3AN-06-05630CI Volume: 007
State of Alaska vs. Eli Lilly & Co
Superior Court Civil

Vol 7

CIVIL

Begin: 12/11/07
end - 2/4/08

ON APPEAL
Appeal to COA/Supreme
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AP-475 (6/90) (TCB green-remov.)(4¼"x2")
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PLAINTIFF'S ATTORNEY

EFENDANT'S TORNEY

TYPE OF PROCEEDING

MASTER ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED

JUDGE ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED
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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.	)	

SUPPLEMENTAL PAGE 77 TO
PLAINTIFF'S TRIAL DEPOSITION DESIGNATIONS

Plaintiff, the State of Alaska, hereby submits the attached page (page 77 of 137) of the testimony for the witness listed below. The attached page was inadvertently omitted when the deposition designations were filed with this court on January 22, 2008.

Exhibit	Description	Date of Deposition
Exhibit 1	Michael Bandick	June 9, 2006

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& SANDERS
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FAX: 907.274.0819

DATED this 25 day of January, 2008.

FELDMAN, ORLANKSY & SANDERS

By _____
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Matthew L. Garretson
Joseph W. Steele

RICHARDSON, PATRICK,
WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
David L. Suggs
Christiaan A. Marcum
Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Supplemental Page 77 to Plaintiff's Trial Deposition Designations** was served by messenger on:

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

By Annette R. Carter
Date 1-25-08

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A B C D E F G

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 DEPOSITION DESIGNATIONS FOR TRIAL

Defendant Eli Lilly and Company ("Lilly") designates for trial the following deposition transcript excerpts:

I. Deposition of Charles Beasley, Jr. M.D.—Volume 1, designated pages Exhibit A.

Start (Page:Line)	End (Page:Line)
26:10	27:16
30:11	33:3
33: 4	33:19
34:19	38:24
46:5	52:15
53:2	55:3
57:1	57:20
112:8	114:7
137:24	139:15
139:16	141:14
141:15	142:2
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156:9	158:7
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161:22	162: 7
162:9	162:17
162:22	163:5
163:7	163:11

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Start (Page:Line)	End (Page:Line)
191:23	192:7
192:10	193:2
196:16	197:24
199:17	201:3
261:18	262:21
365:24	366:11

II. **Deposition of Charles Beasley, Jr. M.D.—Volume 2**, designated pages Exhibit B.

Start (Page:Line)	End (Page:Line)
520:7	521:13
530:19	531:3
532:1	532:16
532:22	533:9
535:5	536:14
537:24	540:13
540:14	541:16
541:17	543:8
543:9	544:13
544:14	545:11
545:12	546:13
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553:14	555:15
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557:10	557:19
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558:5	559:24

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560:1	561:20
561:21	562:22
562:23	564:13
564:14	564:20
564:21	565:7
565:8	567:9
567:13	567:20
567:21	569:11
569:12	570:13
570:14	572:21
572:22	573:12
573:13	575:12
575:13	578:1
578:5	578:6
578:18	580:21
580:22	582:20
583:4	583:16
584:1	586:1
586:2	586:23
586:24	590:10
722:8	723:11

III. **Deposition of David Campana—Volume 1**, designated pages Exhibit C.

Start (Page:Line)	End (Page:Line)
5:8	5:14
7:15	7:23
8:18	9:1
9:6	11:12
34:4	34:8
169:3	169:9

IV. **Deposition of David Campana—Volume 2**, designated pages Exhibit D.

Start (Page:Line)	End (Page:Line)
191:19	192:14
208:13	208:20
209:13	209:19
210:13	211:15
214:12	214:25
215:16	216:5
218:2	219:13
222:25	223:13
224:3	224:6
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229:11	229:13
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250:24	252:9
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271:18	272:12
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307:23	308:22
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311:17	312:5
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314:16	315:15
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334:8	334:18
334:25	340:24
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V. **Deposition of Lucy Curtiss, M.D.**, designated pages Exhibit E.

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9:1	13:2
13:5	22:19
22:25	23:17
24:20	26:3
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37:6	38:5
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42:23	46:11
47:14	47:17
49:5	51:4

VI. **Deposition of Joel Gilbertson**, designated pages Exhibit F.

Start (Page:Line)	End (Page:Line)
5:17	5:22
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15:8	15:21

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18:21	19:7
19:17	20:1
20:20	22:23
61:11	62:7
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64:10	66:19
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72:18	73:18
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VII. **Deposition of Duane Hopson, M.D.**, designated pages Exhibit G.

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6:22	10:16
11:5	11:25
12:4	17:8
17:12	29:5
29:8	34:2
35:19	37:20
38:15	41:22
42:14	46:13
48:14	50:22
51:8	54:12
55:1	56:9
56:12	59:2
59:14	60:4
61:23	61:25
62:14	69:22
70:3	78:6
79:15	91:3

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91:13	93:15
94:2	95:16
96:12	99:23
101:3	105:4
105:17	106:14
106:1	106:1

VIII. **Deposition of Karleen Kay Jackson**, designated pages Exhibit H.

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5:17	5:22
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7:3	7:14
8:5	8:11
8:22	9:3
9:24	10:7
14:23	15:4
15:21	16:2
23:24	25:3
30:3	31:13
31:19	32:9
33:20	34:12

IX. **Deposition of Gary Tollefson, M.D.**, designated pages Exhibit I.

Start (Page:Line)	End (Page:Line)
11:19	11:23
13:6	13:9
13:18	15:3
29:19	32:4
35:10	37:3

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Start (Page:Line)	End (Page:Line)
37:21	43:10
51:11	51:24
52:3	52:19
52:22	55:3
55:6	55:9
105:16	105:20
105:23	106:20
106:23	107:8
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115:14	117:9
117:17	118:4
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183:9	183:22
187:3	188:4
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298:16	298:21
369:19	370:1
370:4	370:7
370:10	370:11
380:11	383:14
383:17	388:2

X. **Deposition of Robin Pitts Wojcieszek**, designated pages Exhibit J.

Start (Page:Line)	End (Page:Line)
6:10	6:17
9:19	11:3
11:6	12:17
130:2	130:19
130:21	131:4
167:15	169:23

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180:12	182:18
182:23	182:25
183:2	183:17
183:19	189:12
189:14	192:5
192:7	192:23

Lilly reserves the right to introduce any of the deposition testimony set forth in plaintiff's deposition designations. Lilly further reserves the right to affirmatively designate any deposition testimony not yet taken in this or any other matter. Lilly further reserves the right to introduce additional deposition testimony not included above, if deemed necessary for the rebuttal of testimony from witnesses called by plaintiff or exhibits introduced by plaintiff at the trial of this action.

DATED this 22nd day of January, 2008.

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Eric J. Rothschild, admitted *pro hac vice*
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Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

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009867/0038/162773.1

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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 EVIDENCE RELATING TO DEFENDANT'S PROFITS, NET WORTH AND THE PRICE OF ZYPREXA

COMES NOW Defendant Eli Lilly and Company ("Lilly") and hereby requests that the Court bar the State from introducing at trial any evidence of Lilly's Zyprexa® based profits or general net worth and evidence relating to the price of Zyprexa. Such evidence is irrelevant and prejudicial to Lilly and should be excluded under Alaska Rules of Evidence 402 and 403.

I. EVIDENCE RELATING TO LILLY'S PROFITS OR NET WORTH IS NOT RELEVANT TO THE FIRST PHASE OF THE COURT'S BIFURCATED TRIAL PLAN.

Under Alaska Rule of Evidence 402, relevant evidence is that evidence that tends to make the existence of a fact in dispute more or less probable. Absent a claim for punitive damages, evidence of a defendant's size and financial condition is irrelevant and should be excluded. *Fleegel v. Estate of Boyles*, 61 P.3d1267, 1271 (Alaska 2002); *Laidlaw Transit Inc., v. Crouse*, 53 P.3d 1093, 1102 (Alaska 2002); *see also Smith v. Lightning Bolt Productions*, 861 F.2d 373 (2d. Cir. 1988) (noting that evidence of a defendant's wealth is normally inadmissible with respect to claims for compensatory damages). Evidence of

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Lilly's financial condition is irrelevant due to the Court's bifurcated trial plan in which issues of damages are not relevant unless a second trial phase is required. Lilly's financial condition simply does not relate to any issue before the Court during the liability phase. To the extent the State seeks to argue that Lilly's intent or motive provides a basis for such evidence, neither is an element of any cause of action alleged by the State. Therefore, evidence relating to motive or intent is irrelevant. *See* Pl's. Mem. Describing Claims and Proofs at 12.

