine* to Exclude References to Recent Regulatory Communications and Developments will permit the State to introduce evidence relating to Symbyax, to the extent that the evidence relates specifically to Zyprexa safety issues.

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jury into a mini-trial on such complex, collateral issues as patent protection and litigation,[8] and pharmaceutical finances.[9]

The better tack is the one originally ordered by the Court, keeping extraneous evidence of other medications and financial issues out of the case; the only thing the jury needs to decide regarding Lilly marketing during Phase I of this trial is *how* Lilly acted in Alaska, not *why* Lilly acted. Accordingly, the focus of admitted evidence should be on the actions that Lilly actually took in Alaska, including the communication of marketing messages, not on any alleged motivation that the State ascribes to those actions. However, as Lilly has argued in its pending motion for summary judgment, the State has not mustered competent evidence of improper marketing conduct in Alaska. Evidence relating to Lilly's alleged profit motives may distract the jury from the absence of evidence of improper

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[8] The State's reliance on the history of the Prozac patent also runs afoul of this Court's Order excluding evidence of other litigation involving Lilly. Specifically, statements such as "Lilly was stunned by a U.S. Court of Appeals decision. . ." run afoul of the Court's Order. State's Request for Clarification of Court Order Regarding Other Drugs at 5.

[9] *See Alaska Northern Development, Inc. v. Alyeska Pipeline Service Co.*, 666 P.2d 33, 42 (Alaska 1993) (excluding evidence of motivation relating to an alleged conspiracy "to prevent the side show from swallowing up the circus.").

marketing in Alaska, and cause it to ascribe liability based on considerations far removed temporally, geographically, and logically from the marketing to Alaska doctors.[10]

The admission of this evidence will also further skew this unusual bifurcated proceeding in the State's favor. The jury will be provided "context" (albeit irrelevant to the elements of the State's claims) for Lilly's alleged misbehavior in Alaska, but be deprived of the context of why Alaska doctors chose to prescribe Zyprexa, both for on-label and off-label uses, and how their patients fared on them.

III. CONCLUSION

The State's two requests for clarification seek permission for the State to introduce wide swaths of irrelevant evidence that would prejudice the jury by forcing a protracted examination of irrelevant side issues. For the foregoing reasons, the Court should deny the State's request for clarification.

[10] Although not necessary to the disposition of these motions, Lilly disputes the State's characterizations of Lilly's documents and testimony, many of which are misleadingly described. In addition, Lilly wishes to correct a misperception regarding Exhibit C to 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. The quoted language "Are NOW making us "Number 1" with Zyprexa – Schizophrenia, Bipolar, Depression," is cited by the State for the proposition that Lilly intended to promote Zyprexa for the non-indicated condition, depression. In fact, the word "Prozac" is redacted from that statement, as was permitted by the MDL court. Without the redaction, the document refers to two medications – Zyprexa and Prozac – which together are approved for all the listed conditions. To the extent the non-Prozac references in the document are admissible; the word "depression" should be redacted from the document as well.

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DATED this 27th day of February, 2008.

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

STATE OF ALASKA'S OBJECTION TO ELI LILLY AND COMPANY'S PROPOSED JUROR QUESTIONNAIRE

INTRODUCTION

The State of Alaska is strongly opposed to Lilly's juror questionnaire because it is invasive, offensive, and unnecessary. The use of the questionnaire would prolong the jury selection process, prejudice the plaintiff, and favor the defendant. The Court will hear argument on this issue on Wednesday, February 27, 2008, at which time the State will explain in detail the many reasons why it objects to Lilly's questionnaire. Filed on shortened time, this pleading will briefly identify some of the State's concerns.

A. THE JUROR QUESTIONNAIRE IS UNNECESSARY.

In every jury trial the parties are entitled to a panel of jurors who will be fair and impartial. To achieve this goal, Alaska Civil Rule 47 permits the parties to conduct an

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examination of prospective jurors. The rule does not provide that the parties have a right to require prospective jurors to first answer detailed questions about themselves, family members or people they are close to.

In the Anchorage Superior Court, fair jurors are frequently and routinely impaneled under the procedure described in Alaska Civil Rule 47. Short jury questionnaires are rarely used, and a questionnaire similar to that proposed by Lilly is unprecedented. There is no reason why the Court should deviate from the normal procedure in this case.

B. THE JUROR QUESTIONNAIRE WILL PROLONG THE JURY SELECTION PROCESS AND PREJUDICE THE STATE OF ALASKA.

At the hearing on January 29, 2008, the State of Alaska expressed a concern with scheduling because it would have many expert witnesses traveling from other states. Because of other commitments, these witnesses needed to have some certainty about when they would be expected to testify in Alaska. After some discussion the Court ruled that jury selection would occur on March 4, 2008, opening statements and pending pretrial matters would occur on March 5, and the State's first witness would be presented on March 6, 2008, at 8:30 a.m. Based upon this schedule, the State has two expert witnesses who have been promised that their testimony will be concluded no later than Friday, March 7, at 1:30 p.m. These critical witnesses cannot appear in Alaska after March 7.

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The jury questionnaire will undoubtedly extend the jury selection process far beyond the one day currently scheduled. The State will be severely prejudiced if the voir dire process is extended so that one of the State's witnesses is unable to testify.

Even a cursory review of Lilly's proposed questionnaire shows that it will significantly expand and prolong the process of selecting a jury in this case. For example, question no. 19 asks: "Has anyone in your family or close to you ever suffered from a mental illness?" Since virtually everybody will answer this question "yes," follow-up examination to obtain meaningless information about this subject will then occur. Another example is question no. 39, which asks: "Do you have an opinion (positive or negative) about the Alaska State Government?" Of course, every juror will have an opinion about the Alaska State Government, but those opinions will not benefit the jury selection process. The jury questionnaire, with all its subparts, has approximately 75 questions. Most of the information it seeks is not necessary for the Court or the parties to determine whether a particular juror can be fair or impartial in this case.

C. THE JUROR QUESTIONNAIRE IS OFFENSIVE AND INVASIVE.

Lilly's questionnaire asks jurors to answer questions that are offensive and invasive. For example, prospective jurors would be required to disclose their race, annual family income, what they least like about their job, and what medications they use. It is

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improper to ask such questions, and prospective jurors will no doubt be offended that the State of Alaska is seeking this information from people who have been asked to serve as jurors.

The questionnaire also asks if:

- Anyone "close" to you who ever suffered from a mental illness;
- Whether they "know" anyone who believes they have diabetes or a related condition;
- Whether the juror or family member received any "financial aid" from the federal government;
- Whether the juror or any family member received any "financial aid" from the state government;
- Whether the juror or any family member received any "assistance" from the federal government;
- Whether the juror or any family member received any "assistance" from the state government;
- Whether they smoke;
- Their opinions regarding lawsuits involving liability for personal injuries;
- Opinions about the Food and Drug Administration;
- Opinions about the Alaska Department of Health;

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- Favorite websites; and
- Use of the internet.

It is hard to image how obtaining all this information is necessary for Lilly to determine if a juror can be fair and impartial. For reasons which will be explained at the hearing, the State of Alaska cannot and should not be associated with this questionnaire. Hence, if the Court requires the prospective jurors to answer these questions, it should be identified as Eli Lilly's juror questionnaire.

D. THE QUESTIONNAIRE IS DESIGNED TO FAVOR ELI LILLY.

Eli Lilly's questionnaire was undoubtedly developed by a jury selection consultant who was hired to obtain information which would enable Lilly to select jurors favorable to its position and unfavorable to the State's position. The Court will note that the questionnaire has numbered coding, which clearly has a hidden use for Lilly's jury consultants. Without question, the jury questionnaire gives wealthy defendants with unlimited resources an unfair advantage.

CONCLUSION

There are many reasons why this Court should not use a juror questionnaire. It is invasive, offensive and unnecessary.

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Certificate of Service

I hereby certify that a true and correct copy of **State of Alaska's Objection to Eli Lilly and Company's Proposed Juror Questionnaire** was served by messenger on:

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

FILED IN OPEN COURT
Date: 2/26/08
Clerk: MLD

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ELI LILLY'S NOTICE OF FILING PROPOSED JUROR QUESTIONNAIRE

Defendant, by and through counsel, provides notice to the court that it is filing herewith, Eli Lilly's Notice of Filing Proposed Juror Questionnaire.

Eli Lilly respectfully requests that this court administer this questionnaire to the jury panel on Monday, March 3, 2008, with copies distributed to the parties on Monday. In order to limit the burden on Court staff, Lilly will undertake to make sufficient copies of the blank questionnaires for the Jury Clerk, and will immediately copy and distribute the completed questionnairs to all parties.

Eli Lilly believes that a written questionnaire is necessary in this case. As the court knows, this case involves questions of severe mental illnesses and the pharmaceuticals used to treat them. It is necessary to inquire with prospective jurors on this topic, and forcing a prospective juror to disclose such information in a public setting is an unnecessary invasion of privacy and embarrassment. In addition, this questionnaire should help the parties and court quickly identify prospective jurors who should be challenged for cause, and this will aid the parties and court to proceed efficiently with the voir dire process.

This proposed questionnaire was transmitted to the State's lead trial counsel, Tommy Fibich, via email early yesterday morning. He initially indicated he wanted to add some questions to it, but he has since advised that the State objects to it as "too long." The State has not objected to any particular question contained on Lilly's proposed questionnaire. Mr. Fibich

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further advised that if the Court allows administration of a juror questionnaire, the State will seek to add questions to it. Lilly has no objection to the State asking additional questions, but hereby reserves the right to object to any particular question proposed by the State.

DATED this 26th day of February, 2008.

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PROPOSED JUROR QUESTIONNAIRE

You have been selected to serve as a prospective juror in a civil case. This questionnaire is designed to assist counsel and the court in selecting fair and impartial jurors. Please answer all of the following questions on the form: However, if there is information that you would prefer to keep confidential, state on this form those questions as to which you would like to speak privately to the judge. In all events, the information is then returned to you or destroyed by court personnel after jury selection. Thank you for your cooperation.

YOUR JUROR NUMBER_____

1. NAME: (Please Print Clearly)

_____

2. AGE: _____

3. ADDRESS:

_____

_____

A. How long have you lived at that address? _____

B. List your prior residences over the past 10 years.

_____

_____

_____

For the following questions, please circle the number next to the response that best describes you and your current situation:

4. Gender:

Male 1

Female 2

5. What is your current marital status?

Never Married	1
Married	2
Separated	3
Divorced	4
Widowed	5

6. Race/Ethnicity:

White/Caucasian	1
Hispanic/Latino	2
Black/African American	3
Asian/Pacific Islander	4
Native American	5
Other	6

7. Highest level of education:

Less than high school	1
GED	2
High school	3
Technical/trade school	4
Some college	5
Bachelor's degree	6
Some graduate study	7

Master's or Doctoral degree 8

If you have attended college, or have done post-graduate work, what was your major course of study?

_____

8. Do you have any difficulty reading, understanding, or speaking the English language?

Yes _____ No _____

9. Do you live alone?

Yes _____ No _____

If not, with whom do you reside?

_____

10. Annual family income:

Under $25,000	1
$25,000 - $50,000	2
$50,000 - $100,000	3
$100,000 or more	4

11. What is your current employment status?

Full time	1
Part time	2
Retired	3
Unemployed	4
Homemaker	5

Disabled 6

12. Job title (if unemployed or retired, write most recent job title):

_____

Describe your duties

_____

What part of your job do you like most?

_____

What part of your job do you like least?

_____

13. Name of employer (if unemployed or retired, please list your most recent employer):

_____

_____

14. If you have a spouse or significant other what is your spouse's or significant other's current employment status?

Full time	1
Part time	2
Retired	3
Unemployed	4
Homemaker	5
Disabled	6

15. Spouse or significant other's job title (if unemployed or retired, please list most recent job title):

_____

16. Name of spouse or significant other's employer (if unemployed or retired, please list the most recent employer):

_____

_____

17. Have you or anyone close to you ever experienced a side effect from a pharmaceutical product?

If so, please explain:

_____

18. Have you ever suffered from a mental illness?

Yes 1

No 2

If yes, please explain:

_____

19. Has anyone in your family or close to you ever suffered from a mental illness?

Yes 1

No 2

If yes, please explain:

_____

20. Have you ever cared for a person with a mental illness?

Yes 1

No 2

If yes, please explain:

_____

21. Have you ever taken medication to treat mental illness?

Yes 1

No 2

If yes, please explain:

_____

22. Has a family member or anyone close to you ever taken medication to treat mental illness?

Yes 1

No 2

If yes, please explain:

_____

23. Have you ever heard of the medicine Zyprexa?

Yes 1

No 2

If yes, do you have an opinion (positive or negative) about Zyprexa? Please explain:

_____

_____

_____

24. Have you heard of "schizophrenia" or "bipolar disorder"?

Yes 1

No 2

A. Do you know anyone who has been diagnosed with "schizophrenia" or "bipolar disorder"?

Yes 1

No 2

B. If yes, please explain:

_____

_____

25. Have you heard of the disease "diabetes"?

Yes 1

No 2

C. Do you know anyone who believes they have had diabetes or a related condition?

Yes 1

No 2

D. If yes, please explain:

_____

_____

E. Have you ever cared for a person who has diabetes or a related condition?

Yes 1

No 2

F. If yes, please explain:

_____

_____

26. Do you or a family member receive any financial aid or assistance from the federal or state government, including Medicaid?

Yes 1

No 2

If yes, please explain:

_____

27. How long have you lived in Alaska?

0-5 years 1

6-10 years 2

11-20 years 3

Over 20 years 4

All my life 5

28. Are you a smoker?

Yes, currently 1

Yes, in the past 2

No 3

29. Do you or someone close to you work for a federal, state, or local government agency?

Yes, currently 1

Yes, in the past 2

No 3

If yes, which agency:

_____

30. Do you have any children? What are their genders, ages, and occupations?

_____

_____

A. If they attend college, university, technical or vocational school, please indicate where they attend.

_____

_____

31. Generally, do you have any opinions regarding lawsuits involving liability for personal injuries? What are they?

_____

_____

32. Have you or anyone close to you ever been injured where you believed a product, a medicine, or a medical device played a major role. If yes, please explain:

_____

33. Have you (or anyone close to you) ever filed a lawsuit or been sued in a civil case?

Yes, sued 1

Yes, been sued 2

Yes, both 3

No, neither 4

Please explain any "yes" answer below:

34. Have you ever sat as a juror in a civil case? or a criminal case?

Did you deliberate?

What was the result of the case?

Were you satisfied with the experience? If not, please explain:

35. Have you heard of Eli Lilly and Company?

Yes 1

No 2

If yes, do you have an opinion (positive or negative) about Eli Lilly and Company? Please explain:

Have you ever used any products made by Eli Lilly and Company?

Yes 1

No 2

If yes, please explain:

_____

36. Have you or a close family member ever served in the military?

Yes 1

No 2

If yes, when and in what branch of the armed services?

_____

_____

Please describe your duties during your military service:

_____

_____

37. Have you heard of the Federal Food and Drug Administration, also known as the FDA?

Yes 1

No 2

If yes, do you have an opinion (positive or negative) about the Food and Drug Administration? Please explain:

_____

_____

38. Do you have an opinion (positive or negative) about the Alaska Department of Health and Social Services? Please explain:

39. Do you have an opinion (positive or negative) about the Alaska State Government? Please explain:

40. Do you have an opinion (positive or negative) about pharmaceutical companies? Please explain:

41. Have you heard or read anything about this lawsuit or any other lawsuit in which the State of Alaska has sued a pharmaceutical company to recover monies paid for medicines?

Yes 1

No 2

If yes, please state what you have read or heard in the lines below:

42. If you have heard or read about this or a similar lawsuit, have you already formed an opinion about this case?

Yes	1
No	2
I have never heard about this case	3

If yes, please state what you have read or heard in the lines below:

_____

_____

43. Is there any reason, no matter how small, that would not allow you to be a fair juror in this case?

Yes	1
No	2

If you answered yes, please explain:

_____

_____

_____

_____

44. This case is estimated to start on _____ and last between _____ and _____ weeks. Is there any reason that would affect your ability to serve as a juror in this case? (This would include, but not be limited to, paid vacations, physical conditions, economic hardships, family events, child care, aged parent care, etc.)

Yes	1
No	2

If you answered yes, please explain the reason(s):

45. What social, civic, or other organizations do you belong to or are you affiliated with?

46. What are your hobbies/ special interests? _____

47. Who are the people you admire most? _____

48. What are your favorite TV shows? _____

49. What are your favorite web sites? _____

50. Do you use the internet to get information about medical issues?

Yes 1

No 2

If yes, which ones:

51. Are there any magazines or newspapers that you subscribe to or read on a regular basis?

Yes 1

No 2

If yes, which ones:

_____

_____

52. From what sources do you get most of your news?

_____

_____

53. Are you personally familiar with or have you or your spouse done business with any of the following individuals, entities firms or companies? (CIRCLE ALL THAT APPLY)

Alaska Psychiatric Institute

T. Scott Allen, Jr. (Cruse, Scott, Henderson & Allen, L.L.P.)

Dr. David Allison, Ph.D.

Dr. Robert Baker

Michael Edwin Bandick

Dr. Charles M. Beasley

Dr. Frederick Brancati, Ph.D.

Dr. Alan Breier

John F. Brenner (Pepper Hamilton LLP)

David Campana

Dr. Patrizia Cavazzoni

Cruse, Scott, Henderson & Allen, L.L.P.

Dr. Lucy Curtiss

Joey Eski

Feldman Orlansky & Sanders

Kenneth T ("Tommy") Fibich (Fibich Hampton & Leebron)

Fibich Hampton & Leebron

Dr. Timothy Franson

James Gottstein

Dr. John L. Gueriguian

Nina M. Gussack (Pepper Hamilton LLP)

H. Blair Hahn (Richardson, Patrick, Westbrook & Brickman, LLC)

Dr. R. Duane Hopson

Dr. Silvio Inzucchi

Brewster Jamieson (Lane Powell LLC)

Jack E. Jordan

Dr. David Kahn

Dr. Bruce Kinon

Lane Powell LLC

Dr. John Clifford Lechleiter, Ph.D.

George A. Lehner (Pepper Hamilton LLP)

David Noesges

Dr. Mark Olfson, M.P.H.

Pepper Hamilton LLP

Richardson, Patrick, Westbrook & Brickman, LLC

Eric T. Sanders (Feldman Orlansky & Sanders)

Dr. Thomas Schwenk

Ed Sniffen (Attorney General's Office State of Alaska)

David Suggs (Richardson, Patrick, Westbrook & Brickman, LLC)

Sidney Taurel

Gary Tollefson

Denice Torres

Dr. William C. Wirshing

THANK YOU. PLEASE GO BACK AND MAKE SURE YOU ANSWERED EACH QUESTION.

_____ _____

Signature Date

002861

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

FILED
STATE OF ALASKA
THIRD DISTRICT
2008 FEB 25 PM 4:29
CLERK OF TRIAL COURTS
DEPUTY CLERK

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ELI LILLY AND COMPANY'S 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 this 25th day of February, 2008.

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac vice*
George A. Lehner, *pro hac vice*
John F. Brenner, *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 February 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

_____
009867.0038/163592.1

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

TABLE OF PROPOSED INSTRUCTIONS

No.	Subject	Source	Corresponding Pattern Instruction	Disputed
1.	Empaneling The Jury	State's Instruction No. 1, with revisions as agreed by parties.[1]	CPJI 1.01	No
2.	Explanation Of Trial Day	State's Instruction No. 2, with revisions as agreed by parties.	CPJI 1.02	No
3.	Introductory Instruction On Procedure	State's Instruction No. 3, with revisions as agreed by parties.	CPJI 1.03	No
4.	Evidence	State's Instruction No. 4.	CPJI 1.05	No
5.	Kinds Of Evidence	State's Instruction No. 8.	CPJI 1.06	No
6.	Credibility of Witnesses	State's Instruction No. 9.	CPJI 1.07	No
7.	Credibility of Expert Witnesses	State's Instruction No. 10.	CPJI 1.08	No
8.	Questions by the Court	State's Instruction No. 13.	CPJI 1.09	No
9.	Relationship of Exhibits to Testimony	State's Instruction No. 11, with revisions as agreed by parties.	CPJI 1.10	No
10.	Note Taking	State's Instruction No. 15.	CPJI 1.11	No
11.	Questions by Jurors	State's Instruction No. 14, with revisions as agreed by parties.	CPJI 1.12	No
12.	Exclusion of Evidence	State's Instruction No. 12.	CPJI 1.13	No
13.	Communications By Jurors With Court	State's Instruction No. 13.	CPJI 1.14	No

[1] 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	Corresponding Pattern Instruction	Disputed
14.	General Remarks	See attached.	CPJI 2.01	Yes
15	Instructions By Court	State's Instruction No. 18.	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 No. 21.	CPJI 2.13	Yes
27.	Videotape Depositions	State's Instruction No. 21.	CPJI 2.14	Yes
28.	Exhibits	See attached.	CPJI 2.17	Yes
29.	Stipulations; Binding Admissions	See attached.	CPJI 2.19	Yes
30.	Questions; Inadmissibility of Evidence; Arguments and Statements of Counsel	State's Instruction No. 20.	CPJI 2.22	No
31.	Failure to Present Evidence	See attached.	CPJI 2.23	Yes

No.	Subject	Source	Corresponding Pattern Instruction	Disputed
32.	Unsworn Oral Admission of Party	See attached.	CPJI 2.25	Yes
33.	Evaluation of Evidence	State's Instruction No. 19.	CPJI 2.26	No
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
37.	Definition Of "Off-Label"	See attached.	n/a	Yes
38.	Off-Label Use Of Medicines	See attached.	n/a	Yes
39.	Dissemination Of Off-Label Information	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
47.	UTPCPA Claims Considered Separately	See attached.	n/a	Yes
48.	Identification Of Alleged UTPCPA Violations	See attached.	n/a	Yes
49.	Damages Determined Separately	See attached.	n/a	Yes

No.	Subject	Source	Corresponding Pattern Instruction	Disputed
50.	Comparative Negligence	See attached.	CPJI 7.06 & 3.03A	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

INSTRUCTION NO. 14. GENERAL REMARKS[2]

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.

[2] Source: AK CPJI 2.01.

INSTRUCTION NO. 16. USE OF PRONOUNS[3]

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.

[3] Source: AK CPJI 2.03.

INSTRUCTION NO. 17. PLAINTIFF'S CLAIMS[4]

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. In order to recover, the plaintiff must establish the elements of at least one of these theories by a preponderance of the evidence. I will now explain preponderance of the evidence to you.

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

INSTRUCTION NO. 21. CREDIBILITY OF WITNESSES[5]

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) any opinion or reputation evidence about the witness's truthfulness;][6]
[(9) any prior criminal convictions of the witness which relate to honesty or veracity;][7]
(10) 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.

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[5] Source: AK CPJI 2.08.
[6] If applicable.
[7] If applicable.

INSTRUCTION NO. 21. (Cont'd)

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.

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.

INSTRUCTION NO. 22. STATUS OF WITNESSES IN COMMUNITY[8]

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.

[8] Source: AK CPJI 2.09.

INSTRUCTION NO. 23. PARTIES EQUAL BEFORE LAW[9]

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.[10]

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[9] Source: materials cited.

[10] *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).

INSTRUCTION NO. 24. CREDIBILITY OF EXPERT WITNESSES[11]

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.

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[11] Source: AK CPJI 2.10.

INSTRUCTION NO. 25. QUESTIONS ASKED BY COURT[12]

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.

[12] Source: AK CPJI 2.12.

INSTRUCTION NO. 28. EXHIBITS[13]

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.

[13] Source: AK CPJI 2.17.

INSTRUCTION NO. 29. STIPULATIONS; BINDING ADMISSIONS[14]

There is no dispute in this case as to the following facts:

[*Insert stipulated facts and facts admitted in pleadings or in requests for admission.*]

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.

[14] Source: AK CPJI 2.19.

INSTRUCTION NO. 31. FAILURE TO PRESENT EVIDENCE[15]

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.

[15] Source: AK CPJI 2.23.

INSTRUCTION NO. 32. UNSWORN ORAL ADMISSIONS OF PARTY[16]

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.

[16] Source: AK CPJI 2.25.

INSTRUCTION NO. 34. FDA APPROVAL PROCESS[17]

The United States Food and Drug Administration, known as the FDA, is the federal agency responsible for regulating prescription drugs.[18] I want to give you some background about the nature of the FDA's role in this regard.

The FDA is "charged by Congress with ensuring that drugs are safe and effective and that product labeling is truthful and not misleading."[19] Before the sponsor of a new drug may begin clinical testing of the drug in humans, the sponsor must demonstrate to the FDA that there is not an unacceptable safety risk to the participants in the clinical studies.[20] During the clinical testing process, the FDA oversees the sponsor's conduct to protect the health and safety of human test subjects, ensure that patients make fully informed decisions about whether to take place in a clinical study, and ensure the integrity and usefulness of the resulting data.[21]

After the clinical trials are completed, the drug sponsor prepares and submits an application to the FDA requesting approval of the drug and its labeling. This application is referred to as a New Drug Application, or "NDA." The FDA regulates the information that must be included in the NDA.[22] An NDA must contain proposed labeling and all information about the drug (whether favorable or unfavorable) that is pertinent to evaluating the application.[23]

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[17] Source: Materials cited.
[18] *See* Food and Drug Administration, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3934-36, 3967 (Jan. 24, 2006); *see also* 21 U.S.C. § 393(b)(2)(B).
[19] 71 Fed. Reg. 3967; *see also* 21 U.S.C. § 393(b)(2)(B).
[20] 21 C.F.R. Part 312.
[21] 21 C.F.R. §§ 312.2, 312.32, 312.33; 21 C.F.R. Part 50.
[22] 21 U.S.C. § 355(b)(1)(A), (b)(1)(F); 21 C.F.R. § 314.50(c), (d)(2), (d)(3), (d)(5), (e).
[23] 71 Fed. Reg. 3967-68; 21 C.F.R. § 314.50.

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.[24] 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.[25] 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.[26] 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.[27]

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[24] 21 U.S.C. § 355(d).
[25] 21 U.S.C. § 355(a).
[26] 21 U.S.C. § 355(d)(1).
[27] 21 U.S.C. § 355(b)(1), 21 C.F.R. Parts 201, 202, and 314.

INSTRUCTION NO. 35. FDA REGULATION OF LABELS[28]

The FDA regulates and must approve the format and the content of prescription drug labeling.[29] You are instructed that Zyprexa and its labeling, including the changes that have been made to Zyprexa's labeling, have been approved by the FDA at all times since September 30, 1996.

Under FDA regulations, the label of a prescription drug must contain several sections intended to provide information to prescribing physicians.[30] 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.[31] 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.[32] The "warnings" section lists serious potential side effects of the drug.[33] 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.[34] 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).[35]

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[28] Source: Materials cited.
[29] 21 C.F.R. Part 201.
[30] 21 C.F.R. § 201.56 & § 201.80.
[31] 21 C.F.R. § 201.80(c) and (j).
[32] 21 C.F.R. § 201.80(d).
[33] 21 C.F.R. § 201.80(e).
[34] 21 C.F.R. § 201.80(f); 65 Fed. Reg. 81082, 81092 (Dec. 22, 2000).
[35] 21 C.F.R. § 201.80(g).

INSTRUCTION NO. 35. (Cont'd.)

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."[36] For some label changes, advance FDA approval is required, while retroactive FDA approval is permitted for other types of label changes.[37] In all cases, however, the final decision "whether labeling revisions are necessary" is made by the FDA, rather than by the drug manufacturer.[38]

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[36] *See* Food and Drug Administration, *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.

[37] 71 Fed. Reg. 3934; *see also* 21 C.F.R. §§ 314.70 & 601.12.

[38] 71 Fed. Reg. 3934-35; *see also* 21 U.S.C. §§ 331, 352; 21 C.F.R. §§ 314.70, 601.12(f).

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]

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[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* Food and Drug Administration, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3968 (Jan. 24, 2006); 21 C.F.R. §§ 201.80(e).

INSTRUCTION NO. 37. DEFINITION OF "OFF-LABEL"[43]

During this trial you heard the phrase "off-label." I want to give you a little background about "off-label" use of prescription drugs. "An off-label use is the prescription of a drug by a doctor for a condition not indicated on the label or for a dosing regimen or patient population not specified on the label."[44]

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[43] Source: Materials cited.

[44] *Association of American Physicians & Surgeons v. United States Food & Drug Administration*, 226 F. Supp. 2d 204, 206 (D.D.C. 2002); *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998) ("*WLF I*") *vacated as moot sub nom. Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000) ("*WLF IV*").

INSTRUCTION NO. 38. OFF-LABEL USE OF MEDICINES[45]

Doctors are allowed to prescribe FDA-approved drugs for "any purpose that [they] deem[] appropriate, regardless of whether the drug has been approved for that use by the FDA."[46] In other words, it is legal for doctors to prescribe FDA-approved drugs for off-label uses.[47]

[45] Source: Materials cited.

[46] *Washington Legal Foundation v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000); *In re Neurontin Marketing & Sales Pract. Litig.*, 244 F.R.D. 89, 92 (D. Mass. 2007).

[47] *Washington Legal Foundation v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000); *In re Neurontin Marketing & Sales Pract. Litig.*, 244 F.R.D. 89, 92 (D. Mass. 2007).

INSTRUCTION NO. 39. DISSEMINATION OF OFF-LABEL INFORMATION[48]

Although doctors are allowed to prescribe FDA-approved drugs for off-label uses, drug manufacturers may not market or promote drugs for off-label uses.[49]

However, drug manufacturers do have a First Amendment right of free speech to disseminate accurate information to doctors about off-label uses of drugs in a non-promotional manner.[50] For example, a drug manufacturer may provide a doctor with information about an off-label use if the doctor asks for information about the off-label use.

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[48] Source: Materials cited.

[49] 21 U.S.C. § 331; *see also, e.g.*, *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001); *In re Neurontin Marketing & Sales Pract. Litig.*, 244 F.R.D. 89, 92 (D. Mass. 2007).

[50] *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999) (*WLF III*); *Washington Legal Foundation v. Friedman*, 36 F. Supp. 2d 16 (D.D.C. 1999) (*WLF II*); *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) (*WLF I*); *vacated as moot sub nom. Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000) (*WLF IV*).

INSTRUCTION NO. 40. LIABILITY FOR DEFECT IN A PRODUCT[51]

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.

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

INSTRUCTION NO. 41. DEFECTIVENESS DEFINED[52]

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.

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[52] 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).

INSTRUCTION NO. 42. SCIENTIFIC UNKNOWABILITY[53]

A product is not defective with regard to any particular danger if the defendant proves it is more likely true than not true that that particular danger was not scientifically knowable when the product left the defendant's possession.

[53] Source: AK CPJI 7.03A (modified for Phase I to reflect modifications in AK CPJI 7.03).

INSTRUCTION NO. 43. EFFECT OF PASSAGE OF TIME ON DUTY TO WARN[54]

The State claims that Zyprexa that was prescribed during the period between September 30, 1996 through September 16, 2003 was defective due to inadequate warnings for the following risks:

(a) **[insert risks based on evidence at trial]**.

You will be given a verdict form that will require you to determine whether Zyprexa was defective during this period. If you find that Zyprexa was defective due to an inadequate warning for one or more of these risks at one point between September 30, 1996 and September 16, 2003, you should not assume that the warning for that risk was inadequate 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 for these risks 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 each risk:

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

(b) the extent to which physicians who prescribed Zyprexa were already knowledgeable about the risk and 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.

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[54] 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").

INSTRUCTION NO. 44. CONSIDERATION OF FDA APPROVAL[55]

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. As I previously instructed you, Zyprexa and its labeling, including changes to the labeling, have been approved by the FDA since September 30, 1996.

In determining the adequacy of the warnings in the Zyprexa label for the risks of **[insert risks based on evidence at trial]**, you may take into account the fact that the FDA approved the Zyprexa labeling, including its warning.

---

[55] Lilly maintains that the State's failure to warn claims are wholly preempted, for the reasons stated in its briefing to the Court in support of its summary judgment motion, and should not be submitted to the jury. However, Lilly acknowledges that the Court has not yet ruled 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 Fed. Reg. 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").

INSTRUCTION NO. 45. UNFAIR OR DECEPTIVE ACT DEFINED[56]

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;[57]

(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;[58]

(3) Advertising goods or services with intent not to sell them as advertised;[59]

(4) 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;[60] and

(5) 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.[61]

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[56] Source: Jury Instruction No. 11, *State of Alaska v. Anchorage-Nissan, Inc.*, CA No. 3AN-93-7761 CI (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).

[57] AS § 45.50.471(b)(4).

[58] AS § 45.50.471(b)(6).

[59] AS § 45.50.471(b)(8).

[60] AS § 45.50.471(b)(11).

[61] AS § 45.50.471(b)(12).

INSTRUCTION NO. 46. "TRADE OR COMMERCE" DEFINED[62]

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

[62] Source: AK CPJI 10.02.

INSTRUCTION NO. 47. UTPCPA CLAIMS CONSIDERED SEPARATELY[63]

The State has alleged a number of different violations of the UTPCPA. You are to decide whether Defendant committed each alleged violation on its own merits, separately from the other alleged violations. Thus, if you find that Defendant committed one of the alleged violations, you may not assume that it is more likely true that not true that Defendant committed other violations. This is called "propensity" evidence, and it is forbidden under Alaska law. When deciding a particular claim, however, you may consider evidence relating to other violations to decide whether Defendant had any specific intent, plan or motive in connection with the particular transaction under consideration.

The following instructions identify for you the State's specific claims in connection with each alleged violation. To decide whether each alleged violation occurred, you must decide two things with respect to that alleged violation. 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.

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[63] Source: Jury Instructions Nos. 18 & 20, *State of Alaska v. Anchorage-Nissan, Inc.*, CA No. 3AN-93-7761 CI (Super. Ct., 3d Jud. Dist., 1/12/1995), *approved*, *State of Alaska v. Anchorage-Nissan, Inc.*, 941 P.2d 1229, 1221 (Alaska 1997) (modified and consolidated to reduce length).

INSTRUCTION NO. 48. IDENTIFICATION OF ALLEGED UTPCPA VIOLATIONS.[64]

First Alleged UTPCPA Violation

The first UTPCPA violation alleged by the State is that Defendant committed an unfair or deceptive act or practice by engaging in the following conduct:

[Insert "who, what, where, when" identification of the alleged acts on which the violation is based, following presentation of State's evidence at trial, so that verdict form can include a separate question for each alleged violation.]

Defendant denies that it committed these acts.

Second Alleged UTPCPA Violation

The second UTPCPA violation alleged by the State is that Defendant committed an unfair or deceptive act or practice by engaging in the following conduct:

[Insert "who, what, where, when" identification of the alleged acts on which the violation is based, following presentation of State's evidence at trial, so that verdict form can include a separate question for each alleged violation.]

Defendant denies that it committed these acts.

[NOTE: add or delete identification of alleged violations as warranted by evidence at trial]

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[64] Source: Jury Instructions Nos. 21-29, *State of Alaska v. Anchorage-Nissan, Inc.*, CA No. 3AN-93-7761 CI (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).

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.

INSTRUCTION NO. 50. COMPARATIVE NEGLIGENCE[65]

In response to the State's claim, the Defendant alleges that the State was negligent. In order to establish this claim, the Defendant must prove that it is more likely true than not true that the State was negligent.

I will now define negligence for you. Negligence is the failure to use reasonable care. Reasonable care is that amount of care that a reasonably prudent person would use under similar circumstances. Negligence may consist of doing something which a reasonably prudent person would not do, or it may consist of failing to do something which a reasonably prudent person would do. A reasonably prudent person is not the exceptionally cautious or skillful individual, but a person of reasonable and ordinary carefulness.

In this case, you must decide whether the State used reasonable care under the circumstances.

If you find that the Plaintiff was negligent, the Court will determine in a separate proceeding what effect, if any, the Plaintiff's negligence should have on whether the Plaintiff is entitled to any money from the Defendant. Your duty is to answer the questions that are presented to you in Special Verdict form, based on the evidence that has been presented and the instructions that I have given you.

---

[65] Source: AK CPJI 7.06 (modified for Phase I to eliminate portions related to causation and damages) and AK CPJI 3.03A. *See also* AS § 09.17.060 (extending defense of comparative negligence to actions "based on fault"); 09.17.900 (defining fault to include "acts or omissions that are in any measure negligent, reckless, or intentional toward the person or property of the actor or others, or that subject a person to strict tort liability"); *Smith v. Ingersoll-Rand Co.*, 14 P.3d 990, 996 (Alaska 2000) (recognizing comparative negligence as a defense in strict product liability cases); *see also, e.g., Loughridge v. Goodyear Tire & Rubber Co.*, 207 F. Supp. 2d 1187, 1192 (D. Colo. 2002) (applying comparative fault principles to statutory consumer protection claim); *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 367 (N.J. 1997) (same).

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 it is more likely true than not true that Zyprexa was defective due to inadequate warnings for the risk of ***[insert risks based on proofs at trial]****, you should check "No." Conversely, if the State proved that it is more likely true than not true that Zyprexa was defective due to inadequate warnings for the risk of* ***[insert risks based on proofs at trial]****, you should check "Yes," unless the Defendant proved that it is more likely true than not true that that risk was not scientifically knowable.*

(1) At any time between September 30, 1996 and September 16, 2003, 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 for each alleged UTPCPA violation identified in Instruction No. 48. In answering Question No. 2, you must consider each alleged violation separately. If the State failed to prove that it is more likely true than not true that Defendant committed an unfair or deceptive act or practice with respect to an alleged violation, you should check "No" for that alleged violation. Conversely, if the State proved that it is more likely true than not true that Defendant committed an unfair or deceptive act or practice with respect to an alleged violation, you should check "Yes" for that alleged violation.

(2) Did Defendant commit an unfair or deceptive act or practice with respect to any of the following alleged UTPCPA violations as identified in Instruction No. 48?

First Alleged UTPCPA Violation: _____ Yes _____ No
Second Alleged UTPCPA Violation: _____ Yes _____ No
[Insert or delete alleged violations as the evidence presented at trial warrants.]

If your answer to Question Nos. 1 and 2 was "No," then do not answer Question No. 3. If you answered "Yes" to Question No. 1 or any part of Question No. 2, then you must answer Question No. 3. If the Defendant failed to prove that it is more likely true than not true that the State was negligent, you should check "No." Conversely, if the Defendant proved that it is more likely true than not true that the State was negligent, you should check "Yes."

(3) At any time between September 30, 1996 and September 16, 2003, was the State negligent? 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

FILED
STATE OF ALASKA
THIRD DISTRICT
FEB 25 PM 4:29
DEPUTY CLERK

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

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

[CLEAN 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 this 25th day of February, 2008.

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac vice*
George A. Lehner, *pro hac vice*
John F. Brenner, *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 February 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 99501-3911

_____
009867/0038/163594.1

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Anchorage, Alaska 99503-2648
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TABLE OF PROPOSED INSTRUCTIONS

No.	Subject	Source	Corresponding Pattern Instruction	Disputed
1.	Empaneling The Jury	State's Instruction No. 1, with revisions as agreed by parties.[1]	CPJI 1.01	No
2.	Explanation Of Trial Day	State's Instruction No. 2, with revisions as agreed by parties.	CPJI 1.02	No
3.	Introductory Instruction On Procedure	State's Instruction No. 3, with revisions as agreed by parties.	CPJI 1.03	No
4.	Evidence	State's Instruction No. 4.	CPJI 1.05	No
5.	Kinds Of Evidence	State's Instruction No. 8.	CPJI 1.06	No
6.	Credibility of Witnesses	State's Instruction No. 9.	CPJI 1.07	No
7.	Credibility of Expert Witnesses	State's Instruction No. 10.	CPJI 1.08	No
8.	Questions by the Court	State's Instruction No. 13.	CPJI 1.09	No
9.	Relationship of Exhibits to Testimony	State's Instruction No. 11, with revisions as agreed by parties.	CPJI 1.10	No
10.	Note Taking	State's Instruction No. 15.	CPJI 1.11	No
11.	Questions by Jurors	State's Instruction No. 14, with revisions as agreed by parties.	CPJI 1.12	No
12.	Exclusion of Evidence	State's Instruction No. 12.	CPJI 1.13	No
13.	Communications By Jurors With Court	State's Instruction No. 13.	CPJI 1.14	No

[1] 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	Corresponding Pattern Instruction	Disputed
14.	General Remarks	See attached.	CPJI 2.01	Yes
15	Instructions By Court	State's Instruction No. 18.	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 No. 21.	CPJI 2.13	Yes
27.	Videotape Depositions	State's Instruction No. 21.	CPJI 2.14	Yes
28.	Exhibits	See attached.	CPJI 2.17	Yes
29.	Stipulations; Binding Admissions	See attached.	CPJI 2.19	Yes
30.	Questions; Inadmissibility of Evidence; Arguments and Statements of Counsel	State's Instruction No. 20.	CPJI 2.22	No
31.	Failure to Present Evidence	See attached.	CPJI 2.23	Yes

No.	Subject	Source	Corresponding Pattern Instruction	Disputed
32.	Unsworn Oral Admission of Party	See attached.	CPJI 2.25	Yes
33.	Evaluation of Evidence	State's Instruction No. 19.	CPJI 2.26	No
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
37.	Definition Of "Off-Label"	See attached.	n/a	Yes
38.	Off-Label Use Of Medicines	See attached.	n/a	Yes
39.	Dissemination Of Off-Label Information	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
47.	UTPCPA Claims Considered Separately	See attached.	n/a	Yes
48.	Identification Of Alleged UTPCPA Violations	See attached.	n/a	Yes
49.	Damages Determined Separately	See attached.	n/a	Yes

No.	Subject	Source	Corresponding Pattern Instruction	Disputed
50.	Comparative Negligence	See attached.	CPJI 7.06 & 3.03A	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

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. _____.