Finally, evidence relating to Lilly's financial condition should be excluded under Rule 403. Rule 403 states that relevant "evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Even if evidence relating to Lilly's profits or net worth is relevant, such evidence should be excluded due to the danger of unfair prejudice that might result from the jurors' consideration of the issue. If evidence of Lilly's financial status were admitted, jurors might assume that Lilly's net worth enables it to compensate the State, thereby influencing the liability determination. The prejudice to Lilly that would result from the introduction of irrelevant financial information during the liability phase of this trial outweighs whatever negligible probative value that could be gleaned from this evidence.

II. EVIDENCE RELATING TO THE PRICE OF ZYPREXA IS NOT RELEVANT AND IS UNDULY PREJUDICIAL.

The State concedes that the price of Zyprexa is not relevant to the issues to be determined in the first phase of this trial. In its Opposition to Summary Judgment, the State admitted it "is not contending that Lilly's [alleged] misrepresentations and concealments artificially inflated the price of Zyprexa." State's Opp. to Lilly's Motion for Summary Judgment at 12. Moreover, the State's causes of action "do not include claims that it

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overpaid for each Zyprexa prescription that it purchased," and it "is not claiming, and will not attempt to prove, that the drug was overpriced as a result of fraudulent promotions." *Id.; see also* Pl's. Resp. to Def's. First Set of Interrogs. at 18. As the State recognizes, the price of the Zyprexa lends no support to its theory of recovery, and all evidence of the medication's price should therefore be excluded.

Even if evidence concerning price were relevant to the issues in Phase I of this trial, the danger of unfair prejudice, confusion of the issues, and misleading of the jury outweigh the probative value of this evidence. For reasons already discussed, any probative value of such evidence would be negligible because the State's theory of recovery does not depend on a showing of price inflation or overpayment. Such evidence carries a danger of unfair prejudice and confusion; survey results show that an overwhelming majority of people has a negative view of medication prices and pharmaceutical companies. *Kaiser Public Opinion Spotlight: Views on Prescription Drugs in the Pharmaceutical Industry,* February 2005, *available at* www.kff.org/spotlight/rxdrugs/index.cfm) (last visited January 28, 2008). Evidence of Zyprexa's price would tempt jurors to "punish" Lilly with a liability verdict for what they might perceive as unjustly high prices of medications. *See State v. Carpenter,* 171 P.3d 41, 64 (Alaska 2007) (affirming trial court's exclusion of compensation evidence, where such evidence could be "misused or misunderstood by the jury" and there was already risk that the jurors would impose liability based on their dislike of the defendant "as opposed to determining the narrow liability issues presented.") The parties agree that liability does not attach here for overpricing; the jury should not be allowed to conclude otherwise.

III. CONCLUSION

For the reasons set forth above, Lilly requests that the Court order all evidence of Lilly's profits, net worth and pricing excluded at trial.

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DATED this 4th day of February, 2008.

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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 4, 2008, a copy of
The foregoing was served by hand on:

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[illegible]

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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 TESTIMONY AND CALL NOTES OF NON-ALASKA BASED SALES REPRESENTATIVES

COMES NOW Defendant Eli Lilly and Company ("Lilly") and hereby requests that this Court bar the State from introducing at trial (i) testimony given by Lilly sales representatives who work in states other than Alaska, and (ii) call notes generated by Lilly sales representatives who work in states other than Alaska.[1]

In this case, the State bears the burden to establish that Lilly violated the Alaska Unfair Trade Practices and Consumer Protection Act ("UTPCPA") by delivering illegal sales messages to physicians in Alaska.[2] The conduct and call notes of Lilly sales representatives who work outside Alaska are not relevant to establishing the State's claim. Moreover, even

[1] Call notes are rough, idiosyncratic shorthand concerning sales representatives' discussions with physicians.

[2] *See State v. O'Neill Investigations*, 609 P.2d 520, 523 (Alaska 1980) (noting, in a constitutional challenge to the UTPCPA, that the conduct regulated by the Act was that of businesses "operating in this state."); *see also* Pltf's Suppl. Responses to Lilly's Fourth Set of Interrogatories at 6 (discussing that the basis for its UTPCPA claims are messages delivered by Lilly sales representatives to Alaska physicians).

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if this evidence were marginally relevant, the unfair prejudice that would result in the introduction of this evidence outweighs its probative value.

I. TESTIMONY AND CALL NOTES FROM LILLY SALES REPRESENTATIVES WHO WORK OUTSIDE ALASKA ARE NOT RELEVANT TO PROVING ALASKA'S UTPCPA CLAIMS.

The testimony and call notes of Lilly sales representatives who work outside Alaska should be excluded because such evidence is not relevant. "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."[3] Evidence that is not relevant is inadmissible.[4] "Relevancy is not an inherent characteristic of any item of evidence but exists only as a relation between an item of evidence and a matter properly provable in the case."[5] Only conduct occurring in Alaska can serve as a basis for liability in this case. For evidence to be relevant, therefore, it must relate to what the State has to establish in Phase I, namely that messages delivered by Lilly sales representatives to Alaska physicians constituted unfair practices.

No such relationship exists between the conduct or call notes of Lilly sales representatives who work outside Alaska and what the State must prove at trial. Evidence of a Lilly sales representative's conduct in another jurisdiction does not make it more or less probable that some other Lilly sales representative engaged in certain conduct in Alaska.[6]

---

[3] Alaska R. Evid. 401.

[4] Alaska R. Evid. 402.

[5] Alaska Rules of Evidence Commentary, Rule 401.

[6] *Reeves v. Alyeska Pipeline Serv. Co.*, 56 P.3d 660, 669 (Alaska 2002) (holding evidence of future plans for a building were not relevant to a case about terms of a contract regarding the building and resulting damages for breach thereof); *see also Timmerman v. U.S. Bank N.A.*, 483 F.3d 1106, 1116 (10th Cir. 2007) (finding evidence of possible discriminatory terminations of other employees not relevant to the case of a plaintiff where the employer did

(continued . . .)

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Accordingly, evidence of the conduct of Lilly sales representatives who work outside Alaska is not relevant and is inadmissible under Alaska Rule of Evidence 402.

II. EVIDENCE THAT CONDUCT OCCURRED IN OTHER JURISDICTIONS IS PREJUDICIAL TO LILLY AND CONFUSING TO THE JURY.

Even if this evidence is relevant, it should be excluded because the prejudice to Lilly and likelihood of jury confusion outweighs its slight probative value. "Although relevant, evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."[7] Evidence of Lilly sales representatives' conduct elsewhere and the contents of the call notes generated by these sales representatives will confuse the jury when it must decide whether Lilly's Alaska conduct violated the UTPCPA.[8] The jury should not consider the conduct of Lilly sales representatives in other jurisdictions, or the call notes they generated, when making this decision, as this would prejudice Lilly. Thus, testimony and call notes from Lilly sales representatives who work outside of Alaska should be excluded.

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(. . . continued)
not raise the same pre-textual basis in the plaintiff's case which was possibly at issue in those earlier cases).

[7] Alaska R. Evid. 403.

[8] *Hilbschman v. Valdez*, 821 P.2d 1354, 1366 (Alaska 1991) (upholding trial court determination that potential prejudice of a jury punishing party for other conduct outweighs probative value of evidence); *Korean Air Lines Co. v. State*, 779 P.2d 333, 340 (Alaska 1989) (upholding exclusion of evidence of an uncontested fact because potential confusion of jury as to what issues were before them).

III. CONCLUSION

For the reasons set forth above, Lilly requests that the Court order all evidence of testimony call notes and conduct of non-Alaska based Lilly sales representatives excluded at trial.

DATED this 4th day of February, 2008.

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Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
and
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Attorneys for Defendant

By _____
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Andrea E. Girolamo-Welp, ASBA No. 0211044

I certify that on February 4, 2008, a copy of The foregoing was served by hand on:

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doc#: 1018.163311.1

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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 REFERENCES TO FOREIGN REGULATORY ACTION

COMES NOW Defendant Eli Lilly and Company ("Lilly") and hereby requests that this Court bar the State of Alaska from introducing at trial evidence relating to foreign regulatory action regarding Zyprexa®.

I. INTRODUCTION

The State intends to introduce evidence relating to foreign regulatory action, despite the fact that foreign regulatory action is compelled by many diverse factors, regarding Zyprexa in support of its claim that Zyprexa's United States product labeling was inadequate.