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. In order to recover, the plaintiff must establish the elements of at least one of these theories by a preponderance of the evidence. I will now explain preponderance of the evidence to you.

INSTRUCTION NO. _____.

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) any opinion or reputation evidence about the witness's truthfulness;
(9) any prior criminal convictions of the witness which relate to honesty or veracity;
(10) 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.

INSTRUCTION NO. _____. (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.

INSTRUCTION NO. ____.

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.

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. ____.

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.

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. _____.

There is no dispute in this case as to the following facts:

[*Insert stipulated facts and facts admitted in pleadings or in requests for admission.*]

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.

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. _____.

The United States Food and Drug Administration, known as the FDA, is the federal agency responsible for regulating prescription drugs. I want to give you some background about the nature of the FDA's role in this regard.

The FDA is charged by Congress with ensuring that drugs are safe and effective and that product labeling is truthful and not misleading. Before the sponsor of a new drug may begin clinical testing of the drug in humans, the sponsor must demonstrate to the FDA that there is not an unacceptable safety risk to the participants in the clinical studies. During the clinical testing process, the FDA oversees the sponsor's conduct to protect the health and safety of human test subjects, ensure that patients make fully informed decisions about whether to take place in a clinical study, and ensure the integrity and usefulness of the resulting data.

After the clinical trials are completed, the drug sponsor prepares and submits an application to the FDA requesting approval of the drug and its labeling. This application is referred to as a New Drug Application, or "NDA." The FDA regulates the information that must be included in the NDA. An NDA must contain proposed labeling and all information about the drug (whether favorable or unfavorable) that is pertinent to evaluating the application.

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. 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. 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. 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.

INSTRUCTION NO. _____.

The FDA regulates and must approve the format and the content of prescription drug labeling. You are instructed that Zyprexa and its labeling, including the changes that have been made to Zyprexa's labeling, have been approved by the FDA at all times since September 30, 1996.

Under FDA regulations, the label of a prescription drug must contain several sections intended to provide information to prescribing physicians. 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. 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. The "warnings" section lists serious potential side effects of the drug. 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. 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).

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. For some label changes, advance FDA approval is required, while retroactive FDA approval is permitted for other types of label changes. In all cases, however, the final decision whether labeling revisions are necessary is made by the FDA, rather than by the drug manufacturer.

INSTRUCTION NO. _____.

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. 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, or it may require the manufacturer to make changes to the drug's labeling based on the new information.

INSTRUCTION NO. _____.

During this trial you heard the phrase "off-label." I want to give you a little background about off-label use of prescription drugs. An off-label use is the prescription of a drug by a doctor for a condition not indicated on the label or for a dosing regimen or patient population not specified on the label.

INSTRUCTION NO. _____.

Doctors are allowed to prescribe FDA-approved drugs for any purpose that they deem appropriate, regardless of whether the drug has been approved for that use by the FDA. In other words, it is legal for doctors to prescribe FDA-approved drugs for off-label uses.

INSTRUCTION NO. ____.

Although doctors are allowed to prescribe FDA-approved drugs for off-label uses, drug manufacturers may not market or promote drugs for off-label uses.

However, drug manufacturers do have a First Amendment right of free speech to disseminate accurate information to doctors about off-label uses of drugs in a non-promotional manner. For example, a drug manufacturer may provide a doctor with information about an off-label use if the doctor asks for information about the off-label use.

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. _____.

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.

INSTRUCTION NO. _____.

A product is not defective with regard to any particular danger if the defendant proves it is more likely true than not true that that particular danger was not scientifically knowable when the product left the defendant's possession.

INSTRUCTION NO. _____.

The State claims that Zyprexa that was prescribed during the period between September 30, 1996 through September 16, 2003 was defective due to inadequate warnings for the following risks:

(a) **[insert risks based on evidence at trial]**.

You will be given a verdict form that will require you to determine whether Zyprexa was defective during this period. If you find that Zyprexa was defective due to an inadequate warning for one or more of these risks at one point between September 30, 1996 and September 16, 2003, you should not assume that the warning for that risk was inadequate 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 for these risks 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 each risk:

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

(b) the extent to which physicians who prescribed Zyprexa were already knowledgeable about the risk and 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.

INSTRUCTION NO. _____.

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. As I previously instructed you, Zyprexa and its labeling, including changes to the labeling, have been approved by the FDA since September 30, 1996.

In determining the adequacy of the warnings in the Zyprexa label for the risks of [**insert risks based on evidence at trial**], you may take into account the fact that the FDA approved the Zyprexa labeling, including its warning.

INSTRUCTION NO. _____.

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;

(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;

(3) Advertising goods or services with intent not to sell them as advertised;

(4) 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; and

(5) 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.

INSTRUCTION NO. _____.

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

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INSTRUCTION NO. _____.

The State has alleged a number of different violations of the UTPCPA. You are to decide whether Defendant committed each alleged violation on its own merits, separately from the other alleged violations. Thus, if you find that Defendant committed one of the alleged violations, you may not assume that it is more likely true that not true that Defendant committed other violations. This is called "propensity" evidence, and it is forbidden under Alaska law. When deciding a particular claim, however, you may consider evidence relating to other violations to decide whether Defendant had any specific intent, plan or motive in connection with the particular transaction under consideration.

The following instructions identify for you the State's specific claims in connection with each alleged violation. To decide whether each alleged violation occurred, you must decide two things with respect to that alleged violation. 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.

INSTRUCTION NO. ____.

First Alleged UTPCPA Violation

The first UTPCPA violation alleged by the State is that Defendant committed an unfair or deceptive act or practice by engaging in the following conduct:

[Insert "who, what, where, when" identification of the alleged acts on which the violation is based, following presentation of State's evidence at trial, so that verdict form can include a separate question for each alleged violation.]

Defendant denies that it committed these acts.

Second Alleged UTPCPA Violation

The second UTPCPA violation alleged by the State is that Defendant committed an unfair or deceptive act or practice by engaging in the following conduct:

[Insert "who, what, where, when" identification of the alleged acts on which the violation is based, following presentation of State's evidence at trial, so that verdict form can include a separate question for each alleged violation.]

Defendant denies that it committed these acts.

[NOTE: add or delete identification of alleged violations as warranted by evidence at trial]

INSTRUCTION NO. ____.

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.

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INSTRUCTION NO. _____.

In response to the State's claim, the Defendant alleges that the State was negligent. In order to establish this claim, the Defendant must prove that it is more likely true than not true that the State was negligent.

I will now define negligence for you. Negligence is the failure to use reasonable care. Reasonable care is that amount of care that a reasonably prudent person would use under similar circumstances. Negligence may consist of doing something which a reasonably prudent person would not do, or it may consist of failing to do something which a reasonably prudent person would do. A reasonably prudent person is not the exceptionally cautious or skillful individual, but a person of reasonable and ordinary carefulness.

In this case, you must decide whether the State used reasonable care under the circumstances.

If you find that the Plaintiff was negligent, the Court will determine in a separate proceeding what effect, if any, the Plaintiff's negligence should have on whether the Plaintiff is entitled to any money from the Defendant. Your duty is to answer the questions that are presented to you in Special Verdict form, based on the evidence that has been presented and the instructions that I have given you.

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 it is more likely true than not true that Zyprexa was defective due to inadequate warnings for the risk of ***[insert risks based on proofs at trial]****, you should check "No." Conversely, if the State proved that it is more likely true than not true that Zyprexa was defective due to inadequate warnings for the risk of* ***[insert risks based on proofs at trial]****, you should check "Yes," unless the Defendant proved that it is more likely true than not true that that risk was not scientifically knowable.*

(1) At any time between September 30, 1996 and September 16, 2003, was Zyprexa defective when it left the possession of Defendant? If so, when?

___ No

___ Yes. Date(s): _____

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Answer "yes" or "no" to Question No. 2 for each alleged UTPCPA violation identified in Instruction No. 48. In answering Question No. 2, you must consider each alleged violation separately. If the State failed to prove that it is more likely true than not true that Defendant committed an unfair or deceptive act or practice with respect to an alleged violation, you should check "No" for that alleged violation. Conversely, if the State proved that it is more likely true than not true that Defendant committed an unfair or deceptive act or practice with respect to an alleged violation, you should check "Yes" for that alleged violation.

(2) Did Defendant commit an unfair or deceptive act or practice with respect to any of the following alleged UTPCPA violations as identified in Instruction No. 48?

First Alleged UTPCPA Violation: _____ Yes _____ No
Second Alleged UTPCPA Violation: _____ Yes _____ No
[Insert or delete alleged violations as the evidence presented at trial warrants.]

If your answer to Question Nos. 1 and 2 was "No," then do not answer Question No. 3. If you answered "Yes" to Question No. 1 or any part of Question No. 2, then you must answer Question No. 3. If the Defendant failed to prove that it is more likely true than not true that the State was negligent, you should check "No." Conversely, if the Defendant proved that it is more likely true than not true that the State was negligent, you should check "Yes."

(3) At any time between September 30, 1996 and September 16, 2003, was the State negligent? 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, vs. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CIV

STATE OF ALASKA'S JURY INSTRUCTIONS

In accordance with the pretrial order, the State of Alaska submits its proposed jury instructions organized as follows: Behind the first tab are agreed-upon instructions. Behind the second tab are the State's proposed instructions to which Lilly has objected. Each instruction is provided twice: a numbered copy with citations at the bottom, followed by a blank copy.

DATED this 25 day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
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Certificate of Service
I hereby certify that a true and correct copy of
State of Alaska's Jury Instructions was served by messenger on:

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Instructions

State's Instruction 1

You have been chosen as a juror in this case. Before you take the juror's oath, I must impress upon you the seriousness and importance of being a member of a jury. Trial by jury is a fundamental right in Alaska. Each case is to be decided by citizens who are fairly selected, who act without bias, and who render a fair verdict based upon the evidence presented at trial.

You took one oath before you were questioned about your qualifications to be a juror. Now you will take a second oath. By this oath you swear or affirm that you will decide the case on the evidence presented and according to the law as explained by me.

When you take the oath you accept serious and important obligations. The jury system depends on the honesty and the integrity of each individual juror. By this oath, you affirm that the answers you have given concerning your qualifications to sit on this jury were complete and correct. You affirm that you are truly impartial in this case. You affirm that you have told the parties and me everything we should know about your ability to sit as a juror in this case.

If you believe you should not take this oath or that there is something else that the parties or I should know, please raise your hand. You can give your information to me and to the parties privately.

I will now administer the oath.

Alaska Civil Pattern Jury Instruction No. 1.01 (eliminating reference to alternates)

Instruction _____

You have been chosen as a juror in this case. Before you take the juror's oath, I must impress upon you the seriousness and importance of being a member of a jury. Trial by jury is a fundamental right in Alaska. Each case is to be decided by citizens who are fairly selected, who act without bias, and who render a fair verdict based upon the evidence presented at trial.

You took one oath before you were questioned about your qualifications to be a juror. Now you will take a second oath. By this oath you swear or affirm that you will decide the case on the evidence presented and according to the law as explained by me.

When you take the oath you accept serious and important obligations. The jury system depends on the honesty and the integrity of each individual juror. By this oath, you affirm that the answers you have given concerning your qualifications to sit on this jury were complete and correct. You affirm that you are truly impartial in this case. You affirm that you have told the parties and me everything we should know about your ability to sit as a juror in this case.

If you believe you should not take this oath or that there is something else that the parties or I should know, please raise your hand. You can give your information to me and to the parties privately.

I will now administer the oath.

State's Instruction 2

First, some housekeeping matters. Our trial day will start at 8:30 a.m. You must be in the jury room every morning by _____. We cannot begin until you are all here.

_____ is the in-court deputy and will escort you from the jury room when the trial is in session.

The trial will continue until 1:30 p.m. each day. We will not take a break for lunch, but we will have recesses, and you may bring snacks with you that you may eat when you are in the jury room. After the case is submitted to you for deliberation, if you are deliberating at lunch time, arrangements will be made to provide lunch for you.

During the recesses that we take during the trial day, you will retire to the jury room together. Coffee and restrooms are available in the jury room. When we recess at the end of the trial day, you will not be required to remain together. This is not a sequestered jury. However, you must obey the following instructions during each and every recess of the court:

First, do not discuss the case either among yourselves or with anyone else until the end of the trial. Do not read newspaper articles about the case or watch or listen to television or radio news stories about this case until the trial is over. Do not read about this case or any matters related to this case on the internet.

In fairness to the parties to this lawsuit, you must keep an open mind throughout the trial. You must not reach your conclusion until final deliberations which will be after all the evidence is in, after you have heard the attorneys' closing arguments, and after my instructions to you on the law. During deliberations, you should reach your conclusion only after an exchange of views with the other members of the jury.

Second, do not permit anyone to discuss the case in your presence. If anyone tries to do so, you should tell him or her to stop. If they persist, report that fact to the in-court deputy as soon as you are able. You should not, however, discuss with your fellow jurors either the fact that someone tried to talk to you about this case or any other fact that you feel necessary to bring to the attention of the court.

Third, although it is a normal human tendency to talk with people with whom one is thrown in contact, during the time you serve on this jury, please do not talk, in or out of the courtroom, with any of the parties, their attorneys, or any witness. By this I mean not only do not talk to them about the case, but do not talk to them at all, even to pass the time of day. Parties and attorneys have been instructed likewise. In no other way can all parties be assured of the absolute impartiality they are entitled to expect from you as jurors.

State's Instruction 2 (cont.)

Fourth, do not conduct any investigations on your own or do any research concerning this case outside of the courtroom, either in the library or on the internet or any other place. Do not visit any locations where any of the events of the case have occurred. You must decide this case based only on the evidence presented here in court.

Alaska Civil Pattern Jury Instruction No. 1.02 (with modifications to the first and third paragraph, to reflect local practice)

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A Instructions

Instruction ___

First, some housekeeping matters. Our trial day will start at 8:30 a.m. You must be in the jury room every morning by _____. We cannot begin until you are all here.

_____ is the in-court deputy and will escort you from the jury room when the trial is in session.

The trial will continue until 1:30 p.m. each day. We will not take a break for lunch, but we will have recesses, and you may bring snacks with you that you may eat when you are in the jury room. After the case is submitted to you for deliberation, if you are deliberating at lunch time, arrangements will be made to provide lunch for you.

During the recesses that we take during the trial day, you will retire to the jury room together. Coffee and restrooms are available in the jury room. When we recess at the end of the trial day, you will not be required to remain together. This is not a sequestered jury. However, you must obey the following instructions during each and every recess of the court:

First, do not discuss the case either among yourselves or with anyone else until the end of the trial. Do not read newspaper articles about the case or watch or listen to television or radio news stories about this case until the trial is over. Do not read about this case or any matters related to this case on the internet.

In fairness to the parties to this lawsuit, you must keep an open mind throughout the trial. You must not reach your conclusion until final deliberations which will be after all the evidence is in, after you have heard the attorneys' closing arguments, and after my instructions to you on the law. During deliberations, you should reach your conclusion only after an exchange of views with the other members of the jury.

Second, do not permit anyone to discuss the case in your presence. If anyone tries to do so, you should tell him or her to stop. If they persist, report that fact to the in-court deputy as soon as you are able. You should not, however, discuss with your fellow jurors either the fact that someone tried to talk to you about this case or any other fact that you feel necessary to bring to the attention of the court.

Instruction __ (cont.)

Third, although it is a normal human tendency to talk with people with whom one is thrown in contact, during the time you serve on this jury, please do not talk, in or out of the courtroom, with any of the parties, their attorneys, or any witness. By this I mean not only do not talk to them about the case, but do not talk to them at all, even to pass the time of day. Parties and attorneys have been instructed likewise. In no other way can all parties be assured of the absolute impartiality they are entitled to expect from you as jurors.

Fourth, do not conduct any investigations on your own or do any research concerning this case outside of the courtroom, either in the library or on the internet or any other place. Do not visit any locations where any of the events of the case have occurred. You must decide this case based only on the evidence presented here in court.

State's Instruction 3

Now that you have taken your oath, you are ready to serve as jurors. To assist you in your task, I am going to explain how a trial is conducted.

There are five parts to a trial. The first part will be opening statements. Each party will make an opening statement outlining its case. What is said in opening statements is not evidence. The purpose of opening statements is to provide you with a preview of the evidence which the party intends to present.

The second part of the trial is the longest part of the trial because it is the presentation of evidence by each party. Most of the evidence will be either testimony by witnesses or exhibits.

The third part of the trial will be closing arguments. During closing arguments, the parties will tell you what they believe the evidence has proved and urge you to draw certain conclusions from the evidence. What is said in closing arguments is not evidence.

In the fourth part of the trial, I will instruct you about the law which you must apply to reach your decision.

The fifth part of the trial will be jury deliberations. This is the time when you meet together to discuss the evidence, to decide what the facts are, to apply the law, and to make the decisions required to arrive at a verdict.

Alaska Civil Pattern Jury Instruction No. 1.03 (with reference to alternate jurors deleted)

Instruction ___

Now that you have taken your oath, you are ready to serve as jurors. To assist you in your task, I am going to explain how a trial is conducted.

There are five parts to a trial. The first part will be opening statements. Each party will make an opening statement outlining its case. What is said in opening statements is not evidence. The purpose of opening statements is to provide you with a preview of the evidence which the party intends to present.

The second part of the trial is the longest part of the trial because it is the presentation of evidence by each party. Most of the evidence will be either testimony by witnesses or exhibits.

The third part of the trial will be closing arguments. During closing arguments, the parties will tell you what they believe the evidence has proved and urge you to draw certain conclusions from the evidence. What is said in closing arguments is not evidence.

In the fourth part of the trial, I will instruct you about the law which you must apply to reach your decision.

The fifth part of the trial will be jury deliberations. This is the time when you meet together to discuss the evidence, to decide what the facts are, to apply the law, and to make the decisions required to arrive at a verdict.

State's Instruction 4

We are almost ready for the first part of the trial, the attorneys' opening statements.

Before you hear from the attorneys, I will give you a very brief introduction to the case and to the parties' claims. I do not mean to give any indication whatsoever about how you should decide the case. My goal is only to give you some orientation that will save the lawyers some time and perhaps help you in listening to the lawyers.

Instruction ___

We are almost ready for the first part of the trial, the attorneys' opening statements.

Before you hear from the attorneys, I will give you a very brief introduction to the case and to the parties' claims. I do not mean to give any indication whatsoever about how you should decide the case. My goal is only to give you some orientation that will save the lawyers some time and perhaps help you in listening to the lawyers.

State's Instruction 7

You have now heard the opening statements. We will next proceed to the second part of the trial. This is your opportunity to see and hear the evidence upon which you will decide the case.

Each side will have an opportunity to present evidence. In our system, the plaintiff is entitled to present its evidence first. Then the defendant presents its evidence. Then each party may have an additional opportunity to present rebuttal evidence.

Some of the evidence may be sworn testimony by witnesses. This testimony may be presented in person, telephonically, by videotape, or read to you from a sworn statement. You must evaluate all sworn testimony regardless of how it is presented.

Each side will have an opportunity to question each witness twice. This process is why we call our system an adversarial system. We begin with direct examination, followed by cross-examination, then re-direct and re-cross. The party who calls the witness will start the questioning.

Some of the evidence may be exhibits such as documents, pictures, or objects. The exhibits will be identified for you by number or by letter.

There is one other kind of evidence that may be presented during the trial. The parties may agree that certain facts are true. This is called a stipulation. You must accept as true any facts that are read to you in a stipulation. There are also certain facts that the law requires you to accept as true. This is called judicial notice. The court will clearly identify stipulations and any facts of which the court takes judicial notice.

I have told you about the sources of evidence. I will now tell you what is not evidence. Nothing the attorneys say is evidence and nothing the court says is evidence. If there are any exceptions to this during the trial, I will clearly identify them for you. Remember you must decide this case based only on the evidence presented here in court.

Alaska Civil Pattern Jury Instruction No. 1.05 (modified to eliminate reference to judicial notice and presumption; sentences added with respect to stipulations)

Instruction ___

You have now heard the opening statements. We will next proceed to the second part of the trial. This is your opportunity to see and hear the evidence upon which you will decide the case.

Each side will have an opportunity to present evidence. In our system, the plaintiff is entitled to present its evidence first. Then the defendant presents its evidence. Then each party may have an additional opportunity to present rebuttal evidence.

Some of the evidence may be sworn testimony by witnesses. This testimony may be presented in person, telephonically, by videotape, or read to you from a sworn statement. You must evaluate all sworn testimony regardless of how it is presented.

Each side will have an opportunity to question each witness twice. This process is why we call our system an adversarial system. We begin with direct examination, followed by cross-examination, then re-direct and re-cross. The party who calls the witness will start the questioning.

Some of the evidence may be exhibits such as documents, pictures, or objects. The exhibits will be identified for you by number or by letter.

There is one other kind of evidence that may be presented during the trial. The parties may agree that certain facts are true. This is called a stipulation. You must accept as true any facts that are read to you in a stipulation. There are also certain facts that the law requires you to accept as true. This is called judicial notice. The court will clearly identify stipulations and any facts of which the court takes judicial notice.

I have told you about the sources of evidence. I will now tell you what is not evidence. Nothing the attorneys say is evidence and nothing the court says is evidence. If there are any exceptions to this during the trial, I will clearly identify them for you. Remember you must decide this case based only on the evidence presented here in court.

State's Instruction 8

I have just described the ways that evidence may be presented. Regardless of the way it is presented, evidence is either direct or circumstantial. Direct evidence, if you accept it as true, proves a fact. Circumstantial evidence, if you accept it as true, proves a fact from which you may infer that another fact is also true.

Let me give you an example. Let us pretend that as a juror you are asked to decide the following question: Did snow fall during a particular night? Direct evidence would be a witness testifying that the witness awoke during that night, went to the window, and saw the snow falling. From this evidence you could conclude that snow fell during the night.

Circumstantial evidence would be a witness testifying that the ground was bare when the witness went to sleep at 10:00 p.m., but the next morning when the witness awoke and looked out the window, the witness saw that the ground was covered with snow. From this evidence you could also conclude that snow fell during the night.

Facts may be proved by either direct or circumstantial evidence. The law accepts each as a reasonable method of proof.

Alaska Civil Pattern Jury Instruction No. 1.06

Instruction ___

I have just described the ways that evidence may be presented. Regardless of the way it is presented, evidence is either direct or circumstantial. Direct evidence, if you accept it as true, proves a fact. Circumstantial evidence, if you accept it as true, proves a fact from which you may infer that another fact is also true.

Let me give you an example. Let us pretend that as a juror you are asked to decide the following question: Did snow fall during a particular night? Direct evidence would be a witness testifying that the witness awoke during that night, went to the window, and saw the snow falling. From this evidence you could conclude that snow fell during the night.

Circumstantial evidence would be a witness testifying that the ground was bare when the witness went to sleep at 10:00 p.m., but the next morning when the witness awoke and looked out the window, the witness saw that the ground was covered with snow. From this evidence you could also conclude that snow fell during the night.

Facts may be proved by either direct or circumstantial evidence. The law accepts each as a reasonable method of proof.

State's Instruction 9

Every person who testifies under oath is a witness. You, as jurors, are the sole judges of the credibility of the witnesses.

In deciding whether to believe a witness and how much weight to give a witness' 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' appearance, attitude, and behavior on the stand and the way the witness testifies;

(2) the witness' age, intelligence, and experience;

(3) the witness' opportunity and ability to see or hear the things the witness testifies about;

(4) the accuracy of the witness' 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) any opinion or reputation evidence about the witness' truthfulness;

(9) any prior criminal convictions of the witness which relate to honesty or veracity; and

(10) the consistency of the witness' testimony and whether it is supported or contradicted by other evidence.

You should bear in mind that inconsistencies and contradictions in a witness' testimony, or between a witness' testimony and that of others, do not necessarily mean that you should disbelieve the witness. It is not uncommon for people to forget or remember things incorrectly and this may explain some inconsistencies and contradictions. It is 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.

State's Instruction 9 (cont.)

If you believe that part of a witness' testimony is false, you may choose to distrust other parts also, 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' testimony is uncontradicted. However, you should act reasonably in deciding whether you believe a witness and how much weight to give to the witness' testimony.

Alaska Civil Pattern Jury Instruction No. 1.07

Instruction ___

Every person who testifies under oath is a witness. You, as jurors, are the sole judges of the credibility of the witnesses.

In deciding whether to believe a witness and how much weight to give a witness' 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' appearance, attitude, and behavior on the stand and the way the witness testifies;

(2) the witness' age, intelligence, and experience;

(3) the witness' opportunity and ability to see or hear the things the witness testifies about;

(4) the accuracy of the witness' 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) any opinion or reputation evidence about the witness' truthfulness;

(9) any prior criminal convictions of the witness which relate to honesty or veracity; and

(10) the consistency of the witness' testimony and whether it is supported or contradicted by other evidence.

You should bear in mind that inconsistencies and contradictions in a witness' testimony, or between a witness' testimony and that of others, do not necessarily mean that you should disbelieve the witness. It is not uncommon for people to forget or remember things incorrectly and this may explain some inconsistencies and contradictions. It is 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.

Instruction ___ (cont.)

If you believe that part of a witness' testimony is false, you may choose to distrust other parts also, 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' testimony is uncontradicted. However, you should act reasonably in deciding whether you believe a witness and how much weight to give to the witness' testimony.

State's Instruction 10

Expert witnesses will testify 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 or not 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 you believe an expert witness and how much weight to give expert testimony.

Alaska Civil Pattern Jury Instruction No. 1.08

002958

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Instructions

Instruction ___

Expert witnesses will testify 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 or not 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 you believe an expert witness and how much weight to give expert testimony.

State's Instruction 11

You will have exhibits, such as documents, pictures, or objects, to consider as evidence. In deciding how much to rely on an exhibit in reaching a verdict, 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.

Alaska Civil Pattern Jury Instruction No. 1.10

Instruction ___

You will have exhibits, such as documents, pictures, or objects, to consider as evidence. In deciding how much to rely on an exhibit in reaching a verdict, 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.

State's Instruction 12

The law prevents some types of information from being presented as evidence in a court of law. This helps you focus on important and reliable evidence by excluding irrelevant, improper, or unreliable information.

An attorney has a duty to object when the other side offers evidence that the attorney believes is not admissible. You should not be influenced by the fact that objections are made to certain questions or to certain evidence. You should also not be influenced by the number of objections that are made.

When an objection is made the court will decide whether the evidence should be excluded. The court may "overrule" an objection and permit the evidence to be considered. That does not indicate any opinion of the court as to the weight or effect of that evidence. The decision will be based only on whether the law permits you to consider such evidence.

If the court sustains an objection, you must disregard the question and any answer entirely. You may not draw any inference from the question, or speculate what the witness would have said if permitted to finish answering the question.

I may direct that certain evidence be stricken from the record and instruct you to disregard that evidence. If that happens you must not consider any evidence which the court has instructed you to disregard. Your verdict must be based solely on legally admissible evidence.

My rulings on these matters will be determined by the law and are not based on my views as to the merits of the case, the evidence, the witnesses, or the attorneys.

Alaska Civil Pattern Jury Instruction No. 1.13

Instruction ___

The law prevents some types of information from being presented as evidence in a court of law. This helps you focus on important and reliable evidence by excluding irrelevant, improper, or unreliable information.

An attorney has a duty to object when the other side offers evidence that the attorney believes is not admissible. You should not be influenced by the fact that objections are made to certain questions or to certain evidence. You should also not be influenced by the number of objections that are made.

When an objection is made the court will decide whether the evidence should be excluded. The court may "overrule" an objection and permit the evidence to be considered. That does not indicate any opinion of the court as to the weight or effect of that evidence. The decision will be based only on whether the law permits you to consider such evidence.

If the court sustains an objection, you must disregard the question and any answer entirely. You may not draw any inference from the question, or speculate what the witness would have said if permitted to finish answering the question.

I may direct that certain evidence be stricken from the record and instruct you to disregard that evidence. If that happens you must not consider any evidence which the court has instructed you to disregard. Your verdict must be based solely on legally admissible evidence.

My rulings on these matters will be determined by the law and are not based on my views as to the merits of the case, the evidence, the witnesses, or the attorneys.

State's Instruction 13

During the trial, I may ask questions of witnesses called by the parties. My questions are not more or less important than the questions that are asked by attorneys in the case. You should consider the answers to my questions just as you would other answers in the case. Do not assume that because I ask questions I have any opinion about the case or the matters to which my questions relate.

Nothing I do or say during the trial is intended to indicate what I think the facts are or that I believe or disbelieve any witness. If anything I do or say seems to indicate that to you, you are to disregard it and form your own opinion.

It is the jury's job, not the judge's, to evaluate the evidence and to decide what evidence to believe and what weight to give the evidence.

Alaska Civil Pattern Jury Instruction No. 1.09

Instruction ___

During the trial, I may ask questions of witnesses called by the parties. My questions are not more or less important than the questions that are asked by attorneys in the case. You should consider the answers to my questions just as you would other answers in the case. Do not assume that because I ask questions I have any opinion about the case or the matters to which my questions relate.

Nothing I do or say during the trial is intended to indicate what I think the facts are or that I believe or disbelieve any witness. If anything I do or say seems to indicate that to you, you are to disregard it and form your own opinion.

It is the jury's job, not the judge's, to evaluate the evidence and to decide what evidence to believe and what weight to give the evidence.

State's Instruction 14

After a witness has testified, you may propose questions to the witness, but you are not required to do so. The purpose of allowing you to submit questions is to help you understand the evidence. You should not become aligned with any party or attempt to help or respond to any party with your questions. You must remain neutral and impartial throughout this trial, and you must not assume the role of investigator or advocate.

Please write down any questions you want to ask. Add your [Jury Member Number], and pass the questions to me. I will review them and show them to the parties. I may ask your questions or I may allow the parties to ask them.

You must decide independently whether to ask any questions. Do not discuss questions with anyone else including other members of the jury.

I will only allow questions that comply with the rules of evidence. Do not hold it against either party if I decide not to ask your questions. The decision whether to ask questions is for the court, and not the parties.

You should consider answers to juror questions the same way that you consider answers to questions posed by the parties. You should not give an answer to a juror question special weight or consideration.

Alaska Civil Pattern Jury Instruction No. 1.12

002966

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Instructions

Instruction ___

After a witness has testified, you may propose questions to the witness, but you are not required to do so. The purpose of allowing you to submit questions is to help you understand the evidence. You should not become aligned with any party or attempt to help or respond to any party with your questions. You must remain neutral and impartial throughout this trial, and you must not assume the role of investigator or advocate.

Please write down any questions you want to ask. Add your [Jury Member Number], and pass the questions to me. I will review them and show them to the parties. I may ask your questions or I may allow the parties to ask them.

You must decide independently whether to ask any questions. Do not discuss questions with anyone else including other members of the jury.

I will only allow questions that comply with the rules of evidence. Do not hold it against either party if I decide not to ask your questions. The decision whether to ask questions is for the court, and not the parties.

You should consider answers to juror questions the same way that you consider answers to questions posed by the parties. You should not give an answer to a juror question special weight or consideration.

State's Instruction 15

You may take notes during the trial, but you are not required to do so. If you decide to take notes, do not let your note taking distract you from hearing and seeing all the evidence.

Your notes are to be used only by you to refresh your own recollection during deliberations. Do not read your notes aloud or show them to other jurors. During deliberations, the recollection of a juror who took notes is not necessarily more accurate than the recollection of another juror who did not take notes.

During each recess, you must leave your pads and pencils on your chairs. Your notes are kept confidential by being locked up overnight and placed on your chairs each morning. After you have completed your deliberations, your notes will be collected and shredded.

Alaska Civil Pattern Jury Instruction No. 1.11

Instruction ___

You may take notes during the trial, but you are not required to do so. If you decide to take notes, do not let your note taking distract you from hearing and seeing all the evidence.

Your notes are to be used only by you to refresh your own recollection during deliberations. Do not read your notes aloud or show them to other jurors. During deliberations, the recollection of a juror who took notes is not necessarily more accurate than the recollection of another juror who did not take notes.

During each recess, you must leave your pads and pencils on your chairs. Your notes are kept confidential by being locked up overnight and placed on your chairs each morning. After you have completed your deliberations, your notes will be collected and shredded.

State's Instruction 16

If at any time during the trial you cannot see or hear a witness or an attorney, please raise your hand and I will correct the situation. If you have another problem that you would like to bring to my attention, or if you feel ill or need to go to the restroom, please give a note to the in-court clerk, who will deliver it to me.

I want you to be comfortable as you carry out your important duties. So do not hesitate to inform me of any problem that you may have.

Alaska Civil Pattern Jury Instruction No. 1.14

Instruction ___

If at any time during the trial you cannot see or hear a witness or an attorney, please raise your hand and I will correct the situation. If you have another problem that you would like to bring to my attention, or if you feel ill or need to go to the restroom, please give a note to the in-court clerk, who will deliver it to me.

I want you to be comfortable as you carry out your important duties. So do not hesitate to inform me of any problem that you may have.

State's Instruction 18

Do not assume that I have any views about the case because of the instructions that I am now giving you. What I am telling you in these instructions is the law that applies to all parties appearing before the court. Nothing that I say or do should lead you to think that I favor or disfavor any party. I try to be fair and impartial, just as you are required to be. But if anything that I have said or done during the trial or in these instructions has caused you to believe that I favor or disfavor any party, I now instruct you that it is your duty to disregard my actions. You must decide the case without favoritism or prejudice on the basis of the evidence and the law as it is explained to you.

Alaska Civil Pattern Jury Instruction No. 2.02

002972

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Objected-To Instructions

Instruction ___

Do not assume that I have any views about the case because of the instructions that I am now giving you. What I am telling you in these instructions is the law that applies to all parties appearing before the court. Nothing that I say or do should lead you to think that I favor or disfavor any party. I try to be fair and impartial, just as you are required to be. But if anything that I have said or done during the trial or in these instructions has caused you to believe that I favor or disfavor any party, I now instruct you that it is your duty to disregard my actions. You must decide the case without favoritism or prejudice on the basis of the evidence and the law as it is explained to you.

State's Instruction 19

The weight to be given the evidence is for you to determine. You must examine the evidence carefully and decide how to evaluate it in light of the law that I have given you in these instructions.

In your deliberations, you must not be governed by mere sentiment, unsupported conjecture, sympathy, passion, prejudice, public opinion, or public feeling. You should consider the evidence in light of your own common sense and observations and experiences in everyday life. But you may not consider other sources of information not presented to you in this court.

Alaska Civil Pattern Jury Instruction No. 2.26

002974

A

Objected-To Instructions

Instruction ___

The weight to be given the evidence is for you to determine. You must examine the evidence carefully and decide how to evaluate it in light of the law that I have given you in these instructions.

In your deliberations, you must not be governed by mere sentiment, unsupported conjecture, sympathy, passion, prejudice, public opinion, or public feeling. You should consider the evidence in light of your own common sense and observations and experiences in everyday life. But you may not consider other sources of information not presented to you in this court.

State's Instruction 20

You are reminded that the law prohibits some types of information from being presented as evidence in a court of law. This helps you to focus on important and reliable evidence by excluding irrelevant, improper, or unreliable information.

An attorney has a duty to object when the other side offers evidence that the attorney believes is not admissible. You should not be influenced by the fact that objections were made to certain questions or to certain evidence. You should also not be influenced by the number of objections that were made.

You should also draw no conclusions about the case from my rulings on the objections. These rulings were determined by the law and were not based on my views as to the merits of the case, the evidence, the witnesses, or the attorneys.

If I sustained an objection, you must disregard the question and any answer entirely. You may not draw any inference from the question, or speculate what the witness would have said if permitted to finish answering the question.

During your deliberations, you must not consider any evidence that I instructed you to disregard.

Remember that the questions asked by attorneys are not evidence. Only the answers to questions are evidence. You may consider questions only to help you understand the answers.

After the evidence was presented, you heard closing arguments. During closing arguments, the parties told you what they believe the evidence has proved and urged you to draw certain conclusions about the evidence. Remember that what was said in closing arguments is not evidence.

Alaska Civil Pattern Jury Instruction No. 2.22

002976

A

Objected-To Instructions

Instruction ___

You are reminded that the law prohibits some types of information from being presented as evidence in a court of law. This helps you to focus on important and reliable evidence by excluding irrelevant, improper, or unreliable information.

An attorney has a duty to object when the other side offers evidence that the attorney believes is not admissible. You should not be influenced by the fact that objections were made to certain questions or to certain evidence. You should also not be influenced by the number of objections that were made.

You should also draw no conclusions about the case from my rulings on the objections. These rulings were determined by the law and were not based on my views as to the merits of the case, the evidence, the witnesses, or the attorneys.

If I sustained an objection, you must disregard the question and any answer entirely. You may not draw any inference from the question, or speculate what the witness would have said if permitted to finish answering the question.

During your deliberations, you must not consider any evidence that I instructed you to disregard.

Remember that the questions asked by attorneys are not evidence. Only the answers to questions are evidence. You may consider questions only to help you understand the answers.

After the evidence was presented, you heard closing arguments. During closing arguments, the parties told you what they believe the evidence has proved and urged you to draw certain conclusions about the evidence. Remember that what was said in closing arguments is not evidence.

State's Instruction 21

The testimony of some witnesses was read to you from depositions. The deposition testimony of some other witnesses was shown to you on videotape.

When a deposition is taken, the witness takes an oath that is identical in purpose to the oath given to the witnesses who testify before you here in the courtroom. All parties are given an opportunity to ask questions of a witness during a deposition.

The law does not distinguish between deposition testimony and live testimony. Both are valid forms of testimony. Deposition testimony should be weighed by you as you would any other testimony.

However, with regard to deposition testimony that was read to you, you may consider that you have not seen and heard the witness testify. It is for you to decide whether this is significant.

Alaska Civil Pattern Jury Instruction No. 2.13 and 2.14 (combined)

002978

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Objected-To Instructions

Instruction ___

The testimony of some witnesses was read to you from depositions. The deposition testimony of some other witnesses was shown to you on videotape.

When a deposition is taken, the witness takes an oath that is identical in purpose to the oath given to the witnesses who testify before you here in the courtroom. All parties are given an opportunity to ask questions of a witness during a deposition.

The law does not distinguish between deposition testimony and live testimony. Both are valid forms of testimony. Deposition testimony should be weighed by you as you would any other testimony.

However, with regard to deposition testimony that was read to you, you may consider that you have not seen and heard the witness testify. It is for you to decide whether this is significant.

State's Instruction 22

Some of the instructions that follow ask you to decide whether something is more likely true than not true. Something is more likely true than not true if you believe that the chance that it is true is even the slightest bit greater than the chance that it is not true. In more familiar language, something is more likely true than not true if you believe that there is a greater than 50 percent chance that it is true. Fifty-one percent probability is enough; no more is required for you to decide that something is more likely true than not true.

If you believe that the chance that something is true is 50/50 or less, you must decide that it is not true.

Alaska Civil Pattern Jury Instruction No. 2.04

Instruction ___

Some of the instructions that follow ask you to decide whether something is more likely true than not true. Something is more likely true than not true if you believe that the chance that it is true is even the slightest bit greater than the chance that it is not true. In more familiar language, something is more likely true than not true if you believe that there is a greater than 50 percent chance that it is true. Fifty-one percent probability is enough; no more is required for you to decide that something is more likely true than not true.

If you believe that the chance that something is true is 50/50 or less, you must decide that it is not true.

State's Instruction 27

You must not determine any issue in this case by flipping a coin, drawing straws, or other resort to chance. Each of you should use your independent judgment in deciding how to answer the questions. Ten of you must agree on an answer before entering it on the verdict form.

Alaska Civil Pattern Jury Instruction No. 2.07 (edited, because damages are not an issue)

Instruction ___

You must not determine any issue in this case by flipping a coin, drawing straws, or other resort to chance. Each of you should use your independent judgment in deciding how to answer the questions. Ten of you must agree on an answer before entering it on the verdict form.

State's Instruction 28

The court will decide whether any party should be reimbursed for some or all of the expenses of this lawsuit, including attorney fees. You should not discuss this subject during your deliberations because it has no bearing on any issue that you will decide.

Alaska Civil Pattern Jury Instruction No. 2.06

Instruction ___

The court will decide whether any party should be reimbursed for some or all of the expenses of this lawsuit, including attorney fees. You should not discuss this subject during your deliberations because it has no bearing on any issue that you will decide.

State's Instruction 29

You are still bound by your oath as a juror to render a verdict according to the law and the evidence. During deliberations, you must conscientiously consider and weigh the evidence, apply the law, and work to reach a verdict.

You will take my instructions, the exhibits, and the verdict form with you to the jury room. When you get to the jury room, you should elect one juror to be your foreperson. That person will preside over the deliberations and speak for you in court.

You will then discuss the case with your fellow jurors. Each of you must decide the case for yourself, but only after you have fully considered the evidence, discussed it with the other jurors, and listened to their views. It is rarely productive for a juror, upon entering the jury room, to make an emphatic expression of his or her opinion on the case or to insist upon a certain verdict. When that happens, that juror may hesitate to change his or her announced position even if shown that it is incorrect.