For example, the State's Complaint cites regulatory action by British and Japanese regulatory agencies to suggest that Lilly was aware of certain safety information about the medication, but failed to change its label in the United States:

> In April 2002, the British Medicines Control Agency warned about the risk of diabetes for patients prescribed Zyprexa. The agency reported forty known incidents of diabetes, hyperglycemia, diabetic ketoacidosis, diabetic coma, and one death among users of Zyprexa. Subsequently, the British government required Defendant to warn consumers about the risk of diabetes and diabetic ketoacidosis, and further required Defendant to instruct patients who were using Zyprexa to monitor their blood sugar levels.

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Complaint ¶15.

> In that same month, the Japanese Health and Welfare Ministry issued emergency safety information regarding the risk of diabetes, diabetic ketoacidosis, and diabetic coma for users of Zyprexa.

Complaint ¶16.

Similarly, the State's Opposition to Lilly's Motion for Summary Judgment attaches a July 1, 2002 Lilly memorandum referencing Japanese regulatory action, in support of its assertion that Lilly was aware of other safety information that was not disclosed to physicians in the United States:

> The State's evidence shows that in places where adequate warnings were provided, Zyprexa use declined. FN 14: *See* Exhibit 6 (July 1, 2002 Lilly Memorandum noting that prescriptions of Zyprexa dropped precipitously in 2002 after the Japanese regulatory authority required a stringent warning on the risk of diabetes, contraindicated the use of Zyprexa for patients with diabetes, and mandated blood glucose monitoring for all patients started on the drug…).

Opposition to Lilly's Motion for Summary Judgment, p. 6.

Evidence relating to foreign regulatory action should be excluded as beyond the scope of this case, irrelevant, unfairly prejudicial, confusing, misleading, and because such evidence would cause undue delay at trial.

II. ARGUMENT

A. Evidence of Foreign Regulatory Action Is Irrelevant and Inadmissible In This Case.

Evidence of foreign regulatory action is irrelevant to the question of liability under the laws of the United States, and should be excluded. "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 or less probable than it would be without the evidence."

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Alaska R. Evid. 402. Zyprexa is approved for sale in more than eighty countries throughout the world, and no two countries promulgate regulations for the same reasons or in the same manner. Compelled by diverse factors (political, social, and economic) and settings distinguishable from the United States, each country's regulatory agency applies unique laws and policies for the product label for that country. Thus, the Zyprexa product label, as for any other medication, can be markedly dissimilar from one country to the next. That foreign regulatory bodies took or did not take certain action regarding Zyprexa does not make more or less probable any fact pertinent to whether the United States label was adequate or inadequate. Accordingly, in prescription drug and products liability cases, courts have excluded such evidence.[1]

> Questions as to the safety of drugs marketed in a foreign country are properly the concern of that country; the courts of the United States are ill-equipped to set a standard of product safety for drugs sold in other countries. The issues raised here concern the knowledge, if any, of an allegedly unreasonable risk, and the sufficiency of the warning of that risk to users of the product. Both the British and American governments have established requirements as to the standards of safety for drugs and the adequacy of any warnings to be given in connection with its use. Each government must weigh the merits of permitting the drug's use and the necessity of requiring a warning. Each makes its own determination as to the standard or degree of safety and duty of care. This balancing of the overall benefits to be derived from a product's use with the risk of harm associated with that use is peculiarly suited to a forum of the country in which the product is to be used. Each country has its own legitimate concerns and its own unique needs which must be factored into its process of

[1] *See Hurt v. Coyne Cylinder Co.*, 956 F.2d 1319, 1327 (C.A.6 (Tenn.), 1992)(foreign legal standards excluded in products liability case); *Garmon v. Cincinnati, Inc.*, 1993 WL 190923 (Tenn.Ct.App., June 4, 1993)(foreign law inextricably bound to foreign custom and usage, all of which were inadmissible); *Colangelo v. Novartis Pharmaceuticals Corp.*, 2002 WL 31253354 (Ill. Cir., December 17, 2002)(court excluded evidence regarding foreign package inserts in pharmaceutical product liability lawsuit).

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> weighing the drug's merits, and which will tip the balance for it one way or the other . . . . fairness to the defendant mandates that defendant's conduct be judged by the standards of the community affected by its actions . . . . it is manifestly unfair to the defendant, as well as an inappropriate usurpation of a foreign court's proper authority to decide as a matter of local interest, for a court in this country to set a higher standard of care than is required by the government of the country in which the product is sold and used.

Harrison v. Wyatt Laboratories, et al., 510 F. Supp. 1, 4-5 (D.C.Pa. 1980), *aff'd*, 676 F.2d 685 (3rd Cir. 1982).

The question of liability in this Alaska case, where the relevant events occurred in the United States, turns solely upon United States regulatory action. Zyprexa and other prescription drugs sold in Alaska are regulated by the FDA under United States law, not by foreign regulatory agencies. 21 U.S.C. § 335(d). Only evidence of FDA approval and Lilly's compliance with FDA standards are probative regarding liability here.[2] (*See, e.g., Tri-Bio Labs, Inc. v. United States*, 836 F.2d 135, 142 (3rd Cir. (Pa.), 1987)("in evaluating scientific evidence in the drug field, the FDA possesses an expertise entitled to respectful consideration by this court.").

[2] Under the Food, Drug & Cosmetic Act, 21 U.S.C. §§ 321, *et seq.*, the FDA can approve a drug for marketing only after it has determined that the drug is safe and effective as labeled under standards set forth in the Act. *Id.* § 35(d)(1982). The FDA, therefore, approves not only the marketing of the drug within the United States, but also the language of all warnings and product literature which accompany the drug as marketed in the United States. The United States Supreme Court has noted that "[the determination of] whether a drug is generally recognized as safe and effective…necessarily implicates complex chemical and pharmacological considerations." *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653-54, 37 L.Ed.2d 235, 243 (1973). Because such considerations are "not within the conventional experience of judges," *id.* at 654, the responsibility and authority to evaluate a drug's safety and effectiveness lies with the FDA, which has the requisite technical expertise. *See, e.g., Premo Pharmaceutical Labs, Inc. v. United States*, 629 F.2d 795 (2nd Cir (N.Y.), 1980). Judgments made by the FDA regarding the safety and efficacy of drugs merit deference from courts. *Schering Corp. v. Food and Drug Administration*, 51 F.3d 390, 399 (3rd Cir (N.J.), 1995).

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Furthermore, because of the FDA's expertise in evaluating safety and efficacy of medicines, United States courts generally defer to FDA decisions with respect to regulation of medicines.[3] The actions of foreign regulatory bodies are not entitled to this same presumption of expertise or reliability in United States courts, and United States courts do not defer to such foreign regulatory decisions. *See Garmon*, 1993 WL 190923 at *3 (foreign rules and standards not having the force and effect of law not admissible in U.S. products case).

B. Evidence Of Foreign Regulatory Action Would Be Unfairly Prejudicial to Lilly, Confuse the Issues, Mislead The Jury, And Waste Time.

Evidence of foreign regulatory action regarding Zyprexa also is prejudicial and misleading. "Evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Alaska R. Evid. 403. The State will offer evidence of foreign regulatory action to "springboard" its argument that Lilly's United States label was deficient. Due to the differences in regulatory procedure in foreign countries, and that foreign regulators are influenced by factors irrelevant to the safety or efficacy of Zyprexa, this inference would be prejudicial.

To illustrate for the jury that to obtain marketing approval for Zyprexa in foreign countries, Lilly must comply with the regulations for labeling and marketing in those foreign countries, and that such regulations can differ and can be inconsistent, the jury would need to be presented with the applicable rules and regulations of each foreign country involved. This foray into irrelevant foreign intricacies and cultural differences would be off-base, confusing, and misleading. *See Deviner v. Electrolux Motor, AB*, 844 F.2d 769, 773 (11th Cir. (Ala), 1988) (excluding evidence concerning foreign law in products liability case to avoid jury confusion); *In Re Baycol Products Litigation*, 495 F.Supp.2d 977 (D. Minn., 2007)(court

[3] *See, e.g., Ciba Corp. v. Weinberger*, 412 U.S. 640, 37 L.Ed.2d 230 (1973); *Rutherford v. United States*, 806 F.2d 1455 (10th Cir. 1986); *Biotics Research Corp., v. Heckler*, 710 F.2d 1375 (9th Cir. (Nev.), 1983).

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found that allowing evidence of foreign regulatory evidence in case governed by domestic law would likely cause jury confusion); *Garmon*, 1993 WL 190923 at *2-3 (evidence of foreign laws, regulations and statistics properly excluded as confusing and prejudicial).