Do not be afraid to change your opinion if the discussion persuades you that you should. But do not change an honest belief about the evidence simply to reach a verdict.

You are to deliberate from 8:30 a.m. until 4:30 p.m. each day, except Saturday and Sunday. You may decide among yourselves when to take your lunch break. The bailiff will arrange for lunch and will make phone calls to your families if necessary to let them know your schedule.

You are never to reveal to any person -- not even to the bailiff or to the judge -- how the jury stands, numerically or otherwise, on the questions before you, until authorized by the judge in open court.

Any juror who believes there has been a violation of my instructions concerning deliberations must send a note reporting this to me as soon as possible.

Alaska Civil Pattern Jury Instruction No. 2.28

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Objected-To Instructions

Instruction ___

You are still bound by your oath as a juror to render a verdict according to the law and the evidence. During deliberations, you must conscientiously consider and weigh the evidence, apply the law, and work to reach a verdict.

You will take my instructions, the exhibits, and the verdict form with you to the jury room. When you get to the jury room, you should elect one juror to be your foreperson. That person will preside over the deliberations and speak for you in court.

You will then discuss the case with your fellow jurors. Each of you must decide the case for yourself, but only after you have fully considered the evidence, discussed it with the other jurors, and listened to their views. It is rarely productive for a juror, upon entering the jury room, to make an emphatic expression of his or her opinion on the case or to insist upon a certain verdict. When that happens, that juror may hesitate to change his or her announced position even if shown that it is incorrect.

Do not be afraid to change your opinion if the discussion persuades you that you should. But do not change an honest belief about the evidence simply to reach a verdict.

You are to deliberate from 8:30 a.m. until 4:30 p.m. each day, except Saturday and Sunday. You may decide among yourselves when to take your lunch break. The bailiff will arrange for lunch and will make phone calls to your families if necessary to let them know your schedule.

You are never to reveal to any person -- not even to the bailiff or to the judge -- how the jury stands, numerically or otherwise, on the questions before you, until authorized by the judge in open court.

Any juror who believes there has been a violation of my instructions concerning deliberations must send a note reporting this to me as soon as possible.

State's Instruction 30

If it becomes necessary during your deliberations to communicate with me, you may give the bailiff a note. The note should be signed by your foreperson or by one or more members of the jury and should contain the date and time of the communication. No member of the jury should ever communicate with me by any means other than a signed note.

Judges sometimes receive written questions from jurors during their deliberations. Although I cannot always answer those questions, if you desire to ask a question, you may write the question on a piece of paper and hand it to the bailiff. A delay will occur prior to a response to your question, since I must first convene the attorneys for consideration of the question.

The law prohibits the bailiff from answering questions about the case or providing you with any books or materials. The bailiff is forbidden to communicate with any juror about the substance of the case.

If you would like to re-hear the testimony of a witness, you may send me a note, and I will decide whether you should hear the testimony again. No new evidence will be presented.

Alaska Civil Pattern Jury Instruction No. 2.29

Instruction ___

If it becomes necessary during your deliberations to communicate with me, you may give the bailiff a note. The note should be signed by your foreperson or by one or more members of the jury and should contain the date and time of the communication. No member of the jury should ever communicate with me by any means other than a signed note.

Judges sometimes receive written questions from jurors during their deliberations. Although I cannot always answer those questions, if you desire to ask a question, you may write the question on a piece of paper and hand it to the bailiff. A delay will occur prior to a response to your question, since I must first convene the attorneys for consideration of the question.

The law prohibits the bailiff from answering questions about the case or providing you with any books or materials. The bailiff is forbidden to communicate with any juror about the substance of the case.

If you would like to re-hear the testimony of a witness, you may send me a note, and I will decide whether you should hear the testimony again. No new evidence will be presented.

State's Instruction 31

During deliberations, you may have any notes that you took during trial. You may use your notes only to refresh your own recollection. Do not read your notes aloud or show them to other jurors. The recollection of a juror who took notes is not necessarily more accurate than the recollection of another juror who did not take notes.

When the case is over, your notes will be collected and destroyed.

Alaska Civil Pattern Jury Instruction No. 2.30

Instruction ___

During deliberations, you may have any notes that you took during trial. You may use your notes only to refresh your own recollection. Do not read your notes aloud or show them to other jurors. The recollection of a juror who took notes is not necessarily more accurate than the recollection of another juror who did not take notes.

When the case is over, your notes will be collected and destroyed.

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Objected-To Instructions

State's Instruction 32

When I finish instructing you, I will give you a form called a Verdict Form. The verdict form has a list of questions you must answer. Read the verdict form very carefully. Each question is followed by specific instructions telling you what you must do next.

At least ten of you must agree to the answer to each question on the verdict form. But the same ten people need not agree on each answer. When at least ten of you reach agreement on each question that you are required to answer, your foreperson should date and sign the verdict form.

If you agree on a verdict before ___ p.m., your foreperson should advise the bailiff by a written note that you have reached a verdict. The bailiff will advise the court, and the court will contact the parties and counsel. As soon as everyone returns to the courtroom, the jury will present the verdict in open court. After the verdict is presented, members of the jury will be excused.

If you do not agree on a verdict before _____ p.m., but you agree later tonight, your foreperson should date and sign the verdict form and place it, together with the instructions and the exhibits, in the envelope I am giving you. The foreperson will seal the envelope and [keep possession of the sealed envelope] [give the sealed envelope to the bailiff]. [Exhibits that do not fit in the envelope may be kept (insert appropriate place).] If you use this method of sealing your verdict, you must return to the jury room tomorrow morning by _____ a.m. You must not speak with anyone concerning the case and the verdict until the verdict is opened in court in your presence.

If you do not agree on a verdict before _____ p.m., you may return to your homes. You must not talk about the case or your deliberations outside of the jury room. Before you go home, the foreperson of the jury should [take the unsigned verdict form, these instructions and the exhibits, place them in the envelope I am giving you, seal the envelope and [keep possession of the envelope] [give the sealed envelope to bailiff]] [lock the jury room so that the exhibits, instructions, and unsigned verdict form will remain undisturbed]. If you have not agreed on a verdict, you must return to the jury room tomorrow morning by ___ a.m. to continue deliberations.

Alaska Civil Pattern Jury Instruction No. 2.31 (with nonsubstantive modifications to first paragraph)

Instruction ___

When I finish instructing you, I will give you a form called a Verdict Form. The verdict form has a list of questions you must answer. Read the verdict form very carefully. Each question is followed by specific instructions telling you what you must do next.

At least ten of you must agree to the answer to each question on the verdict form. But the same ten people need not agree on each answer. When at least ten of you reach agreement on each question that you are required to answer, your foreperson should date and sign the verdict form.

If you agree on a verdict before ____ p.m., your foreperson should advise the bailiff by a written note that you have reached a verdict. The bailiff will advise the court, and the court will contact the parties and counsel. As soon as everyone returns to the courtroom, the jury will present the verdict in open court. After the verdict is presented, members of the jury will be excused.

If you do not agree on a verdict before _____ p.m., but you agree later tonight, your foreperson should date and sign the verdict form and place it, together with the instructions and the exhibits, in the envelope I am giving you. The foreperson will seal the envelope and [keep possession of the sealed envelope] [give the sealed envelope to the bailiff]. [Exhibits that do not fit in the envelope may be kept (insert appropriate place).] If you use this method of sealing your verdict, you must return to the jury room tomorrow morning by _____ a.m. You must not speak with anyone concerning the case and the verdict until the verdict is opened in court in your presence.

If you do not agree on a verdict before _____ p.m., you may return to your homes. You must not talk about the case or your deliberations outside of the jury room. Before you go home, the foreperson of the jury should [take the unsigned verdict form, these instructions and the exhibits, place them in the envelope I am giving you, seal the envelope and [keep possession of the envelope] [give the sealed envelope to bailiff]] [lock the jury room so that the exhibits, instructions, and unsigned verdict form will remain undisturbed]. If you have not agreed on a verdict, you must return to the jury room tomorrow morning by ___ a.m. to continue deliberations.

State's Instruction 5

At a trial, the person or organization that brings a lawsuit is called the "plaintiff." The person or organization against whom the claims are brought is called the "defendant." The plaintiff and the defendant together are sometimes referred to as "the parties" in the lawsuit.

In this case, the plaintiff is the State of Alaska, which you will sometimes hear referred to simply as "the State."

The defendant is Eli Lilly and Company, which you will sometimes hear referred to simply as "Lilly."

I will give you a very brief introduction to the disagreement between the parties that underlies this lawsuit. The facts that I describe to you here are not disputed by the parties, and you must accept them as true, even if you do not hear evidence during the trial about these facts.

Eli Lilly manufactures and markets a drug called Zyprexa. As with all prescription drugs sold in this country, the federal Food and Drug Administration, or FDA, required Lilly to submit information about Zyprexa, and the FDA then approved the marketing of Zyprexa for the treatment of certain conditions, specifically schizophrenia and bipolar disorder.

Under the law in this country, physicians may prescribe drugs for the FDA-approved purposes, but they may also, in the exercise of their judgment, prescribe drugs for other purposes, when the physician believes the drug will be effective and safe for that purpose. These are called "off-label" uses.

The State participates in a Medicaid program. Under this program, the State pays for health care treatment for eligible citizens of this State. The rules are complex, and you will hear about some of the rules during the course of this trial. For purposes of this introduction, it is enough that you understand that the State pays for medications that are prescribed to Medicaid participants. The State also pays for doctor visits and other health care treatments for Medicaid participants.

This lawsuit focuses on the years between 1999 and October 2007. During that time, the State paid for many prescriptions for Zyprexa. Some of these prescriptions were to treat the FDA-approved conditions, schizophrenia and bipolar disorder. Some of the prescriptions were for off-label uses.

Some people who take Zyprexa develop new diseases, including diabetes, hyperglycemia, and dislipidemia. When Medicaid patients using Zyprexa developed new diseases, the State paid for the treatment of those diseases.

State's Instruction 5 (cont.)

Some people who do not take Zyprexa also develop conditions such as diabetes, hyperglycemia, and dislipidemia. One of the issues you will be asked to decide during the trial is whether Zyprexa caused or made these diseases worse in some patients.

Instruction ___

At a trial, the person or organization that brings a lawsuit is called the "plaintiff." The person or organization against whom the claims are brought is called the "defendant." The plaintiff and the defendant together are sometimes referred to as "the parties" in the lawsuit.

In this case, the plaintiff is the State of Alaska, which you will sometimes hear referred to simply as "the State."

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Under the law in this country, physicians may prescribe drugs for the FDA-approved purposes, but they may also, in the exercise of their judgment, prescribe drugs for other purposes, when the physician believes the drug will be effective and safe for that purpose. These are called "off-label" uses.

The State participates in a Medicaid program. Under this program, the State pays for health care treatment for eligible citizens of this State. The rules are complex, and you will hear about some of the rules during the course of this trial. For purposes of this introduction, it is enough that you understand that the State pays for medications that are prescribed to Medicaid participants. The State also pays for doctor visits and other health care treatments for Medicaid participants.

This lawsuit focuses on the years between 1999 and October 2007. During that time, the State paid for many prescriptions for Zyprexa. Some of these prescriptions were to treat the FDA-approved conditions, schizophrenia and bipolar disorder. Some of the prescriptions were for off-label uses.

Instruction __ (cont.)

Some people who take Zyprexa develop new diseases, including diabetes, hyperglycemia, and dislipidemia. When Medicaid patients using Zyprexa developed new diseases, the State paid for the treatment of those diseases.

Some people who do not take Zyprexa also develop conditions such as diabetes, hyperglycemia, and dislipidemia. One of the issues you will be asked to decide during the trial is whether Zyprexa caused or made these diseases worse in some patients.

State's Instruction 6

Now I will introduce the parties' claims to you. These are simple summaries of complex claims, provided purely to help you listen to the evidence. When I describe the claims, I am not telling you facts that you must accept. As to these claims, you must listen to the evidence and decide the questions I ask you at the end of the trial based solely on the evidence that you hear.

In this trial, you will be asked to decide if the defendant marketed Zyprexa without adequate warnings and whether, in promoting Zyprexa, Lilly violated the Alaska Unfair Trade Practices and Consumer Protection Act. You will not be asked to decide whether Lilly must pay any compensation to the State, or, if so, how much. Those matters will be addressed later, and you are not to concern yourselves with those questions in any way. You must answer the questions that I direct you to answer at the end of the trial based on the evidence presented, and not speculate or be influenced in any way about what might happen later based on your answers.

The State claims that, when prescribed and used for FDA-approved purposes, Zyprexa causes serious side-effects in many patients, including in particular diabetes, hyperglycemia, and dislipidemia. The State contends that Lilly knew that Zyprexa contributes to causing these serious side-effects, but that Lilly failed to disclose the risks adequately to the FDA, physicians, or to the State.

The State also claims that Lilly actively promoted Zyprexa for a variety of off-label uses, although, the State claims, Lilly knew it had no evidence that Zyprexa was effective to treat these off-label conditions.

The State claims that Lilly's promotions of Zyprexa concealed important facts and included misrepresentations and false statements.

Lilly denies that it acted wrongfully in any way.

Instruction ___

Now I will introduce the parties' claims to you. These are simple summaries of complex claims, provided purely to help you listen to the evidence. When I describe the claims, I am not telling you facts that you must accept. As to these claims, you must listen to the evidence and decide the questions I ask you at the end of the trial based solely on the evidence that you hear.

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The State claims that Lilly's promotions of Zyprexa concealed important facts and included misrepresentations and false statements.

Lilly denies that it acted wrongfully in any way.

State's Instruction 17

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.

I gave you some instructions at the start of the trial, too. I will not repeat them now, but you will have a copy of them when you deliberate.

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.

Alaska Civil Pattern Jury Instruction No. 2.01 (with additional third paragraph)

Instruction ___

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.

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State's Instruction 23

The State claims that Lilly failed to warn of certain risks of injury to people who used Zyprexa in a reasonably foreseeable manner for FDA-approved uses.

In order to find that Lilly failed to provide the warnings that it was required to provide, you must find that the State has proved that each of the following is more likely true than not true:

(1) Zyprexa posed a risk of injury to people who used the drug in a reasonably foreseeable way; and

(2) Lilly marketed Zyprexa without adequate warnings of this risk.

A warning is adequate if it

(1) clearly indicates the scope of the risk or danger posed by the product;

(2) reasonably communicates the extent or seriousness of harm that could result from the risk or danger; and

(3) is conveyed in such a manner as to alert the reasonably prudent person.

With a prescription drug marketed to physicians, warnings are sufficient if they put a reasonable physician on notice of the nature and extent of any scientifically knowable risks or dangers inherent in the use of the drug.

Shanks v. Upjohn Co., 835 P.2d 1189, 1199-1200 (Alaska 1992)

Instruction ___

The State claims that Lilly failed to warn of certain risks of injury to people who used Zyprexa in a reasonably foreseeable manner for FDA-approved uses.

In order to find that Lilly failed to provide the warnings that it was required to provide, you must find that the State has proved that each of the following is more likely true than not true:

(1) Zyprexa posed a risk of injury to people who used the drug in a reasonably foreseeable way; and

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(3) is conveyed in such a manner as to alert the reasonably prudent person.

With a prescription drug marketed to physicians, warnings are sufficient if they put a reasonable physician on notice of the nature and extent of any scientifically knowable risks or dangers inherent in the use of the drug.

State's Instruction 24

The State also claims that Lilly's actions in marketing Zyprexa violated the Alaska Unfair Trade Practices and Consumer Protection Act in one or more ways.

In order to find that Lilly violated the Unfair Trade Practices and Consumer Protection Act, you must find that the State has proved that each of the following is more likely true than not true:

(1) Lilly is engaged in trade or commerce; and

(2) Lilly committed an unfair or deceptive act or practice in the conduct of trade or commerce.

There is no dispute that Lilly is engaged in trade or commerce.

Kenai Chrysler Center, Inc. v. Denison, 167 P.3d 1240, 1255 (Alaska 2007); *State v. O'Neill Investigations, Inc.*, 609 P.2d 520, 534 (Alaska 1980).

Instruction ___

The State also claims that Lilly's actions in marketing Zyprexa violated the Alaska Unfair Trade Practices and Consumer Protection Act in one or more ways.

In order to find that Lilly violated the Unfair Trade Practices and Consumer Protection Act, you must find that the State has proved that each of the following is more likely true than not true:

(1) Lilly is engaged in trade or commerce; and

(2) Lilly committed an unfair or deceptive act or practice in the conduct of trade or commerce.

There is no dispute that Lilly is engaged in trade or commerce.

State's Instruction 25

An act or practice is deceptive if it has the capacity or tendency to deceive. Actual injury as a result of the deception is not required. Intent to deceive need not be proved. All that is required is a showing that the acts and practices were capable of being interpreted in a misleading way.

Kenai Chrysler Center, Inc. v. Denison, 167 P.3d 1240, 1255 (Alaska 2007); *State v. O'Neill Investigations, Inc.*, 609 P.2d 520, 534-35 (Alaska 1980).

Instruction ___

An act or practice is deceptive if it has the capacity or tendency to deceive. Actual injury as a result of the deception is not required. Intent to deceive need not be proved. All that is required is a showing that the acts and practices were capable of being interpreted in a misleading way.

State's Instruction 26

A defendant commits an unfair or deceptive act or practice if it does any of the following:

(a) represents that goods have characteristics, uses, or benefits that the goods do not have;

(b) represents that goods are of a particular standard, quality, or grade, if they are of another;

(c) engages in conduct in connection with the sale or advertising of goods that creates a likelihood of confusion or misunderstanding and that misleads, deceives, or damages a buyer;

(d) uses or employs deception, fraud, false pretense, false promise or misrepresentation in connection with the sale or advertising of goods, whether or not a person has in fact been misled, deceived, or damaged;

(e) knowingly conceals, suppresses or omits a material fact with in connection with the sale or advertising of goods, with the intent that others rely upon the concealment, suppression, or omission, whether or not a person has in fact been misled, deceived, or damaged;

(f) markets a drug with a label that is false or misleading in any manner.

AS 45.50.471(a), (b)(4), (6), (11), (12), (48); AS 17.20.090, .300.

Instruction ___

A defendant commits an unfair or deceptive act or practice if it does any of the following:

(a) represents that goods have characteristics, uses, or benefits that the goods do not have;

(b) represents that goods are of a particular standard, quality, or grade, if they are of another;

(c) engages in conduct in connection with the sale or advertising of goods that creates a likelihood of confusion or misunderstanding and that misleads, deceives, or damages a buyer;

(d) uses or employs deception, fraud, false pretense, false promise or misrepresentation in connection with the sale or advertising of goods, whether or not a person has in fact been misled, deceived, or damaged;

(e) knowingly conceals, suppresses or omits a material fact with in connection with the sale or advertising of goods, with the intent that others rely upon the concealment, suppression, or omission, whether or not a person has in fact been misled, deceived, or damaged;

(f) markets a drug with a label that is false or misleading in any manner.

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'S OBJECTIONS TO PLAINTIFF'S PROPOSED JURY INSTRUCTIONS AND SPECIAL VERDICT FORM**

Defendant Eli Lilly and Company ("Lilly") respectfully submits the following objections to the State's proposed jury instructions and special verdict form.

Objection to State's Proposed Instruction Nos. 5 and 6.

These two instructions are intended to give the jury a general summary and overview of the case and the parties' respective claims. Lilly objects to these instructions as written on the ground that they are drafted in a way that is not evenhanded. Lilly also objects to the last three paragraphs of the State's proposed Instruction No. 5 on the ground that those paragraphs incorrectly describe the time period at issue and include statements related to causation that are not at issue in Phase I. In place of the State's proposed Instruction Nos. 5 and 6, Lilly requests that the Court instruct the jury with a single instruction, as follows:

> At a trial, the person or organization that brings a lawsuit is called the "plaintiff." The person or organization against whom the claims are brought is called the "defendant." The plaintiff and the defendant together are sometimes referred to as "the parties" in the lawsuit.
>
> In this case, the plaintiff is the State of Alaska, which you will sometimes hear referred to simply as "the State."
>
> The defendant is Eli Lilly and Company, which you will sometimes hear referred to simply as "Lilly."
>
> I will give you a very brief introduction to the disagreement between the parties that underlies this lawsuit. The facts that I am going to describe to

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you now are not disputed by the parties, and you must accept them as true, even if you do not hear evidence during the trial about these facts.

Eli Lilly manufactures and markets a prescription drug called Zyprexa. As with all prescription drugs sold in this country, the federal Food and Drug Administration, or FDA, required Lilly to submit information about Zyprexa, and the FDA then approved the marketing of Zyprexa for the treatment of certain mental health conditions.