Lastly, evidence may be excluded if its probative value is outweighed by "considerations of undue delay, [or] waste of time." Alaska R. Evid. 403. In order to decide which, if any, foreign regulatory actions are potentially relevant, the Court inevitably would be bogged down with a series of mini-trials to determine the basis of each foreign regulatory action and the foreign legal and regulatory standards and policies that were applied (*e.g.*, foreign country's regulatory policy and procedure, as well as the political, social, and economic climate motivating the regulatory policy).

C. Inquiry Into Motives of Foreign Regulatory Agencies Is Not Permitted in United States Courts.

If the Court allows the State to offer examples of foreign regulatory action – by foreign counties with distinct regulatory standards, requirements, and goals – to underscore its allegations that Lilly's United States label was inadequate, it will invite a trial within a trial, requiring Lilly to put that foreign action into context. Lilly would need to introduce evidence regarding the basis, motivation, and validity of the foreign regulatory action. Inquiry into the motivation of foreign countries is impermissible.[4]

This inquiry, however, would be an essential prerequisite to a determination of why foreign regulators imposed certain requirements or acted in particular ways regarding Zyprexa outside the United States. No American court can "sit in judgment" of the governmental acts of other nations, nor can it determine the validity of a foreign country's

[4] The United States Supreme Court has prohibited questioning the motivation behind a foreign nation's act in order to adjudicate claims in this country. United States courts cannot inquire into or cast judgment on governmental decisions of foreign countries because such activity could adversely affect diplomatic relations.

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action. The actions and motives of a foreign government are "not subject to reexamination and modification by the courts of this country."[5]

III. CONCLUSION

Lilly requests this Court enter an order excluding evidence of foreign regulatory action relating to Zyprexa.

DATED this 4th day of February, 2008.

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[5] *See, e.g., Oetjen v. Central Leather Co.*, 246 U.S. 297, 303, 62 L.Ed. 726, 732 (1918)("[t]o permit validity of the acts of one sovereign state to be reexamined and perhaps condemned by the courts of another would very certainly 'imperil the amicable relations between governments and vex the peace of nations.'").

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 EVIDENCE RELATING TO OTHER LITIGATION INVOLVING THE DEFENDANT

Defendant Eli Lilly and Company ("Lilly") requests that the Court bar the State from introducing at trial any evidence of other Lilly-related litigation, investigations, regulatory action or settlements.

I. INTRODUCTION

The State alleges that Lilly unlawfully marketed its prescription medication Zyprexa®, resulting in unwarranted prescriptions paid for by the State of Alaska. Lilly anticipates that the State will seek to introduce evidence regarding other litigation and government investigations involving Zyprexa and other Lilly products, along with evidence of settlements entered into by Lilly. Such irrelevant evidence will serve only to disparage Lilly and confuse and mislead the jury and should be excluded.

II. ARGUMENT

A. Evidence Regarding Settlements Entered Into by Lilly is Inadmissible Under Rule 408.

Although Lilly has settled lawsuits with litigants alleging Zyprexa-related injuries, Alaska Rules of Evidence 408 prohibits any reference to these settlements at trial. Rule 408 "bars the introduction of evidence of offering a valuable consideration in compromising a

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disputed claim to prove liability for or invalidity of the claims." *Lopez v. Administrator, Public Employees Retirement System*, 20 P.3d 568, 575 (Alaska 2001). This rule facilitates settlements of disputes and reflects "a desire for peace rather than any concession of weakness of position." *Id.* at 576. Courts in other jurisdictions have echoed this sentiment, noting that Federal Rule of Evidence 408 (which is similar to the Alaska Rule) bars the admission of settlement agreements offered against a litigant involved in the settlement. *Kennon v. Slipstreamer, Inc.*, 794 F.2d 1067, 1069 (5th Cr. 1986). Even if a settlement is offered for a purpose other than imputing liability, such as bias, courts still reject the introduction of the settlement under Rule 403. *Plymack v. Copley Pharm., Inc.*, 1997 U.S. Dist LEXIS 3759, at *10 (S.D.N.Y. Mar. 17, 1997).

In this case, allowing plaintiff to offer evidence of settlements would violate public policy favoring compromise and negotiation and would encourage the jury to lean towards an assumption of culpability. Moreover, the settlements the State seeks to introduce occurred in personal injury litigation, not lawsuits brought by a payor – public or private. Lilly anticipates that the State will offer these settlements to prove liability despite the fact those settlements merely show that another person raised a claim against Lilly.

B. Evidence Regarding Other Zyprexa Litigation is Irrelevant and Intended to Mislead the Jury.

Evidence of other Zyprexa personal injury litigation involves irrelevant allegations. Rules 402 and 403 bar admission of such evidence. Alaska Rule of Evidence 402 provides that "evidence which is not relevant is not admissible." Relevant evidence is evidence that tends to make the existence of a fact in dispute more or less probable. Evidence of other litigation is admissible under Rule 402 only if there is substantial similarity between the prior acts and the claim being litigated. *See Walden v. Dept. of Transportation*, 27 P.3d 297, 303 (Alaska 2001) (holding that in the context of traffic accidents, substantially similar accidents are those that occurred at the same place and under similar road conditions); *Bierria v.*

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Dickinson Mfg. Co., Ltd., 36 P.3d 654 (Alaska 2001) (holding that evidence of other boat fires was inadmissible unless plaintiff proved that all fires resulted from the same cause); *Johnson v. State*, 636 P.2d 47, 57 (Alaska 1981) (excluding testimony of three witnesses whose similar accidents at railroad crossing occurred after plaintiffs' accident). Thus, more than circumstantial similarity is required for relevance.

This case is not "substantially similar" to other Zyprexa personal injury litigation for two reasons. First, other Zyprexa litigation focuses on personal injury claims of individual patients treated by physicians who were allegedly exposed to and individually influenced by product marketing. This case does not present the claims of any individual, nor does it provide details of any individual physician's experiences with Lilly's marketing. Instead, the State's case focuses on Lilly's generalized marketing practices. Second, each Zyprexa personal injury case involves a unique set of facts which confound the substantial similarity requirement. Each case involves alleged injuries to different patients with unique medical histories and risk factors. Each case involves a different physician who prescribed Zyprexa, and who purportedly dealt with different sales representatives. Other Zyprexa litigation also involves claims that are temporally and geographically diverse, meaning that each plaintiff and physician was exposed to different marketing at different points in time. The only similarity among other Zyprexa personal injury cases is Lilly, and that one link is far from "substantial similarity." As the *Walden* Court noted, vital variables "can make accidents that look substantially similar on paper very different in reality." *Walden*, 27 P.3d at 303.

Moreover, as the Second Circuit has noted, "admitting evidence about previous cases inevitably results in trying those cases . . . before the jury and the merits of the . . . other cases would become inextricably intertwined with the case at bar." *Arlio v. Lively*, 474 F.3d 46, 53

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(2d Cir. 2007) (quoting *Kinan v. City of Brockton*, 876 F.2d 1029, 1034 (1st Cir. 1989)).[1] Allowing the State to introduce evidence of Zyprexa personal injury litigation would put Lilly in a perilous position, forcing it to relitigate each of those other cases in this Court in an effort to educate the jury, or letting the unchallenged references poison the minds of jurors. Allowing the presentation of such dissimilar evidence would run afoul of Rule 402 and inject reversible error into the case.

Evidence of other Zyprexa litigation should be excluded under Rule 403 as well. Rule 403 states that relevant "evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." If any evidence of other Zyprexa litigation were admitted, the result would be jury confusion on the issue of immediate cause which would dilute the jury's focus, cause undue delay and waste judicial resources. *See Weinstein's Federal Evidence* § 404.05[3][a]. The prejudicial effect on Lilly outweighs any marginal probative gain from the presentation of this evidence.

C. Evidence of Prior Litigation Involving Other Lilly Products is Similarly Irrelevant.

Lilly has been involved in a variety of civil litigation, some of which has received considerable media attention. Use of this prior litigation to impugn Lilly's corporate character will lead the jury to assume that Lilly is a "bad corporate citizen" whose past conduct is an indicator of liability in this case. Rules 402, 403 and 404 bar the use of such evidence.

As noted above, evidence of other litigation is admissible only if it is substantially similar to the current case. Other litigation involving Lilly products is dissimilar because

[1] *See also General Motors Corp. v. Moseley*, 447 S.E.2d 302, 306 (Ga. App. 1994) (*abrogated by Webster v. Boyett*, 269 Ga. 191(1998) (holding that plaintiff's reference to 120 other lawsuits, without a showing of similarity, amounted to reversible error)).

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such litigation involves different medications that treat different conditions. These medications were prescribed by different physicians, all of whom prescribed medications to plaintiffs of varied and diverse backgrounds. Moreover, the majority of other Lilly litigation is comprised of individual lawsuits regarding the alleged effect of medications on individuals, or focusing on Lilly's marketing to individual physicians. The current litigation instead focuses on more generalized conduct and issues. In short, litigation relating to other Lilly products involves events as varied and individual as the claimants themselves, and before such evidence could be admitted plaintiff would be required to establish substantial similarity to the facts of *this* case.

In addition, evidence of other litigation is inadmissible because it has no relevance to any cause of action in this case. Both the Unfair Trade Practices and Consumer Protection Act, and the Strict Liability – Failure to Warn claims focus on Lilly's conduct related to Zyprexa sales in Alaska. Neither cause of action contemplates an examination of conduct outside Alaska, and neither Alaska's case law nor statutes can create liability for conduct occurring outside Alaska. Lilly's conduct relating to other medications, sold at different times in different states, has no relevance to either cause of action.

Rule 403 also bars admission of any other Lilly-related litigation. Any limited probative value from the inclusion of other litigation evidence is outweighed by the very real danger of unfair prejudice, confusion of the issues and undue consumption of time. *See Harned v. Dura Corp.*, 665 P.2d 5, 8 (Alaska 1983)(noting that evidence of prior accidents is relevant in personal injury actions provided the accident took place in similar circumstances and their probative value is not outweighed by their prejudicial effect).[2]

[2] *See also American Home Assurance Co., v. Merck & Co., Inc.* 462 F.Supp.2d 435, 446 (S.D.N.Y. 2006). While ruling on defendant's motion to exclude any reference to the Vioxx litigation the Court noted that "the only possible purpose for offering such evidence would be to generally prejudice the fact finder against Merck through insinuations that it is a careless corporate citizen."

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Finally, Alaska Rule of Evidence 404(b)(1) provides a basis for the exclusion of other litigation and investigation evidence. The Rule states "evidence of other crimes, wrongs, or acts is not admissible if the sole purpose for offering the evidence is to prove the character of a person in order to show that the person acted in conformity therewith." The only common denominator between this case and other Lilly-related litigation is the presence of Lilly itself, and the only purpose for the evidence is to argue that if Lilly acted "wrongfully" in the past, then it likely did in this case as well. The State's desire to introduce evidence of prior litigation involving Lilly is nothing more than an effort to commit character assassination in front of the jury; prior litigation involving Lilly does not relate in any way to the facts of this case. *See generally Monger v. Cessna Aircraft Co.*, 812 F.2d 402, 406 (8th Cir. 1987)(holding that the trial court properly excluded a regulatory agency letter criticizing corporation's past failure to identify safety failures).

D. Evidence of Regulatory or Investigative Action of Lilly Products is Inadmissible Under Rules 402 and 403.

Any mention of government regulation or investigation of other Lilly products is irrelevant to this litigation. Investigations of Lilly products undertaken by government agencies are not substantially similar to the State of Alaska's allegations. Each investigation applies different laws and regulations and presents alleged injuries unique to the circumstances of each state. In addition, reference to any currently pending investigation of any Lilly product is prejudicial to Lilly. Allowing the jury to consider the unsubstantiated allegations of other jurisdictions invites bias against Lilly and turns the State's case into an investigation of all pending cases. Finally, mention of regulatory action involving other Lilly medications would only confuse the issues and mislead the jury, resulting in prejudice to Lilly. *See In re Bendectin Litigation*, 857 F.2d 290, 321 (6th Cir. 1988) (holding that references to FDA review and Thalidomide were prejudicial in a non-Thalidomide case); *Yellow Bayou Plantation, Inc., v. Shell Chem. Inc.*, 491 F.2d 1239, 1243 (5th Cir. 1975)

(refusing to admit a list of lawsuits regarding defendant's behavior because all it indicated was that absent third parties made claims against Shell in the past).

III. CONCLUSION

For the reasons outlined above, evidence regarding other litigation, regulatory action, investigations or settlements involving any Lilly product is inadmissible. Such evidence is not relevant or substantially similar to the claims of this lawsuit, is intended solely to malign Lilly's corporate character, and will create jury confusion and bias if admitted. Accordingly, Lilly requests that the Court enter an order barring any reference to such evidence.

DATED this 4th 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 EVIDENCE RELATING TO THE STATE OF ALASKA'S ALLEGED DAMAGES OR ECONOMIC INJURY

COMES NOW Defendant Eli Lilly and Company ("Lilly") and hereby requests that this Court bar the State from introducing during Phase I of the trial evidence related to its alleged damages or economic injury. Such evidence is not relevant to the liability phase of this lawsuit and should be excluded.

I. ALASKA RULES OF EVIDENCE

Evidence relating to the State's alleged damages does not have "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." Alaska R. Evid. 401. Because Alaska's Rules of Evidence were modeled after the Federal Rules of Evidence, "the evidentiary decisions of federal courts . . . [are given] considerable persuasive weight." *Marron v. Stromstad*, 123 P.3d 992, 1004 (Alaska 2005).

II. EVIDENCE RELATING TO THE STATE'S ALLEGED DAMAGES OR ECONOMIC INJURY IS NOT RELEVANT AND IS UNDULY PREJUDICIAL.

This court has determined that liability and damages will be tried separately. Orders Re: Mot. for Bifurcation and for Six Month Extension of Deadlines at 1 (Nov. 27, 2007). The State insisted on this approach, explaining that "[t]he bifurcation proposed by the State

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would separate issues of liability from damages" and assured the Court that it could establish both its failure-to-warn and UTP claims with no reference to damages. State's Mem. in Supp. of Bifurcation at 3-4. As the State recognized, "[l]ogically, the existence of liability must be resolved before damages are considered. Moreover, the evidence pertinent to the two issues is often wholly unrelated." State's Mem. in Supp. of Bifurcation at 7. Because the State has been unable, to date, to provide sufficient evidence to support its alleged damage claims, any discussion of damages would be theoretical at this point. The State, therefore, should not be permitted to allude to or offer speculative evidence on the scope or nature of damages it may have sustained.

III. CONCLUSION

For the foregoing reasons, Lilly requests that the Court enter an order excluding all evidence relating to the State of Alaska's alleged damages or economic injury.

DATED this 4th 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

PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE TESTIMONY OR ARGUMENT REGARDING THE LACK OF RESTRICTIONS ON THE AVAILABILITY OF ZYPREXA OR LACK OF AN INJUNCTION AGAINST CERTAIN CONDUCT BY DEFENDANT

Plaintiff moves this Court for an order preventing defendant's counsel from making reference to in argument or eliciting testimony that the State should have placed restrictions on the use of Zyprexa, should have required prior approval of the drug before prescribing it to Medicaid patients or that the State should have sought an injunction against defendant for its conduct in this case. The basis for this motion is that any such argument or testimony is irrelevant to this action, lacks any probative value to issues in this action, and is unduly prejudicial.

Relevant evidence is 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

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probable than it would be without the evidence."[1] Irrelevant evidence is not admissible.[2] The Court may even exclude otherwise relevant evidence "if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."[3]

In a number of pleadings, defendant has raised the issue that Zyprexa is available without restriction in Alaska and has argued that the State could have taken action to potentially limit its availability. However, "open access" to Zyprexa in Alaska is in large part the fruit of defendant's own efforts at preventing any restrictions on the availability of Zyprexa through legislative and administrative lobbying efforts by recruiting Alaska physicians to write letters to legislators and by encouraging and supporting lobbying efforts by psychiatric patient support groups. Defendant should not be allowed to argue the State failed to act in a particular manner when defendant itself participated directly and indirectly in dissuading plaintiff from doing so.

More importantly, whether the State placed any restrictions on the availability of Zyprexa is irrelevant to the primary issues in the case, that is, whether defendant appropriately warned of Zyprexa's serious health risks, and whether defendant violated

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1 Alaska Rules of Evidence, Rule 401.

2 Alaska Rules of Evidence, Rule 402.

3 Alaska Rules of Evidence, Rule 403.

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the Alaska Unfair Trade Practices and Consumer Protection Act in its marketing and promotion of Zyprexa. That the State has not moved to restrict the availability of Zyprexa is not a legal defense to either cause of action. Allowing argument or testimony regarding the lack of such restrictions will result in unfair prejudice and confusion of the issues, and could potentially mislead the jury.