Under the law in this country, physicians may prescribe drugs for the FDA-approved purposes, but they may also, in the exercise of their judgment, prescribe drugs for other purposes, when the physician believes the drug will be effective and safe for those purposes. These are called "off-label" uses.

The State participates in a Medicaid program. Under this program, the State pays for health care treatment for eligible citizens of this State. The rules are complex, and you will hear about some of the rules during the course of this trial. For purposes of this introduction, it is enough that you understand that the State pays for medications, doctor visits and other health care treatments for Medicaid participants.

Now I will briefly describe the parties' claims to you. I am only giving you simple summaries of complex claims, purely to help you listen to the evidence. When I describe these claims to you, I am not telling you facts that you must accept. As to these claims, you must listen to the evidence and decide the questions that you will be asked at the end of the trial based solely on the evidence you hear.

The State claims that when Zyprexa is prescribed and used for FDA-approved purposes, it causes serious side-effects in many patients, including diabetes, hyperglycemia and dislipidemia. The State contends that Lilly knew that Zyprexa contributed to causing those side effects, but that Lilly failed to disclose those risks adequately to the FDA or to physicians.

Lilly contends that Zyprexa is a safe and effective drug that continues to be widely prescribed by physicians to help patients who suffer from serious and debilitating mental illnesses. Lilly contends that diabetes, hyperglycemia and dislipidemia are common conditions that are caused by many factors and that there is no reliable scientific evidence that

Zyprexa causes these conditions. Lilly contends that it adequately described the risks associated with this medicine.

The State also claims that Lilly promoted Zyprexa for a variety of off-label uses even though, the State claims, Lilly had no evidence that Zyprexa was effective to treat those off-label conditions. The State claims that Lilly's promotion of Zyprexa concealed important facts and included misrepresentations and false statements.

Lilly contends that it promoted Zyprexa only for FDA-approved uses for which Zyprexa is proven to be effective. Lilly contends that its promotion of Zyprexa was truthful and provided useful information to physicians who treat patients with serious mental illnesses.

The attorneys for each party will give you more information about their claims in their opening statements. We are now ready for the attorneys' opening statements.

Objection to State's Proposed Instruction No. 17.

This is the first of the State's general closing instructions and is based on Alaska Civil Pattern Jury Instruction 2.01. Lilly objects to the third paragraph of this instruction, which the State has added to the pattern instruction and which states, "I gave you some instructions at the start of trial, too. I will not repeat them now, but you will have a copy of them when you deliberate." Lilly's position is that various pattern instruction given at the beginning of trial (e.g., regarding credibility of witnesses, exhibits, etc.) should be also be given at the conclusion of trial, as contemplated by Article 2 of the Alaska Civil Pattern Jury Instructions and to the extent those pattern closing instructions are not included in the State's proposed instructions Lilly intends to include them in its proposed instructions. Lilly therefore believes the third paragraph of the State's proposed Instruction No. 17 should be deleted.

Objection to State's Proposed Instruction No. 23.

This is the State's proposed instruction on its failure-to-warn claim. Lilly objects to this instruction as an incomplete and incorrect statement of the law and not adequately

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tailored to the facts of this case. The State's definition of the adequacy of a warning in terms of a "reasonably prudent person" is confusing and inconsistent with *Shanks v. Upjohn Co.*, 835 P.2d 1189 (Alaska 1992), which holds that "[i]n the case of prescription drugs, the warning should be sufficient to put the physician on notice of the nature and extent of any scientifically knowable risks or dangers inherent in the use of the drug." *Id.* at 1200. The State's proposed instruction also fails to inform the jury of Lilly's defense of scientific unknowability[1] or the jury's ability to consider the fact of FDA approval of Zyprexa's warnings,[2] and is not tailored to reflect the fact that the State's claims span multiple years. Therefore, in place of the State's proposed Instruction No. 23, Lilly requests that the Court give Lilly's proposed Instruction Nos. 40-44, copies of which are attached.

Objection to State's Proposed Instruction Nos. 24-26.

These are the State's proposed instructions on its claim under the Alaska Unfair Trade Practice and Consumer Protection Act. Lilly objects to these instructions as

[1] *See Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992) (discussing defense of scientific unknowability).

[2] Lilly maintains that the State's failure to warn claims are wholly preempted, for the reasons stated in its briefing to the Court in support of its summary judgment motion, and should not be submitted to the jury. However, Lilly acknowledges that the Court has not yet ruled on that issue, and requests an instruction on this issue in the alternative to a finding that the State's failure-to-warn claims are wholly preempted as a matter of law. *See* Lilly's Proposed Instruction No. 44; *see also, 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 (January 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").

incomplete and incorrect statements of the law and not adequately tailored to the facts of this case.

The State's proposed Instruction No. 25, which gives a general definition of when an act or practice is deceptive, is unnecessary and inappropriate here, where the State is not proceeding under the catch-all provision of AS 45.50.471(a), but rather alleges violations of prohibited acts enumerated in § 45.50.471(b), which are "deceptive by definition" and thus do not require the additional definition contained in the State's proposed Instruction No. 25.[3]

The State's proposed Instruction No. 26 would instruct the jury on unlawful acts or practices enumerated in AS 45.50.471(b), by paraphrasing the language of the statute; Lilly's proposed Instruction No. 45 more accurately tracks the statutory language. Additionally, subparagraph (f) of the State's proposed Instruction No. 26, which would instruct the jury that a defendant violates the UTPCPA if it "markets a drug with a label that is false or misleading in any particular" should not be given because it would put the jury in the position of directly second-guessing the FDA's determination that the Zyprexa label is not false or misleading,[4] thus falling outside the scope of the UTPCPA[5] and conflicting with federal law.[6]

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[3] *See* Alaska Civil Pattern Jury Instruction 10.01B, Directions for Use.

[4] The FDCA mandates that a prescription drug's label must be "informative and accurate and neither promotional in tone nor false or misleading in any particular." 21 C.F.R. § 201.56(a)(2). The FDA will not approve a new drug application if it determines that "[t]he proposed labeling is false or misleading in any particular." 21 C.F.R. § 314.125(b)(6). Congress has delegated to the FDA the authority to enforce the prohibition against false or misleading labels. *See* 21 U.S.C. §§ 331 - 37, 352. Additional authority is cited and discussed in Lilly's briefing in support of summary judgment.

[5] *See* AS 45.50.481(1). Lilly maintains that the State's UTPCPA claims are wholly barred by § 45.50.481(1), for the reasons stated in its briefing to the Court in support of its summary judgment motion, and should not be submitted to the jury. However, Lilly acknowledges that the Court has not yet ruled on that issue, and raises this narrower objection to subparagraph (f) of the State's proposed Instruction No. 26 in the alternative to a finding that the State's UTPCPA claims are wholly barred by AS 45.50.481(1).

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Finally, the State's proposed instructions on its UTPCPA claim are not adequately tailored to the facts of this case, in that they fail to identify the alleged violations that the State claims Lilly committed, and also would give the jury no guidance on how to account for the fact that the State's claims span multiple years.[7]

Therefore, in place of these instructions, Lilly requests that the Court give Lilly's proposed Instruction Nos. 45-48, copies of which are attached.

Objection to State's Proposed Verdict Form.

Lilly objects to the State's proposed verdict form on the ground that it is not adequately tailored to the facts of the case and does not take into account the fact that the State's claims span multiple years. The State's proposed verdict form does not specify the beginning and ending dates of the period at issue.

With respect to the State's failure to warn claim, the first question on the State's proposed verdict form is unnecessary and will not assist the Phase II jury in any respect. The

(. . . continued)

[6] *See, e.g., Pennsylvania Employees Benefit Trust Fund v. Zeneca*, 499 F.3d 239, 251 (3d Cir. 2007) ("The purpose of protecting prescription drug users in the FDCA would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by the FDA."). Lilly maintains that the State's UTPCPA claims are wholly barred by preempted by federal law, for the reasons stated in its briefing to the Court in support of its summary judgment motion, and should not be submitted to the jury. However, Lilly acknowledges that the Court has not yet ruled on that issue, and raises this narrower objection to subparagraph (f) of the State's proposed Instruction No. 26 in the alternative to a finding that the State's UTPCPA claims are wholly barred preempted.

[7] *See* Alaska Civil Pattern Jury Instruction 10.01B, Directions for Use (noting that instructions for UTPCPA claim "should be modified in each case to incorporate the specific acts or omissions that the plaintiff is alleging to be deceptive or unfair"); Alaska Civil Pattern Jury Instruction 10.01A (providing for specific identification of the acts or practices the plaintiff alleges were unfair or deceptive); Jury Instructions Nos. 21-29, *State of Alaska v. Anchorage-Nissan, Inc.*, Case No. 3AN-93-7761 CI (Super. Ct., 3d Jud. Dist., January 12, 1995), *approved*, *State of Alaska v. Anchorage-Nissan, Inc.*, 941 P.2d 1229, 1221 (Alaska 1997) (identifying alleged violations with specificity).

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State's second question does not permit the jury to take into account the fact that Zyprexa's labeling and other relevant facts changed during the multi-year period covered by the State's claim.

With respect to the State's UTPCPA claim, the State's proposed verdict form does not provide a means of identifying the individual alleged violations that the State claims and would give the jury no guidance on how to account for the fact that the State's claims span multiple years.[8]

Finally, the State's proposed verdict form omits any question regarding Lilly's defense of comparative negligence.[9]

Therefore, in place of the State's proposed verdict form, Lilly requests that the Court adopt Lilly's proposed verdict form (a copy of which is attached), with additional modifications as may become appropriate during the course of the trial.

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[8] *See* Alaska Civil Pattern Jury Instruction 10.01B, Directions for Use (noting that instructions for UTPCPA claim "should be modified in each case to incorporate the specific acts or omissions that the plaintiff is alleging to be deceptive or unfair"); Alaska Civil Pattern Jury Instruction 10.01A (providing for specific identification of the acts or practices the plaintiff alleges were unfair or deceptive); Jury Instructions Nos. 21-29, *State of Alaska v. Anchorage-Nissan, Inc.*, Case No. 3AN-93-7761 CI (Super. Ct., 3d Jud. Dist., January 12, 1995), *approved*, *State of Alaska v. Anchorage-Nissan, Inc.*, 941 P.2d 1229, 1221 (Alaska 1997) (identifying alleged violations with specificity).

[9] *See* A.S. § 09.17.060 (extending defense of comparative negligence to actions "based on fault"); §09.17.900 (defining fault to include "acts or omissions that are in any measure negligent, reckless, or intentional toward the person or property of the actor or others, or that subject a person to strict tort liability"); *Smith v. Ingersoll-Rand Co.*, 14 P.3d 990, 996 (Alaska 2000) (recognizing comparative negligence as a defense in strict product liability cases); *see also, e.g.*, *Loughridge v. Goodyear Tire & Rubber Co.*, 207 F. Supp. 2d 1187, 1192 (D. Colo. 2002) (applying comparative fault principles to statutory consumer protection claim); *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 367 (N.J. 1997) (same).

DATED this 19th day of February, 2008.

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INSTRUCTION NO. 40

LIABILITY FOR DEFECT IN A PRODUCT

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.

Alaska Civil Pattern Jury Instruction 7.02 (modified for Phase I to eliminate portions related to causation and damages).

INSTRUCTION NO. 41

DEFECTIVENESS DEFINED

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.

Alaska Civil Pattern Jury Instruction 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).

INSTRUCTION NO. 42

SCIENTIFIC UNKNOWABILITY

A product is not defective with regard to any particular danger if the defendant proves it is more likely true than not true that that particular danger was not scientifically knowable when the product left the defendant's possession.

A product is not defective with regard to any particular danger if the defendant proves it is more likely true than not true that that particular danger was not scientifically knowable when the product left the defendant's possession.

INSTRUCTION NO. 43

EFFECT OF PASSAGE OF TIME ON DUTY TO WARN

The State claims that Zyprexa that was prescribed during the period between September 30, 1996 through September 16, 2003 was defective due to inadequate warnings for the following risks:

(1) **[insert risks based on evidence at trial]**.

You will be given a verdict form that will require you to determine whether Zyprexa was defective during this period. If you find that Zyprexa was defective due to an inadequate warning for one or more of these risks at one point between September 30, 1996 and September 16, 2003, you should not assume that the warning for that risk was inadequate 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 for these risks 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 each risk:

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

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

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

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").

INSTRUCTION NO. 44

CONSIDERATION OF FDA APPROVAL

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. As I previously instructed you, Zyprexa and its labeling, including changes to the labeling, have been approved by the FDA since September 30, 1996.

In determining the adequacy of the warnings in the Zyprexa label for the risks of [**insert risks based on evidence at trial**], you may take into account the fact that the FDA approved the Zyprexa labeling, including its warning.

Lilly maintains that the State's failure to warn claims are wholly preempted, for the reasons stated in its briefing to the Court in support of its summary judgment motion, and should not be submitted to the jury. However, Lilly acknowledges that the Court has not yet ruled 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").

INSTRUCTION 45

UNFAIR OR DECEPTIVE ACT DEFINED

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,

(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

(3) Advertising goods or services with intent not to sell them as advertised,

(4) 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; and

(5) 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.

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). AS 45.50.471(b)(4), (6), (8), and (11).

INSTRUCTION NO. 46

"TRADE" OR "COMMERCE" DEFINED

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

Alaska Civil Pattern Jury Instruction 10.02.

INSTRUCTION NO. 47

UTPCPA CLAIMS CONSIDERED SEPARATELY

The State has alleged a number of different violations of the UTPCPA. You are to decide whether Defendant committed each alleged violation on its own merits, separately from the other alleged violations. Thus, if you find that Defendant committed one of the alleged violations, you may not assume that it is more likely true that not true that Defendant committed other violations. This is called "propensity" evidence, and it is forbidden under Alaska law. When deciding a particular claim, however, you may consider evidence relating to other violations to decide whether Defendant had any specific intent, plan or motive in connection with the particular transaction under consideration.

The following instructions identify for you the State's specific claims in connection with each alleged violation. To decide whether each alleged violation occurred, you must decide two things with respect to that alleged violation. 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.

Jury Instructions Nos. 18 & 20, *State of Alaska v. Anchorage-Nissan, Inc.*, CA No. 3AN-93-7761 CI (Superior Court, Third Judicial District, January 12, 1995), *approved*, *State of Alaska v. Anchorage-Nissan, Inc.*, 941 P.2d 1229, 1221 (Alaska 1997) (modified and consolidated to reduce length).

INSTRUCTION NO. 48

IDENTIFICATION OF ALLEGED UTPCPA VIOLATIONS

First Alleged UTPCPA Violation

The first UTPCPA violation alleged by the State is that Defendant committed an unfair or deceptive act or practice by engaging in the following conduct:

[Insert "who, what, where, when" identification of the alleged acts on which the violation is based, following presentation of State's evidence at trial, so that verdict form can include a separate question for each alleged violation.]

Defendant denies that it committed these acts.

Second Alleged UTPCPA Violation

The second UTPCPA violation alleged by the State is that Defendant committed an unfair or deceptive act or practice by engaging in the following conduct:

[Insert "who, what, where, when" identification of the alleged acts on which the violation is based, following presentation of State's evidence at trial, so that verdict form can include a separate question for each alleged violation.]

Defendant denies that it committed these acts.

[NOTE: add or delete identification of alleged violations as warranted by evidence at trial]

Jury Instructions Nos. 21-29, *State of Alaska v. Anchorage-Nissan, Inc.*, Case No. 3AN-93-7761 CI (Superior Court, Third Judicial District, January 12, 1995), *approved*, *State of Alaska v. Anchorage-Nissan, Inc.*, 941 P.2d 1229, 1221 (Alaska 1997) (modified for this case).

SPECIAL VERDICT FORM

INSTRUCTION NO. 51. INTRODUCTION TO SPECIAL VERDICT FORM[86]

I will now give you a form called a "Special Verdict Form." It has a list of questions you must answer. I have already instructed you on the law you are to use in answering these questions. You must follow my instructions and the form carefully. The special verdict form tells you what to do after each question. At least [ten] of you must agree upon an answer to each question, but the same [ten] of you need not agree upon each answer.

[86] Source: Alaska Civil Pattern Jury Instruction 3.09.

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 it is more likely true than not true that Zyprexa was defective due to inadequate warnings for the risk of ***[insert risks based on proofs at trial]****, you should check "No." Conversely, if the State proved that it is more likely true than not true that Zyprexa was defective due to inadequate warnings for the risk of* ***[insert risks based on proofs at trial]****, you should check "Yes," unless the Defendant proved that it is more likely true than not true that that risk was not scientifically knowable.*

(1) At any time between September 30, 1996 and September 16, 2003, 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 for each alleged UTPCPA violation identified in Instruction No. 48. In answering Question No. 2, you must consider each alleged violation separately. If the State failed to prove that it is more likely true than not true that Defendant committed an unfair or deceptive act or practice with respect to an alleged violation, you should check "No" for that alleged violation. Conversely, if the State proved that it is more likely true than not true that Defendant committed an unfair or deceptive act or practice with respect to an alleged violation, you should check "Yes" for that alleged violation.

(2) Did Defendant commit an unfair or deceptive act or practice with respect to any of the following alleged UTPCPA violations as identified in Instruction No. 48?

First Alleged UTPCPA Violation: _____ Yes _____ No
Second Alleged UTPCPA Violation: _____ Yes _____ No
[Insert or delete alleged violations as the evidence presented at trial warrants.]

If your answer to Question Nos. 1 and 2 was "No," then do not answer Question No. 3. If you answered "Yes" to Question No. 1 or any part of Question No. 2, then you must answer Question No. 3. If the Defendant failed to prove that it is more likely true than not true that the State was negligent, you should check "No." Conversely, if the Defendant proved that it is more likely true than not true that the State was negligent, you should check "Yes."

(3) At any time between September 30, 1996 and September 16, 2003, was the State negligent? 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

FILED
STATE OF ALASKA
THIRD DISTRICT
08 FEB 25 PM 4:04
BY DEPUTY CLERK

DEFENDANT ELI LILLY AND COMPANY'S
SUPPLEMENT TO ITS FINAL WITNESS LIST

COMES NOW, Defendant Eli Lilly and Company ("Lilly") and hereby supplements its Final Witness List with the addition of:

1. Karleen Jackson, Commissioner
c/o State of Alaska's Dept. of Health and Social Services
Division of Health Care Services
4501 Business Park Blvd., Suite 24
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DATED this 25th day of February, 2008.

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

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

Case No. 3AN-06-05630-CI

DEFENDANT ELI LILLY AND COMPANY'S MOTION IN LIMINE TO EXCLUDE ADVERSE EVENT REPORTS FOR ANY PURPOSE OTHER THAN ESTABLISHING LILLY KNEW ABOUT THE SPECIFIC ADVERSE EVENT

Defendant Eli Lilly and Company ("Lilly") requests that the Court bar the State from introducing at trial evidence of adverse event reports, including emails and other documents referencing these reports, for purposes of establishing anything other than the fact that Lilly learned of the adverse event.

Adverse event reports are federal Food and Drug Administration reports that Lilly completes when an individual informs Lilly about an adverse event that allegedly emerged during the treatment of a patient with a Lilly product. If admissible at all, these forms, which rely on information typically provided by a patient or healthcare provider, should be admitted only for the narrow purpose of showing Lilly learned of the report of the adverse event.[1] As discussed below, adverse event reports, and emails or other documents referencing such reports, should not be admitted to prove that Zyprexa caused or was related to any adverse

[1] *See, e.g., Golod v. Hoffman La Roche*, 964 F. Supp. 841, 855 (S.D.N.Y. 1997) (admitting adverse event reports only for the purpose of showing "evidence that [defendant] was on notice of potentially serious…side effects").

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event. Even if relevant to establish causation, the prejudice to Lilly in admitting these documents outweighs their probative value. Finally, if the State introduces these reports, or any documents referencing them, to establish that Zyprexa caused an adverse event, these statements would be hearsay, not within any exception.

A. Adverse Event Reports Are Not Relevant to Proving Causation

The Court should not admit adverse event reports, or documents referencing such reports, for the purpose of proving that Zyprexa was related to or caused an adverse event because the use of such reports does not satisfy the test of relevancy in Alaska. "Relevant evidence means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."[2] Evidence that is not relevant is inadmissible.[3]

Many courts have found that adverse event reports cannot be used to establish causation[4] because, as the Eleventh Circuit explained, "these FDA reports reflect complaints called in by product consumers without any medical controls or scientific assessment," and

[2] Alaska R. Evid. 401

[3] Alaska R. Evid. 402.

[4] *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005); *Peters v. Astrazeneca, LP*, No. 05-649, 2006 U.S. Dist. LEXIS 38859, at *8 (W.D. Wis. June 12, 2006) ("An adverse event report does not mean necessarily that a reported adverse event was caused by a drug; it means merely that the adverse event was reported by someone who experienced the adverse event while taking the drug."); *In re Bayer AG Sec. Litig.*, No. 03-1546, 2004 U.S. Dist. LEXIS 19593, at *35-36 (S.D.N.Y. Sept. 30, 2006) ("The adverse event reports did not by themselves establish a causal connection between" the product and the alleged side-effect.).