The Court should further prohibit defendant from arguing or eliciting testimony from any witness regarding the State's decision not to exercise its power under the Unfair Trade Practices and Consumer Protection Act (UTPCPA) to enjoin defendant from any of its conduct in the marketing and promotion of Zyprexa. That the State has chosen to exercise certain remedies over others in the enforcement of the UTPCPA is irrelevant to any issue in the case. The power to enjoin certain conduct would only be effective in stopping conduct that occurred after the injunction was issued, and would provide no remedy for conduct occurring before the issuance of the injunction. In this case, plaintiff filed suit in March 2006. While the State has now learned through discovery in this case that defendant's bad conduct has continued beyond that date, the bulk of the conduct subject to plaintiff's allegations occurred in the ten years between 1996 - 2006. Moreover, defendant has so far refused to produce some of the discovery sought by the State regarding Lilly's conduct after 2004, arguing that it is irrelevant, overly broad and unduly burdensome. Defendant should not be allowed to complain that the State has

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failed to seek a particular remedy, especially where defendant essentially claims all of its relevant conduct at issue occurred in the past where such a remedy would be ineffective.

For the foregoing reasons, the Court should exclude any argument or reference to the availability of Zyprexa without restrictions in Alaska or the State's decision not to seek an injunction against any of defendant's conduct that is the subject of this action.

Respectfully submitted this 14 day of February, 2008.

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Certificate of Service

I hereby certify that a true and correct copy of **Plaintiff's Motion in Limine to Exclude Testimony or Argument Regarding the Lack of Restrictions on the Availability of Zyprexa or Lack of an Injunction Against Certain Conduct by Defendant, and (proposed) Order** was served by messenger on:

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By Peggy S. Cyrus
Date 2/4/08

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A B C D E F G

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 MOTION IN LIMINE TO EXCLUDE TESTIMONY OR ARGUMENT REGARDING EFFICACY OR BENEFITS OF ZYPREXA FOR INDICATED USES

Plaintiff moves this Court for an order preventing defendant's counsel from making reference to in argument or eliciting testimony regarding the efficacy of Zyprexa for the treatment of its indicated uses, Schizophrenia and Bipolar I Disorder. The basis for this motion is that any such argument or testimony is irrelevant to this action, lacks any probative value to issues in this action, and is unduly prejudicial.

Relevant evidence is 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."[1] Irrelevant evidence is not admissible.[2]

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1 Alaska Rules of Evidence, Rule 401.

2 Alaska Rules of Evidence, Rule 402.

A B C D E F G

The Court may even exclude otherwise relevant evidence "if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."[3]

The key elements of a strict liability failure to warn claim are set forth in *Shanks v. Upjohn Co.*[4] Plaintiff must prove, first, that the product posed a risk of injury to one who used the product in a reasonably foreseeable manner and was marketed without adequate warnings of the risk; and, second, that this failure to warn of risks was the proximate cause of plaintiff's injuries.[5] Defendant may avoid liability if it proves that the risk was scientifically unknowable at the time the product was distributed to the plaintiff.[6] Nowhere in this formulation is the efficacy of the product a relevant issue. Neither is it relevant in any respect in a failure to warn case that the product's risks were outweighed by its potential benefits.[7] All that is relevant is defendant's knowledge of a risk and whether it adequately communicated that risk.

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3 Alaska Rules of Evidence, Rule 403.

4 835 P.2d 1189 (Alaska 1992).

5 *See id.* at 1199-1200.

6 *See id.* at 1200.

7 Whether Zyprexa's benefits outweigh its risks or *vice versa* would be relevant in the context of a strict liability design defect claim, but Plaintiff dismissed that claim recently.

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To establish a claim under the Alaska UTPCPA, a plaintiff needs to prove, first, that the defendant is engaged in trade or commerce and, second, that the defendant committed an unfair or deceptive act or practice in the conduct of trade or commerce.[8] Plaintiff's UTPCPA claims focus partly on defendant's failure to warn of Zyprexa's risks and its affirmative deceptive or unfair acts in communicating regarding those risks. Failure to disclose known risks in a product is a clear violation of the Act.[9] The issues and evidence are similar to the failure to warn claim and do not in any way implicate evidence regarding the benefits of Zyprexa in treating Schizophrenia and Bipolar I Disorder.

For the foregoing reasons, the Court should exclude any argument or reference to the efficacy or benefits of Zyprexa for the treatment of Schizophrenia or Bipolar I Disorder.

Respectfully submitted this 4 day of February, 2008.

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[8] *See* AS 45.50.471(a); *State v. O'Neill Investigations, Inc.*, 609 P.2d 520, 534 (Alaska 1980).

[9] *See* AS 45.50.471(b)(4), (6), (11), (12) and (48).

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I hereby certify that a true and correct copy of **Plaintiff's Motion in Limine to Exclude Testimony or Argument Regarding Efficacy or Benefits of Zyprexa for Indicated Uses and (proposed) order** was served by messenger on:

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Date 2/4/08

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A B C D E F G

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 MOTION IN LIMINE TO EXCLUDE TESTIMONY OR ARGUMENT REGARDING EFFICACY OR BENEFITS OF ZYPREXA FOR NON-INDICATED OR "OFF-LABEL" USES

Plaintiff moves this Court for an order preventing defendant's counsel from making reference to in argument or eliciting testimony regarding the efficacy of Zyprexa for the treatment of any non-indicated or "off-label" uses. The basis for this motion is that any such argument or testimony is irrelevant to this action, lacks any probative value to issues in this action, and is unduly prejudicial.

Relevant evidence is 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."[1] Irrelevant evidence is not admissible.[2]

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[1] Alaska Rules of Evidence, Rule 401.

The Court may even exclude otherwise relevant evidence "if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."[3]

The key elements of a strict liability failure to warn claim are set forth in *Shanks v. Upjohn Co.*[4] Plaintiff must prove, first, that the product posed a risk of injury to one who used the product in a reasonably foreseeable manner and was marketed without adequate warnings of the risk; and, second, that this failure to warn of risks was the proximate cause of plaintiff's injuries.[5] Defendant may avoid liability if it proves that the risk was scientifically unknowable at the time the product was distributed to the plaintiff.[6] Nowhere in this formulation is the efficacy of the product for a particular use a relevant issue. Neither is it relevant in any respect in a failure to warn case that the product's risks

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2 Alaska Rules of Evidence, Rule 402.

3 Alaska Rules of Evidence, Rule 403.

4 835 P.2d 1189 (Alaska 1992).

5 *See id.* at 1199-1200.

6 *See id.* at 1200.

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were outweighed by its potential benefits.[7] All that is relevant is defendant's knowledge of a risk and whether it adequately communicated that risk.

To establish a claim under the Alaska UTPCPA, a plaintiff needs to prove, first, that the defendant is engaged in trade or commerce and, second, that the defendant committed an unfair or deceptive act or practice in the conduct of trade or commerce.[8] Plaintiff's UTPCPA claims will focus not only on defendant's failure to warn of Zyprexa's risks and its affirmative deceptive or unfair acts in communicating regarding those risks, but also on the ways that Lilly aggressively promoted Zyprexa for unapproved, off-label uses, such as to treat depression and sleep disorders. Promoting a drug for a usage for which the drug has not been approved to be efficacious is in itself a UTPA violation.[9] Additionally, failure to disclose known risks in a product is a clear violation.[10]

Plaintiff need not and does not intend to offer argument or testimony regarding the efficacy of Zyprexa in the treatment of any diseases. However, as to the over-promotion

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[7] Whether Zyprexa's benefits outweigh its risks or *vice versa* would be relevant in the context of a strict liability design defect claim, but Plaintiff dismissed that claim recently.

[8] *See* AS 45.50.471(a); *State v. O'Neill Investigations, Inc.*, 609 P.2d 520, 534 (Alaska 1980).

[9] *See* AS 45.50.471(b)(4), (48); AS 17.20.110.

[10] *See* AS 45.50.471(b)(4), (6), (11), (12) and (48).

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facet of its UTPCPA claims, plaintiff will offer testimony and argument that Zyprexa was only approved by the FDA as indicated treatment for certain conditions.[11] A drug manufacturer may not actively promote its medications for any uses beyond its FDA approved indications. Such promotion is a violation of criminal law[12] and is also prohibited by Lilly's own Good Promotional Practices Guidelines.[13] Plaintiff will offer evidence at trial that defendant did in fact promote Zyprexa for the treatment of symptoms, conditions, and patient populations for which it had not received FDA approved indications. Thus, defendant's illegal conduct constituted an unfair or deceptive act or practice in the conduct of trade or commerce which renders it liable under the UTPCPA. The relevant inquiry is not whether the patient ultimately received some benefit from the off-label prescription, but whether defendant illegally promoted the drug for that use.

For the foregoing reasons, the Court should exclude any argument or reference to the efficacy or benefits of Zyprexa for the treatment of any non-indicated uses.

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[11] To receive an FDA indication, a drug manufacturer must provide sufficient evidence to the FDA of a drug's efficacy in treating the indication sought.

[12] *See* 21 U.S.C. §§ 331, 352.

[13] Exhibit A (Exhibit 8 to Deposition of David Thomas Noesges, January 11, 2008).

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Certificate of Service

I hereby certify that a true and correct copy of **Plaintiff's Motion in Limine Exclude Testimony or Argument Regarding Efficacy or Benefits of Zyprexa for Non-Indicated or "Off-Label" Uses and (proposed) Order** was served by messenger on:

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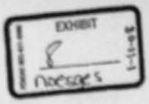

LillyUSA
SALES GOOD PROMOTIONAL PRACTICES
ELI LILLY AND COMPANY
UNSOLICITED QUESTIONS ON OFF-LABEL INFORMATION OR UNAPPROVED PRODUCTS
GPP 02-004

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.

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 MOTION IN LIMINE TO EXCLUDE TESTIMONY OR ARGUMENT REGARDING OTHER DRUGS MANUFACTURED BY DEFENDANT ELI LILLY AND COMPANY

Plaintiff moves this Court for an order preventing defendant's counsel from making reference to in argument or eliciting testimony regarding the uses or benefits of any drugs other than Zyprexa manufactured by defendant. The basis for this motion is that any such argument or testimony is irrelevant to this action, lacks any probative value to issues in this action, and is unduly prejudicial.

Relevant evidence is 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."[1] Irrelevant evidence is not admissible.[2]

---

[1] Alaska Rules of Evidence, Rule 401.

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The Court may even exclude otherwise relevant evidence "if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."[3]

The defendant manufactures a number of prescription drugs indicated for the treatment of a variety of medical conditions. The only product at issue in this case is Zyprexa. During the document discovery in both this case and in the Zyprexa Multidistrict Litigation (MDL), defendant refused to produce documents referring to any of its other drugs, and redacted any such references in the documents it did produce. Plaintiff likewise seeks an order of this Court prohibiting any argument or evidence in any form regarding the benefits or uses of any of defendant's other prescription drugs in this case. Such evidence is irrelevant to the issues to be presented by the parties and could result in undue prejudice or confusion. The fact that defendant produces a number of other prescription drugs that are not the subject of this litigation does not have any bearing on the defendant's conduct with respect to Zyprexa.

For the foregoing reasons, the Court should exclude any argument or reference to other prescription drugs manufactured by defendant.

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[2] Alaska Rules of Evidence, Rule 402.

[3] Alaska Rules of Evidence, Rule 403.

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Respectfully submitted this 4 day of February, 2008.

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Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Motion to Exclude Testimony or Argument Regarding other Drugs Manufactured by Lilly and (proposed) Order** was served by messenger on:

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By _____
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A B C D E F G

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 REFERENCES TO RECENT REGULATORY COMMUNICATIONS AND DEVELOPMENTS

Defendant Eli Lilly and Company ("Lilly") requests that the Court bar the State of Alaska from introducing into evidence at trial (i) communications to or from the United States Food and Drug Administration ("FDA") or (ii) other regulatory communications or developments concerning Zyprexa® labeling, occurring after March 1, 2004.

I. INTRODUCTION

In the course of this litigation, Lilly has provided to the State information related to communications between Lilly and the FDA during 2007.[1] The items produced to the State, upon this Court's Order, included a letter sent to Lilly by the FDA on March 28, 2007, following Lilly's September 2006 supplemental new drug application ("Supplemental

[1] Lilly objected to the State's requests because, *inter alia*, they sought communications between Lilly and the FDA, and information about activities by Lilly taken in response to those communications, that occurred after the date when the State has identified alleged misconduct by Lilly, and concerned a medication that is not the subject of this litigation. *See* Lilly's Brief in Opposition to Plaintiff's Motion to Compel, filed on August 29, 2007.

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NDA") seeking FDA approval for the use of Symbyax®[2] for treatment resistant depression ("TRD").[3] The FDA letter to Lilly asked for more information from Lilly regarding data submitted in support of the Supplemental NDA.[4] The letter stated that the FDA "will work with you to define what studies to pool, and what data to provide to us and in what format."[5] Lilly also produced the documents it had submitted to the FDA in response to the March 28 letter. Such ongoing dialogue is commonplace in the FDA's regulation of prescription drugs, whether for Symbyax, Zyprexa, or any other medication.

Also in 2007, as part of Lilly's and the FDA's ongoing pharmacovigilance, Lilly revised Zyprexa's labeling to include new warnings for weight gain-related issues, and it updated information in the warnings for hyperglycemia and diabetes-related issues.[6]

Lilly anticipates that the State will attempt to introduce some or all of this evidence in ostensible support of its allegation that Zyprexa's warnings were inadequate at the time of the prescriptions in question. The State has already designated deposition testimony from Robin Pitts Wojcieszek, a regulatory scientist with Lilly, related to these issues. This evidence, concerning communications and developments occurring years after the relevant time period established by the State itself, (i) is not relevant to any of the claims in this lawsuit, and is therefore potentially far more prejudicial than probative; and (ii) falls outside the four corners

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[2] Symbyax is a Lilly product not involved in this lawsuit. It combines olanzapine (the active ingredient in Zyprexa) and fluoxetine, and previously was approved only for treatment of bipolar depression. *See* Symbyax Prescribing Information, relevant portions of which are attached as Exhibit A.

[3] *See* FDA Letter (Exh. A to Plaintiff's Second Motion to Compel) at 1.

[4] *Id.* at 2.

[5] *Id.*

[6] *See* October 5, 2007 Dear Health Care Professional letter, describing changes to Zyprexa's labeling, attached as Exhibit B.

of the State's expert reports. Moreover, the Court should bar any evidence of a label change occurring after the prescriptions at issue as a subsequent remedial measure.

II. ARGUMENT

A. By the State's Own Admissions, Regulatory Communications and/or Occurrences After March 1, 2004, Are Not Relevant to Any of the Claims in This Lawsuit.

The State's Complaint, filed in February 2006, claims that Lilly failed to warn prescribers about the side effects of Zyprexa. Later, the State volunteered that the relevant time period for any alleged failure to warn ended with the September 2003 label change (which provided, in the State's words, "adequate warnings"[7]), when physicians became aware of the alleged misrepresentations in the earlier labeling.[8] The State's corporate designee, David Campana, also acknowledged in his deposition that the State was aware of "an issue of Zyprexa and diabetes" by the fall of 2004, and took steps to further investigate the alleged issue at that time. Following that investigation, the State did nothing -- such as communicating the alleged risk to Alaska physicians,[9] or placing restrictions on the reimbursement of Zyprexa[10] -- other than to file this lawsuit.

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[7] *See, e.g.*, Pl's Memo. Describing Its Claims and Proofs at 15 ("[O]nce adequate warnings were given in the United States regarding Zyprexa's risks, physicians' prescribing practices changed and the number of prescriptions went down"); 16 ("[W]hen adequate warnings were given, the number of prescriptions decreased"); 19 ("Lilly did not provide these warnings until forced to do so by the FDA"); 20 ("The State will show the lack of adequate warning through expert testimony and by demonstrating the 75 percent drop in new prescriptions when proper warnings were given in Japan, as well as the drop-off in prescriptions in the United States after warnings were provided").

[8] Pl's Memo Describing Its Claims And Proofs at 27 ("[W]hen Lilly began to issue adequate warnings, prescriptions decreased, demonstrating that physicians as a whole relied upon the misrepresentations, and altered their prescribing practices once those misrepresentations were revealed").

[9] *See* Plaintiff's First Amended Responses to Defendant's First Set of Interrogatories – Response to Interrogatory No. 26 (relevant portions attached as Exhibit C). *See also, e.g.*,

(continued . . .)

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Once the State admits its awareness of the alleged defects, activity after such time is irrelevant under the Alaska Rules of Evidence. Rule 401 of the Alaska Rules of Evidence defines "relevant evidence" as "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."[11] Rule 402 provides, in pertinent part, "Evidence which is not relevant is not admissible."[12] And Rule 403 provides, "Although relevant, evidence may be excluded if its probative value is outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."[13] Given the acknowledgment by the State that any alleged inadequacy of Zyprexa's warnings had been both illuminated and remedied by September 2003, coupled with the testimony that, by the Fall of 2004 at the latest, the State was aware of the alleged risk of which it claimed inadequate warning, evidence of later regulatory communications and developments has no probative value with respect to these issues. At worst, it threatens to prejudice the jury on

(. . . continued)
Transcript of Videotaped Deposition of Lucy Ljubicich Curtiss, M.D., dated December 14, 2007, at p. 27, 11-14 (attached as Exhibit D) (no memory of receiving a letter from the State concerning the use of antipsychotics); Transcript of Videotaped Deposition of Duane Hopson, M.D., dated December 11, 2007, at p.76, ln. 24 - p.77, ln. 2 (attached as Exhibit E) (never received letter from Drug Utilization Committee of State of Alaska concerning use of Zyprexa).