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"[u]ncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation."[5] The State's own expert agrees with this conclusion. When asked about drawing causal conclusions from adverse event reports, Dr. David Allison stated, "[I]f we are talking solely about case reports of an adverse event after exposure to some stimulus and that is all we have, there is no other information, then, yes, I agree that those are a basis for conjecture and not a basis for conclusion."[6] Conjecture does not make it more or less probable that Zyprexa actually caused that adverse event. Thus, adverse event reports, and documents referencing such reports, are not relevant to establishing that Zyprexa was related to or caused an adverse event, and they should be excluded under Rule 402.

Even if the reports were found relevant, they should still be excluded because their potential for prejudice outweighs their probative value.[7] As discussed above, adverse event reports, which are anecdotal in nature, are "one of the least reliable sources" to establish causation. At the same time, however, the jury could attribute the same, if not more, weight to these anecdotal reports than they give to peer-reviewed studies when deciding whether Zyprexa causes a particular side-effect because of the specific nature of the complaints, all to

[5] *McClain*, 401 F.2d at 1250.
[6] Exhibit A, Transcript of Deposition of David B. Allison, Ph.D., May 18, 2007, at 62-63 (emphasis added).
[7] Alaska R. Evid. 403.

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the prejudice of Lilly. Accordingly, these documents should be excluded from evidence under Rule 403 – if they are found relevant at all.[8]

B. Adverse Event Reports Contain Hearsay Not Within any Exception

An adverse event report introduced to establish that Zyprexa caused that adverse event would be hearsay, not within any exception. The same would be true of emails or other documents discussing adverse event reports. Out of court statements offered to prove the truth of the matter asserted are inadmissible as hearsay under the Alaska Rules of Evidence.[9] Adverse event reports offered to prove that Zyprexa caused a particular side-effect would be hearsay.[10] These reports would also not fall within any exception, including the exception for party opponent admissions.[11] Adverse event reports are not party opponent admissions because when Lilly creates them: (i) they are not reports by Lilly, and (ii) Lilly does not necessarily subscribe to the reporter's statements. Lilly only knows that someone has reported an event that might be related to Zyprexa. Thus, when Lilly completes a form, it is not making an admission that Zyprexa has caused an adverse event. Accordingly, adverse

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[8] *See, e.g. Hiibschman v. Valdez*, 821 P.2d 1354, 1366 (Alaska 1991) (upholding exclusion of evidence where plaintiff was likely to be prejudiced).
[9] Alaska R. Evid. 801-802.
[10] *See Appleby v. Glaxo Wellcome, Inc.*, No. 04-0062, 2005 U.S. Dist. LEXIS 32875, at *10 (D.N.J. Dec. 13, 2005) (citing *Golod*, 964 F. Supp. at 855, for the proposition "that adverse event reports are likely inadmissible hearsay to establish causation").
[11] *See, e.g. In re: Accutane Prods. Liab. Litig.*, MDL 1626, 2007 U.S. Dist. LEXIS 32236, at *18-20 (M.D. Fla. May 2, 2007).

event reports, and documents referencing such reports, offered to prove causation should be excluded as hearsay, not within any exception.

DATED this 25th day of February, 2008.

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George A. Lehner, admitted *pro hac vice*
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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

MDL NO. 1596
04 MD 1596

In Re: ZYPREXA PRODUCTS LIABILITY LITIGATION
THIS DOCUMENT RELATES TO: ALL CASES

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05 CV 2948 (JBW)
05 CV 4115 (JBW)
UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, et al.,
vs.
ELI LILLY AND COMPANY.

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06 CV 0021 (JBW)

LOCAL 28 SHEET METALS WORKERS, et al.,
vs.
ELI LILLY AND COMPANY.

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06 CV 6322 (JBW)
SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, et al.,
vs.
ELI LILLY AND COMPANY.

VIDEOTAPED DEPOSITION OF
DAVID B. ALLISON, PH.D.
May 18, 2007

Taken before: Kimberly T. Hoff, CSR,

built on large collections of case reports and other information, which is distinct from the initial bits that go into that of specific case reports.

Q. Let's just stay focused on the initial bits first, and we'll talk about observational studies and how those bits may fit in elsewhere.

A. Certainly.

Q. You agree, though, that case reports, whether it's the case reports in the literature or a spontaneous adverse event reported to the FDA, forms a basis for conjecture, not conclusions, as it results to drug and effect?

MR. DICKENS: Objection to the form of the question.

A. I think that the form of the question is such that a simple "yes" or "no" answer to that would not suffice, and I realize you want to postpone a different aspect of the discussion for later. But I can't give you a simple

"yes" or "no."

I think that, if we are talking solely about case reports of an adverse event after exposure to some stimulus, and that is all we have, there is no other information, then, yes, I agree that those are a basis for conjecture and not a basis for conclusion.

In contrast, when sometimes people are able to take those many case reports and then combine them with many other types of case reports and other information about frequency of exposures, they may be able to essentially build a legitimate observational study out of case reports. And in those cases, case reports may form the basis for some conclusion to make.

Q. And you talk about observational studies in your report, as well, do you not?

A. I believe I do. I have --

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

FILED
STATE OF ALASKA
THIRD DISTRICT
08 FEB 25 PM 4:29
BY: DEPUTY CLERK

DEFENDANT ELI LILLY AND COMPANY'S MOTION TO ACCEPT LATE-FILED MOTION IN LIMINE

Motions in Limine were due on February 4, 2008. Based on developments after that date, including the exchange and review of exhibits, it appears that the State may intend to use Adverse Event Reports as proof of events (or causation) which such documents do not support. This potentially intended improper use should be addressed through a Motion in Limine. Thus, defendant Eli Lilly and Company respectfully requests that this Court now accept its late-filed Motion in Limine to Exclude Adverse Event Reports for Any Purpose Other than Establishing Lilly Knew About the Specific Adverse Event.

DATED this 25th day of February, 2008.

PEPPER HAMILTON LLP
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Attorneys for Defendant

By /s/ A. E. Girolamo-Welp
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I certify that on February 25, 2008, a copy of the foregoing was served by hand on:

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/s/

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

Case No. 3AN-06-5630 CIV

NOTICE OF FILING UNDER SEAL

On this date the State of Alaska is filing 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.**" Because one or more exhibits filed with this pleading may be confidential documents under the Court's April 6, 2007 oral ruling, the State of Alaska is submitting this pleading and the attached exhibits under seal.

DATED this 25th day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

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003042

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

NOTICE OF FILING UNDER SEAL

On this date the State of Alaska is filing 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.**" Because one or more exhibits filed with this pleading may be confidential documents under the Court's April 6, 2007 oral ruling, the State of Alaska is submitting this pleading and the attached exhibits under seal.

DATED this 25th day of February, 2008.

FELDMAN ORLANSKY & SANDERS
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February 25, 2008

HAND DELIVER

The Honorable Mark Rindner
Superior Court Judge
Alaska Court System
825 West Fourth Avenue, Room 432
Anchorage, Alaska 99501-2004

Re: **Citation of Supplemental Authority**
State of Alaska v. Eli Lilly and Company, Case No. 3AN-06-05630 CI
File No. 9867.38

Dear Judge Rindner:

This letter is a citation of supplemental authority made pursuant to Civil Rule 77(l). The supplemental authority referred to herein relates to Lilly's Supplemental Brief Seeking Dismissal of the State's Claims Pursuant to the UTPCPA Exemption and Federal Preemption ("Lilly's Supplemental Brief"), filed February 5, 2008. Oral argument on Lilly's Supplemental Brief has been scheduled for February 26, 2008, beginning at 11:30 a.m.

At page 6 of the State of Alaska's Response to Lilly's Supplemental Brief, the State cited to *Levine v. Wyeth*, __ A.2d __, 2006 WL 3041078 (Vt. October 27, 2006), *cert. granted, Wyeth v. Levine,* 2008 WL 161474 (U.S. January 18, 2008) (No. 06-1249) and addressed the significance of 21 C.F.R. § 314.70. The attached Brief was submitted by the Solicitor General of the United States at the direction of the United States Supreme Court in *Levine*. The Solicitor General's Brief sets forth the Federal Drug Administration's interpretation of 21 C.F.R. § 314.70 (pages 12-15), as well as § 202 of the 1962 Amendments to the Food, Drug, and Cosmetic Act (pages 15-18).

Thank you for considering the above and the attached.

Very truly yours,

LANE POWELL LLC

Brewster H. Jamieson

nlb
Attachment
cc: Eric T. Sanders, Esq. (Hand Delivered)
009867.0038/163596.1

003044

No. 06-1249

In the Supreme Court of the United States

WYETH, PETITIONER

v.

DIANA LEVINE

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF VERMONT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether state-law tort claims are preempted to the extent that they would impose liability for a drug manufacturer's use of labeling that the Food and Drug Administration approved after being informed of the relevant risk.

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In the Supreme Court of the United States

No. 06-1249

WYETH, PETITIONER

v.

DIANA LEVINE

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF VERMONT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be held pending this Court's decisions in *Riegel* v. *Medtronic, Inc.*, No. 06-179 (argued Dec. 4, 2007), and *Warner-Lambert Co., LLC* v. *Kent*, cert. granted, No. 06-1498 (Sept. 25, 2007), and then disposed of as appropriate in light of the decisions in those cases.

STATEMENT

1. Under the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, a drug manufacturer may not market a new drug unless it has submitted a new drug application to the Food and Drug Administration (FDA) and received the agency's approval. 21 U.S.C. 355(a). An application must contain, among other things, "the labeling proposed to be used for such drug,"

21 U.S.C. 355(b)(1)(F) (Supp. V 2005); see 21 C.F.R. 314.50(c)(2)(i) and (e)(2)(ii); "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is * * * effective in use," 21 U.S.C. 355(b)(1)(A) (Supp. V 2005); and "a discussion of why the benefits exceed the risks [of the drug] under the conditions stated in the labeling," 21 C.F.R. 314.50(d)(5)(viii); see 21 C.F.R. 314.50(c)(2)(ix).

The FDCA also requires that drugs not be misbranded. 21 U.S.C. 331(a) and (b). A drug is misbranded if, among other things, the drug's "labeling is false or misleading in any particular;" the labeling does not provide "adequate directions for use" or certain "adequate warnings;" the drug "is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;" or the labeling does not comply with certain FDA regulations. 21 U.S.C. 352(a), (f) and (j). FDA has established specific requirements for prescription drug labeling. 21 C.F.R. Pt. 201.

FDA will approve a new drug application if it finds, among other things, that (i) the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," (ii) there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," and (iii) the proposed labeling is not "false or misleading in any particular." 21 U.S.C. 355(d).

After a drug has been approved and marketed, the manufacturer must investigate and report to FDA any adverse events associated with use of the drug in humans, 21 C.F.R. 314.80, and must periodically submit

any new information that may affect FDA's previous conclusions about the safety, effectiveness, or labeling of the drug, 21 C.F.R. 314.81. See 21 U.S.C. 355(k) (post-approval reporting and record-keeping requirements); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901 *et seq.*, 121 Stat. 922 (enhancing FDA's authority to require postmarket studies and surveillance). FDA "shall" withdraw its approval of an application if it finds, among other things, that the drug is not safe or effective under the conditions of use specified in the drug's labeling. 21 U.S.C. 355(e).

Following FDA's approval of an application, the manufacturer generally may not make changes to the drug, including "[c]hanges in labeling," without first submitting a supplemental application to FDA and securing the agency's prior approval for the change. 21 C.F.R. 314.70(b)(2)(v)(A). A manufacturer must submit such a supplemental application "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 21 C.F.R. 201.57(c)(6). "An applicant may ask FDA to expedite its review of a supplement for public health reasons." 21 C.F.R. 314.70(b)(4). In addition, a manufacturer may change a drug's labeling at the same time that it submits a supplemental application to FDA, without waiting for the agency's approval of the change, if, among other things, the change "add[s] or strengthen[s]" a warning or a statement about administration of the drug in order to promote safety. 21 C.F.R. 314.70(c)(6)(iii)(A) and (C). FDA interprets that regulation to permit changes without prior approval only to address "newly discovered risks." 47 Fed. Reg. 46,623 (1982). If a manufacturer makes a change before receiving FDA's approval, the agency may later reject the

change and order the manufacturer to cease distribution of the changed product. 21 C.F.R. 314.70(c)(7).

2. After FDA approved petitioner's new drug application for the anti-nausea drug Phenergan, petitioner informed FDA of adverse events in which Phenergan apparently was inadvertently injected intra-arterially, resulting in gangrene and amputation. See, *e.g.*, Pet. App. 139a-140a (1967 report). Over the ensuing years, FDA and petitioner engaged in back-and-forth communications concerning the appropriate labeling to address the risks presented by inadvertent intra-arterial injection. See, *e.g.*, *id.* at 141a-166a. As part of its deliberations, FDA convened an expert advisory committee to consider that question. *Id.* at 144a, 147a-148a.

As of 2000 (when the events giving rise to this suit occurred), the FDA-approved labeling stated, in part, that "[u]nder no circumstances should Phenergan Injection be given by intra-arterial injection due to the likelihood of severe arteriospasm and the possibility of subsequent gangrene." Pet. App. 167a. The labeling went on to explain that the "preferred" method of administering the drug is "by deep intramuscular injection," because intravenous administration can result, in some circumstances, in inadvertent intra-arterial injection. *Ibid.* For circumstances in which the drug is injected intravenously, the labeling described in detail how such injection should be done, in order "to avoid * * * inadvertent intra-arterial injection." *Ibid.*

3. In April 2000, respondent sought treatment at a health center for headache and nausea. Pet App. 2a. The health center's staff first administered Phenergan to respondent by intra-muscular injection. *Ibid.* When respondent's nausea continued, the staff administered a second dose of Phenergan by intravenous injection into

her arm. *Ibid.* The intravenous injection was made by a procedure the parties refer to as IV push, whereby the Phenergan solution was not dripped through a free-flowing bag, but instead was directly injected into respondent's arm. See *id.* at 2a, 52a. The IV push apparently resulted in inadvertent arterial injection, which damaged respondent's arteries, caused gangrene, and required amputation of her hand and forearm. *Id.* at 2a.

Respondent brought and settled an action against the health center where she had received the injection of Phenergan. Pet. App. 50a. She also sued petitioner in a Vermont state court, asserting negligence and failure-to-warn claims premised on alleged inadequacies in the drug's labeling. *Id.* at 3a. Respondent asserted that "the label should not have allowed IV push as a means of administration, as it was safer to use other available options, such as intramuscular injection or administration through the tubing of a hanging IV bag." *Ibid.* After the trial court rejected petitioner's preemption defense, *id.* at 49a-74a, the jury found in respondent's favor, and the trial court entered judgment in the amount of $6,774,000, *id.* at 3a.

4. a. The Vermont Supreme Court affirmed. Pet. App. 1a-34a. It interpreted 21 C.F.R. 314.70(c) to "allow unilateral changes to drug labels whenever the manufacturer believes it will make the product safer." *Id.* at 13a. In the court's view, Section 314.70(c) was crucial to the preemption analysis: "While specific federal labeling requirements and state common-law duties might otherwise leave drug manufacturers with conflicting obligations, [Section] 314.70(c) allows manufacturers to avoid state failure-to-warn claims without violating federal law" by making unilateral changes to FDA-approved labeling. *Id.* at 11a.

The Vermont Supreme Court also relied on a provision in the 1962 amendments to the FDCA that states that "[n]othing in th[ose] amendments * * * shall be construed as invalidating any provision of State law * * * unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 793. The court construed that provision to limit preemption to circumstances in which it would be physically impossible for a manufacturer to comply with both federal and state law. Pet. App. 21a. Here, the court determined, there was no such impossibility because there was no indication that FDA would have rejected a supplemental application seeking to strengthen the warning under Section 314.70(c). *Id.* at 17a.

b. Chief Judge Reiber dissented. Pet. App. 35a-48a. He explained that respondent's state-law claims conflict with federal law because, while "FDA concluded that the drug—with its approved methods of administration and as labeled—was both safe and effective," the "jury concluded that the same drug—with its approved methods of administration and as labeled—was 'unreasonably dangerous.'" *Id.* at 35a (quoting *Town of Bridport* v. *Sterling Clark Lurton Corp.*, 693 A.2d 701, 704 (Vt. 1997)). Supporting that conclusion, in the Chief Judge's view, is the fact that FDA does not merely establish minimum safety standards, but instead "balances its assessment of a drug's safety against concerns for the drug's efficacy, taking into account that a safer but less effective drug is not necessarily best for the public health overall." *Id.* at 47a. With respect to drug labels, the Chief Judge explained, "FDA considers not only what information to include, but also what to exclude,"

in part because overwarning can do more harm than good. *Ibid.*

The Chief Judge also took issue with the majority's understanding of Section 314.70(c). Pet. App. 39a-41a. He explained that the regulation "allow[s] manufacturers to address newly discovered risks," but "does not allow manufacturers to simply reassess and draw different conclusions regarding the same risks and benefits already balanced by the FDA." *Id.* at 40a.

DISCUSSION

Petitioners' claims are impliedly preempted by the FDCA because they challenge labeling that FDA approved, after being informed of the relevant health risk, based on its expert weighing of the risks and benefits of requiring additional or different warnings. The Vermont Supreme Court's contrary conclusion rests on its mistaken view that an FDA regulation, 21 C.F.R. 314.70(c), "allow[s] unilateral changes to drug labels whenever the manufacturer believes [the changes] will make the product safer." Pet. App. 13a. That interpretation of the regulation is wrong, because Section 314.70(c) permits unilateral changes based only on newly available information, not based on information that was previously available to FDA, such as the risk at issue here.

While the Vermont Supreme Court's decision is wrong, it does not warrant plenary review at this time. The decision below does not squarely conflict with any decision of a federal court of appeals or another state supreme court. Moreover, this Court's decisions in two pending FDA preemption cases—*Riegel* v. *Medtronic, Inc.*, No. 06-179 (argued Dec. 4, 2007), and *Warner-Lambert, LLC* v. *Kent*, cert. granted, No. 06-1498 (Sept.

25, 2007)—may shed significant light on the question presented in this case. Accordingly, the Court should hold the petition in this case pending its decisions in *Riegel* and *Warner-Lambert*, and then dispose of the petition as appropriate in light of its disposition of those cases.

A. Respondent's Claims Are Impliedly Preempted

Federal law preempts state laws that conflict with federal law, including state laws that either "make it 'impossible' for private parties to comply with both state and federal law," *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 873 (2000), or that "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). Because respondent's claims challenge labeling that FDA approved after being informed of the relevant risk, they conflict with FDA's approval of the labeling and are therefore preempted.

1. FDA's approval of a drug, including its labeling, generally preempts state law claims challenging the drug's safety, efficacy, or labeling

a. FDA may approve a new drug application only if it determines, among other things, that (i) the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," (ii) there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," and (iii) the proposed labeling is not "false or misleading in any particular." 21 U.S.C. 355(d). Thus, FDA specifically considers and approves a drug's labeling. Indeed, the agency's consideration of safety and effectiveness is di-

rectly tied to its consideration of "the proposed labeling," *ibid.*, in part because a drug's safety and effectiveness depend on the conditions under which it is used (*e.g.*, its dosage, its method of administration, and its intended use). Labeling is "[t]he centerpiece of risk management," as it "communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." 71 Fed. Reg. 3934 (2006).

FDA's review of a new drug application is similar to its premarket approval process for Class III medical devices, see 60 Fed. Reg. 39,180 (1995), which this Court has correctly described as "rigorous," *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 477 (1996). As part of the approval process, an applicant must submit "the labeling proposed to be used for such drug," 21 U.S.C. 355(b)(1)(F) (Supp. V 2005), as well as extensive information about the composition, manufacture, and specification of the drug, any studies of the drug's pharmacological actions and toxicological effects in animals, any studies of the drug's bioavailability and pharmacokinetics in humans, any clinical investigations of the drug, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source." 21 C.F.R. 314.50(d); see 21 U.S.C. 355(b)(1)(A) (Supp. V 2005).

If FDA is not ultimately satisfied that a drug is safe for use under the conditions of its labeling and that there is substantial evidence that the drug is effective when used according to the labeling, FDA cannot approve the application. 21 U.S.C. 355(d). Thus, FDA's approval reflects its expert determination, based on a careful review of extensive scientific and technical infor-

mation, that a drug is safe and effective when used according to its labeling, and that the labeling satisfies federal requirements.

b. In making those determinations, FDA does not merely police minimum standards of safety, as the Vermont Supreme Court thought. See Pet. App. 19a. Instead, FDA *weighs* health benefits against health risks. See 71 Fed. Reg. at 3934; 60 Fed. Reg. at 39,180. As this Court has explained, FDA "generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use." *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979); accord *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000). FDA has, for example, approved cancer treatments that are highly toxic and thus not "safe" as that term is ordinarily used, but that are nonetheless safe in the relevant sense under the FDCA because the potential benefits to health outweigh the risks. 61 Fed. Reg. 44,413 (1996); see *Brown & Williamson*, 529 U.S. at 142.

FDA also weighs the overall health consequences of including particular instructions or warnings in a drug's labeling. As explained above, a drug's safety and effectiveness are not determined in the abstract, divorced from its labeling. See 71 Fed. Reg. at 3934. Rather, FDA requires each new drug application to contain "a discussion of why the benefits exceed the risks [of the drug] *under the conditions stated in the labeling*." 21 C.F.R. 314.50(d)(5)(viii) (emphasis added); see 21 C.F.R. 314.50(c)(2)(ix). If FDA then concludes that a drug's benefits outweigh its risks only under certain conditions, the agency may require appropriate labeling to reflect that determination. See, *e.g.*, 21 C.F.R. 314.110(a).

Moreover, a warning in a drug's labeling must strike a balance between notifying users of potential dangers

and not unnecessarily deterring beneficial uses. 71 Fed. Reg. at 3935. "Exaggeration of risk could discourage appropriate use of a beneficial drug," and thereby harm the public health. *Ibid.* In addition, excessive warnings can cause more meaningful risk information to "lose its significance." 44 Fed. Reg. 37,447 (1979); accord 71 Fed. Reg. at 3935; 65 Fed. Reg. 81,083 (2000). "Warnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks." *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 796 (8th Cir. 2001), cert. denied, 535 U.S. 1056 (2002). Thus, as the dissent explained, there are "a number of sound reasons why the FDA may prefer to limit warnings on product labels." Pet. App. 47a (quoting *Brooks*, 273 F.3d at 796).

For those reasons, "FDA interprets the [FDCA] to establish both a 'floor' and a 'ceiling'" with respect to drug labeling. 71 Fed. Reg. at 3935. FDA's approval of labeling for a new drug reflects FDA's expert judgment that the labeling strikes the appropriate balance. *Ibid.* Where, as here, FDA was presented with information concerning the relevant risk, a jury's imposition of liability based on a drug's FDA-approved labeling would interfere with FDA's expert judgment.

That conflict is especially clear in this case because, as the dissent explained, any recovery under state law would be predicated on a finding that Phenergan, as labeled, was "unreasonably dangerous." Pet. App. 35a (quoting *Town of Bridport* v. *Sterling Clark Lurton Corp.*, 693 A.2d at 704). That finding would directly conflict with FDA's determination that the drug, as labeled, was safe and effective. *Id.* at 35a-36a. As such, respondent's claims are preempted. See, *e.g.*, *Geier*, 529 U.S. at 881-883 (holding that state suit seeking to impose

liability for failure to use a particular type of restraint system would stand as an obstacle to the federal agency's decision to encourage the use of a range of restraint systems); *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that state-law fraud-on-FDA claim was impliedly preempted because it would interfere with FDA's ability to strike a "somewhat delicate balance of statutory objectives").

2. Federal law precluded petitioner from unilaterally changing the FDA-approved labeling

The Vermont Supreme Court erroneously interpreted 21 C.F.R. 314.70(c) to "allow unilateral changes to drug labels whenever the manufacturer believes it will make the product safer." Pet. App. 13a. As discussed above, however, the FDCA requires a manufacturer to receive FDA's approval for a new drug's labeling. 21 U.S.C. 355(a) and (d). And because FDA's approval strikes an important balance between, among other things, warning of risks and not overdeterring beneficial uses, manufacturers may *not* ordinarily modify labeling approved by FDA without first obtaining FDA's approval for the change. See 21 C.F.R. 314.70. Here, for example, FDA instructed petitioner that the "final printed labeling * * * must be identical" to the approved labeling. Pet. App. 165a. If manufacturers were free to make unilateral changes to labeling the day after FDA's approval, based on information that was previously available to FDA, the approval process would be greatly undermined and the agency's careful balancing of risks and benefits thwarted. The Vermont Supreme Court's view that "FDA approval of a drug label" is nothing more than "a first step," *id.* at 15a, is there-

fore fundamentally inconsistent with the federal regulatory framework.

Consistent with the stringent statutory and regulatory requirements for approval of a new drug in the first place, a manufacturer ordinarily must submit a supplemental application before making any changes to the drug, including changes in labeling. 21 C.F.R. 314.70(a)(2)(v). As a general rule, the manufacturer must obtain prior approval by FDA before making such changes. Section 314.70(c) provides a limited exception to that rule permitting "the holder of an approved [new drug] application [to] commence distribution of the [changed] drug product involved upon receipt by the agency of a supplement for the change" if, among other things, the change "add[s] or strengthen[s]" a warning or a statement about administration of the drug in order to promote safety. 21 C.F.R. 314.70(c)(6)(iii)(A) and (C).

As FDA explained when it proposed that regulation in 1982, however, changes may be made without prior FDA approval only "to correct concerns about *newly discovered risks* from the use of the drug." 47 Fed. Reg. at 46,623 (emphasis added). FDA explained that, "[a]lthough most changes in labeling would require the applicant to submit a supplement and obtain FDA approval before making a change," some changes that "would make available *important new information* about the safe use of a drug product" could be made upon submission of a supplemental application. *Id.* at 46,635 (emphasis added); compare FDA, *Draft Guidance for Industry and FDA Staff, Modifications to Devices Subject to Premarket Approval (PMA)* 19 (Mar. 9, 2007) <http://www.fda.gov/cdrh/ode/guidance/1584.pdf> (explaining that a manufacturer may make unilateral changes to a device subject to FDA's premarket approval only if "the

manufacturer has newly acquired safety-related information" that "was not previously considered by the FDA").

Thus, any changes to a drug's labeling without prior FDA approval still must be the subject of a supplemental application, which FDA can approve or reject, and must be based on material new information—not information that was previously available to FDA, nor even cumulative new information that does not add materially to the information that was previously available to the agency. As the dissent explained, Section 314.70(c) does not "allow manufacturers to simply reassess and draw different conclusions regarding the same risks and benefits already balanced by the FDA." Pet. App. 40a. FDA's interpretation of its own regulation is entitled to significant deference. See *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997).

In this case, it does not appear that respondent relies on any material new information that was not available to FDA. The parties dispute whether FDA specifically and expressly rejected the stronger warning that respondent asserts should have been included in the labeling. See, *e.g.*, Br. in Opp. 15-17. There is and can be no dispute, however, that FDA was presented with extensive information about the dangers of accidental intra-arterial injection from intravenous administration of the drug, and that Phenergan's FDA-approved labeling provided specific guidance on how to inject the drug, either intramuscularly or intravenously, so as to reduce that risk. See p. 4, *supra*. Nor did the Vermont Supreme Court point to any marked change in the number or type of reported cases of accidental intra-arterial injection from intravenous administration that might have suggested that the risk was of a magnitude that was not

previously known at the time that FDA approved labeling that addressed that risk. Under a correct reading of Section 314.70, therefore, petitioner could not have changed the labeling without prior FDA approval, and respondent's claims are preempted.

Moreover, even when a manufacturer may make a change at the same time that it submits a supplemental application to FDA under Section 314.70(c), the supplemental application must "give a full explanation of the basis for the change." 21 C.F.R. 314.70(c)(3). The agency may then reject the change based on its own balancing of the relevant health risks and benefits. See 21 C.F.R. 314.70(c)(7). If FDA rejects the change, it may order the manufacturer to cease further distribution of the changed product. *Ibid.* Changed labeling also "remains subject to enforcement action" if FDA finds that the change "makes the labeling false or misleading." 71 Fed. Reg. at 3934; see 21 U.S.C. 352 (2000 & Supp. V 2005). Thus, whether to authorize a change is, in the end, "squarely and solely FDA's" decision. 71 Fed. Reg. at 3934. For these reasons, in practice manufacturers typically consult with FDA before making labeling changes that the manufacturer believes could appropriately be made unilaterally under 21 C.F.R. 314.70(c) while a supplemental application was pending before FDA. See 71 Fed. Reg. at 3934.

3. The 1962 amendments to the FDCA did not displace ordinary conflict-preemption principles

The Vermont Supreme Court mistakenly thought that Section 202 of the 1962 amendments to the FDCA precludes the application of ordinary conflict preemption principles in this case. See Pet. App. 21a-23a. That provision states as follows:

> Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law * * * unless there is a direct and positive conflict between such amendments and such provision of State law.

Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962).

At the outset, it is not clear to what extent Section 202 applies here. It is limited to "the amendments made by" the 1962 legislation. § 202, 76 Stat. 793. While those amendments broadened the scope of FDA's new drug approval process by requiring the agency to consider the efficacy as well as the safety of a drug, see § 102(b), 76 Stat. 781, FDA's new drug approval process predated the amendments, see 21 U.S.C. 355(a) and (d) (1958). Indeed, FDA approved Phenergan before 1962. See Pet. 6; Br. in Opp. 23 n.8.

Even assuming *arguendo* that Section 202 is relevant in this case, however, that provision means only that Congress did not intend the 1962 amendments to pre-empt the *field* of drug regulation; it does not manifest an intent to displace ordinary principles of *conflict* preemption. 71 Fed. Reg. at 3935 n.8. Indeed, Section 202 expressly contemplates preemption in circumstances involving "a direct and positive conflict." § 202, 76 Stat. 793.

The Vermont Supreme Court read that phrase to refer only to situations in which it would be impossible to comply with both federal and state law, as distinguished from situations in which state law would frustrate the purpose of the federal scheme. Pet. App. 21a-23a. That interpretation is incorrect. Before 1962, this Court had long used the phrase "direct and positive con-

flict" to refer to conflict preemption generally, not to a mere subset of such preemption. See, *e.g.*, *United Constr. Workers* v. *Laburnum Constr. Corp.*, 347 U.S. 656, 663 n.5 (1954); *Sinnot* v. *Davenport*, 63 U.S. 227, 243 (1859). In so doing, the Court contrasted "direct and positive" conflict preemption to "field" preemption, not to some subset of conflict preemption. *E.g.*, *Kelly* v. *Washington ex rel. Foss Co.*, 302 U.S. 1, 9-10 (1937). More generally, this Court has never "driven a legal wedge—only a terminological one—between 'conflicts' that prevent or frustrate the accomplishment of a federal objective and 'conflicts' that make it 'impossible' for private parties to comply with both state and federal law." *Geier*, 529 U.S. at 873.

In any event, "[t]he Court has * * * refused to read general 'saving' provisions to tolerate actual conflict both in cases involving impossibility and in 'frustration-of-purpose' cases." *Geier*, 529 U.S. at 873-874 (citation omitted). That would appear to apply, *a fortiori*, to a provision that addresses only the effect of particular amendments, not the overall permanent code. See p. 16, *supra*. Moreover, even when a statute contained a savings clause providing that "[c]ompliance with" a federal safety standard "does not exempt any person from *any* liability under common law," 15 U.S.C. 1397(k) (1988) (emphasis added), this Court held that the savings clause did not preclude the application of ordinary conflict preemption principles, including frustration of purpose principles. *Geier*, 529 U.S. at 868, 873-874. The savings clause here, which expressly provides for conflict preemption, likewise does not displace ordinary conflict preemption principles.

In the preamble to its January 2006 rule concerning the labeling of drugs, FDA explained that the govern-

ment's "long standing view[]" is that "FDA approval of labeling under the [FDCA] * * * preempts conflicting or contrary State law," especially considering that "FDA interprets the [FDCA] to establish both a 'floor' and a 'ceiling'" for labeling. 71 Fed. Reg. at 3934, 3935. The agency also "recognized[] that FDA's regulation of drug labeling will not preempt all State law actions." *Id.* at 3936. FDA then provided some specific examples of circumstances in which state laws are preempted, but it did not attempt to exhaust such circumstances. See *id.* at 3935-3936 (noting that "at least" those examples would be preempted). In this brief, the government has articulated a more generally applicable rule of decision, consistent with the framework and examples set forth in the preamble, that reflects FDA's explanation in that preamble that (i) the labeling requirements are not a mere minimum safety standard, but rather strike a balance between risks and benefits, and (ii) FDA's regulations permit changes in labeling without prior approval only in narrow circumstances. See *id.* at 3934-3935.*

* While respondent argues (Br. in Opp. 8, 28) that FDA's 2006 preamble reflected a change in the agency's position, she relies solely on snippets from Federal Register notices that did not squarely address, much less discuss, the preemption question here. See 65 Fed. Reg. at 81,103 (stating that proposed *changes* to existing labeling rules would not have federalism implications); 63 Fed. Reg. 66,384 (1998) (response to comments concerning Medication Guides for "a small number of products," *id.* at 66,379); 44 Fed. Reg. at 37,437 (responding to comment that FDA should use different administrative procedures).

B. This Court Should Hold The Petition For A Writ Of Certiorari Pending The Decisions in *Riegel* and *Warner-Lambert*

Although the Vermont Supreme Court's decision is wrong, it does not warrant this Court's plenary review at this time.

1. Petitioner asserted (Reply 1) for the first time in its reply brief that the decision below conflicts with *Dowhal* v. *Smithkline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004). There is no conflict. In *Dowhal*, California law required over-the-counter stop-smoking products containing nicotine to provide a specific health warning. *Id.* at 3-4. When the drug companies asked FDA for permission to change their labels to comply with the California law, FDA repeatedly denied their requests, told them to continue to use a different FDA-approved warning, and stressed that "*[a]ny additional or modified warning may render the product misbranded.*" *Id.* at 5-6. FDA was concerned that a stronger warning against the use of stop-smoking products would harm the public health by causing pregnant women to continue smoking instead of using the (less harmful) stop-smoking products. *Id.* at 4-5. Even when FDA ultimately permitted the companies to modify their warning labels, it prohibited them from using the particular labels required by the California law. *Id.* at 10-11. Against that unusual backdrop, the California Supreme Court correctly held that the state law was preempted. *Id.* at 11.

There is no square conflict because the *Dowhal* court tied its holding, not to FDA's approval of a new drug application, but to the agency's subsequent, specific prohibition of the warnings that would have complied with

California law. 88 P.3d at 10-11. On the facts of this case, in contrast, the Vermont Supreme Court determined that "FDA has not indicated that a stronger warning would be misleading." Pet. App. 13a; see *id.* at 16a-19a. While FDA had rejected alternative labeling proposed by petitioner, the court below determined that there was no indication that FDA did so "to preserve the use of IV push as a method of administering Phenergan." *Id.* at 17a. Thus, the two decisions are reconcilable based on the differing findings of fact in each case, and the Vermont Supreme Court might have found preemption in a case like *Dowhal* even under its erroneous impossibility standard of conflict preemption. To be sure, petitioner may dispute the Vermont Supreme Court's interpretation of the record in this case. And the United States submits that respondent's claims are preempted regardless of whether FDA explicitly rejected the specific warning now proposed by respondent, because the agency nonetheless balanced the relevant considerations in approving the product's labeling after being informed of the relevant risks. But those disagreements with the decision below do not amount to a conflict in legal authority.

2. Petitioner also relies (Reply 1-2) on a circuit split concerning the preemptive effect of FDA's premarket approval of Class III medical devices. That conflict is real, but is not directly implicated here because this case involves implied preemption based on FDA's approval of a new drug application and regulations governing changes in labeling, not express preemption based on FDA's premarket approval of a medical device. Cf. 21 U.S.C. 360k(a) (expressly preempting certain requirements with respect to medical devices). Most importantly, this Court already granted review in *Riegel* to determine the

preemptive scope of FDA's premarket approval of a Class III medical device, and the Court heard argument in that case on December 4, 2007.

As petitioner's reliance (Reply 1-2) on the medical-device cases reflects, there is significant overlap between the preemption question in this case and the preemption question in *Riegel*. While the FDCA contains an express preemption provision concerning devices (but not drugs), see 21 U.S.C. 360k, this Court has determined that implied preemption principles are relevant to the interpretation of that provision. See *Lohr*, 518 U.S. at 500; *id.* at 508 (Breyer, J., concurring).

Moreover, FDA's review of new drug applications and its premarket approval process for Class III devices are similar. See 60 Fed. Reg. at 39,180-39,181. In both instances, FDA conducts an extensive review of a product's safety and efficacy, balances health benefits against health risks in determining whether to grant approval, and generally precludes the manufacturer from making changes without the agency's prior approval. See U.S. Br. at 10-14, *Riegel*, *supra* (No. 06-179); pp. 8-14, *supra*. Under each regulatory regime, the manufacturer can make unilateral changes in labeling only in narrow circumstances while its supplemental application is pending with FDA. See *ibid.* Accordingly, this Court's resolution of *Riegel* is likely to be instructive on the question presented here.

In addition, the petition in *Warner-Lambert* (which the Court granted after inviting the views of the Solicitor General in this case) poses the related question whether the FDCA impliedly preempts state tort claims that require a court to determine, as a condition for imposing damages liability, whether a drug manufacturer defrauded FDA in a new drug application and whether

FDA would have denied or withdrawn approval of the drug but for that fraud. See Pet. at (i), *Warner-Lambert*, *supra*. That case differs from this one because the question there involves preemption of state-law determinations of fraud on FDA, while the question here involves preemption of common-law tort claims based on FDA's approval of a new drug application. Nonetheless, because *Warner-Lambert* involves implied preemption of claims involving FDA's approval of a new drug application, the decision in *Warner-Lambert* may also shed light on the proper resolution of the question in this case. For that reason as well, the Court should hold the petition in this FDA preemption case pending its resolution of the two FDA preemption petitions it has already granted for this Term.

CONCLUSION

The Court should hold the petition for a writ of certiorari pending its disposition of *Riegel* v. *Medtronic, Inc.*, No. 06-179 (argued Dec. 4, 2007), and *Warner-Lambert Co., LLC* v. *Kent*, cert. granted, No. 06-1498 (Sept. 25, 2007), and then dispose of the petition as appropriate in light of its disposition of those cases.

Respectfully submitted.

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DECEMBER 2007

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or three paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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VIII. Proposed Effective Date

FDA is proposing that any final rule that may issue based on this proposal be effective on the date of its publication in the **Federal Register**.

List of Subjects

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 314, 601, and 814 be amended as follows:

PART 314–APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

2. Section 314.3 is amended in paragraph (b) by alphabetically adding the definition for "newly acquired information" to read as follows:

§ 314.3 Definitions.

* * * * *

(b) * * *

Newly acquired information means data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events of a different type or greater severity or frequency than previously included in submissions to FDA, or new analyses of previously submitted data (*e.g.*, meta-analyses).

* * * * *

3. Section 314.70 is amended by revising paragraphs (c)(6)(iii) introductory text and (c)(6)(iii)(A) to read as follows:

§ 314.70 Supplements and other changes to an approved application.

* * * * *

(c) * * *

(6) * * *

(iii) Changes in the labeling to reflect newly acquired information, except for changes to the information required in § 201.57(a) of this chapter (which must be made under paragraph (b)(2)(v)(C) of this section), to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under 201.57(c) of this chapter;

* * * * *

PART 601–LICENSING

4. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C 1451-1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c-360f, 360h-360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122 Pub. L. 105-115, 111 Stat. 2322 (21 U.S.C. 355 note).

5. Section 601.12 is amended by revising paragraphs (f)(2)(i) introductory text and (f)(2)(i)(A), and by adding paragraph (f)(6) to read as follows:

§ 601.12 Changes to an approved application.

* * * * *

(f) * * *

(2) Labeling changes requiring supplement submission--product with a labeling change that may be distributed before FDA approval. (i) An applicant shall submit, at the time such change is made, a supplement for any change in the package insert, package label, or container label to reflect newly acquired information, except for changes to the package insert required in § 201.57(a) of this chapter (which must be made under paragraph (f)(1) of this section), to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter;

* * * * *

(5) For purposes of paragraph (f)(2) of this section, information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events of a different type or greater severity or frequency than previously included in submissions to FDA, or new analyses of previously submitted data (e.g., meta-analyses).

* * * * *

PART 814–PREMARKET APPROVAL OF MEDICAL DEVICES

6. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

7. Section 814.3 is amended by adding paragraph (o) to read as follows:

§ 814.3 Definitions.

* * * * *

(o) Newly acquired information means data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events of a different type or greater severity or frequency than previously included in submissions to FDA, or new analyses of previously submitted data (e.g., meta-analyses).

8. Section 814.39 is amended by revising paragraphs (d)(1) introductory text and (d)(2)(i) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under § 814.17 of a written FDA order approving the PMA supplement provided that:

* * * * *

(2) * * *

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association.

* * * * *

DATE: 12/4/07
December 4,, 2007.

SIGNED: _____
Jeffrey Shuren,
Assistant Commissioner for Policy.

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