[10] *See* Transcript of September 19, 2007 Videotaped Deposition of State of Alaska 30(b)(6) Designee David Campana, relevant portions of which are attached as Exhibit F, at 260-69 (testifying that, in fall 2004, or perhaps earlier, he had gathered information he interpreted to be communicating that Zyprexa caused diabetes, yet never required prior authorization for Medicaid reimbursement of Zyprexa prescriptions, implemented a "step-edit" procedure, or created a PDL for antipsychotics.

[11] Alaska R. Evid. 401.

[12] Alaska R. Evid. 402.

[13] Alaska R. Evid. 403.

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issues which are already admitted on the record. Rule 403 demands that it be excluded from evidence at trial.

B. The State's Experts Are Precluded From Testifying About Post-2004 Regulatory Communications or Developments.

In pharmaceutical product liability litigation, evidence of the alleged inadequacy of a warning reaches the jury only through the testimony of a properly qualified expert witness.[14] The State's expert reports, including reports of its ostensible "warnings experts," pre-dated the March 2007 FDA letter and the October 2007 Zyprexa label change, and the State has not supplemented them, despite the Court's invitation to do so.

During the Status Conference of October 24, 2007, this Court permitted the parties to seek leave to file supplemental expert reports if such supplementation should become necessary.[15] In addition, this Court provided a period of three weeks for the parties to file rebuttal reports in response to new expert testimony.[16] In its Notice of Filing its experts' reports, the State recognized the need to supplement its experts' reports if it wanted its experts to address these recent developments.[17] To date, however, the State has not filed one supplemental expert report on any issue. Because "[t]he orderly conduct of litigation

[14] *See, e.g., Brown v. SmithKline Beecham Corp.*, 2008 WL 205410, *5 (N.D.Ill. 2008); *Beale v. Biomet, Inc.* 492 F. Supp. 2d 1360, 1369 (S.D. Fla. 2007); *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 36 (D.D.C. 2003); *Willard v. Park Industries*, 69 F. Supp. 2d 268, 272 (D.N.H. 1999); *Burton v. Danek Medical, Inc.*, 1999 WL 118020, *8 (E.D. Pa. 1999).

[15] *See* Transcript of Status Conference of October 24, 2007, relevant portions of which are attached as Exhibit G, at 35.

[16] *Id.* at 50.

[17] *See* State of Alaska's Notice of Expert Disclosures, dated November 13, 2007, at 2 ("It is anticipated that the State of Alaska will supplement these reports after it has obtained discovery concerning the defendant's October 2007 label change for Zyprexa. Accordingly, as permitted by the Court's October 24, 2007 oral ruling, the State of Alaska reserves the right to supplement its expert's opinions about the inadequacy of prior labeling and proof of the connection between Zyprexa and weight gain, hyperglycemia, and hyperlipidemia.").

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demands that expert opinions reach closure,"[18] the State's experts must now rest on their reports as they have been produced. Trial is now four weeks away; time is up.

The expert reports set the boundaries of each expert's testimony at trial.[19] Because none of the State's experts has supplemented his report to include any mention of the March 2007 FDA letter, the 2007 Zyprexa label change, or any regulatory communications or developments occurring after 2004, the State must be precluded from introducing or referring to any such evidence at trial.

C. Evidence of Changes to Zyprexa's Label After the Filing of the State's Complaint Would Be Introduced by the State as a Subsequent Remedial Measure, and Such Evidence Is Inadmissible.

The State's February 28, 2006 Complaint seeks damages related to all Zyprexa prescriptions written before then. It includes claims sounding in negligence and strict liability based in part on allegedly inadequate hyperglycemia and diabetes warnings contained in Zyprexa's FDA-approved label. In October 2007, more than 18 months after the Complaint was filed, Lilly modified the warnings in Zyprexa's label.[20] Any attempt by the State to introduce evidence of post-Complaint label changes would violate the ban on evidence of a "subsequent remedial measure" found in Rule 407 of the Alaska Rules of Evidence.

Rule 407, which is substantively identical to the analogous federal rule, provides, in pertinent part: "When, after an event, measures are taken which, if taken previously, would have made the event less likely to occur, evidence of the subsequent measures is not

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[18] *Miller v. Pfizer, Inc.*, 356 F.3d 1326, 1334 (10th Cir. 2004).

[19] *See, e.g., Medtronic Inc. v. Guidant Corp.* 2004 WL 5501181, *1 (D. Del. 2004); *Klaczak v. Consolidated Medical Transport Inc.* 2005 WL 1564981, *11 (N.D.Ill. 2005).

[20] *See* Lilly's October 5, 2007 "Dear Health Care Professional" letter, attached as Exhibit B.

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admissible to prove negligence or other culpable conduct."[21] Such evidence is excluded to "encourage defendants to take safety precautions after accidents."[22] The rule applies with particular force where the "subsequent remedial measures" consist of revised prescription drug warnings. *See, e.g., Appleby v. Glaxo Wellcome, Inc.*, 2005 WL 3440440 *6 n.7 (D.N.J. December 13, 2005) (evidence of revised warnings inadmissible as subsequent remedial measures); *Stahl v. Novartis Pharmaceuticals Corp.* 283 F.3d 254, 271 (5th Cir. 2002) (same).

While the language of Rule 407 bans evidence of subsequent remedial measures related to Zyprexa from the State's negligence proof, several courts have considered, in the context of the analogous federal rule, whether "other culpable conduct" includes strict liability. Nearly all have concluded that the public policy interests underlying Rule 407 demand the exclusion of evidence of subsequent remedial measures in strict liability cases as well.[23] Accordingly, under Rule 407, the State should not be permitted to introduce any evidence related to post-Complaint modifications of Zyprexa's labeling in support of either its negligent or strict liability failure-to-warn claims.

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[21] Alaska R. Evid. 407.

[22] *City of Bethel v. Peters*, 97 P.3d 822, 825 (Alaska 2004), *citing Robles v. Shoreside Petroleum, Inc.*, 29 P.3d 838, 845 (Alaska 2001).

[23] *Gauthier v. AMF, Inc.* 788 F.2d 634, 636 (9th Cir.1986), *citing Roy v. Star Chopper Co.*, 584 F.2d 1124, 1134 (1st Cir. 1978); *Cann v. Ford Motor Co.*, 658 F.2d 54, 59-60 (2d Cir.1981); *Josephs v. Harris Corp.*, 677 F.2d 985, 991 (3d Cir.1982); *Werner v. Upjohn Co.*, 628 F.2d 848, 854 (4th Cir.1980); *Grenada Steel Industries v. Alabama Oxygen Co.*, 695 F.2d 883, 886 (5th Cir.1983); *Bauman v. Volkswagenwerk Aktiengesellschaft*, 621 F.2d 230, 232 (6th Cir.1980); *Flaminio v. Honda Motor Co.*, 733 F.2d 463, 469 (7th Cir. 1984); *but see, e.g., Ault v. International Harvester Co.*, 528 P.2d 1148 (Cal. 1974).

III. CONCLUSION

For the reasons set forth above, Lilly requests that this Court enter an order precluding the State from introducing evidence at trial related in any way to (i) communications to or from the United States Food and Drug Administration ("FDA"); or (ii) other regulatory communications or developments concerning Zyprexa labeling, occurring after 2004.

DATED this 4th day of February, 2008.

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I certify that on February 4, 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 99501-5915

_____

A B C D E F G

PV 6230 AMP

SYMBYAX®

(olanzapine and fluoxetine HCl capsules)

WARNING

Suicidality and Antidepressant Drugs — Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of SYMBYAX or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. SYMBYAX is not approved for use in pediatric patients. (*See* WARNINGS, Clinical Worsening and Suicide Risk, PRECAUTIONS, Information for Patients, *and* PRECAUTIONS, Pediatric Use.)

Increased Mortality in Elderly Patients with Dementia-Related Psychosis — Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. SYMBYAX (olanzapine and fluoxetine HCl) is not approved for the treatment of patients with dementia-related psychosis (*see* WARNINGS).

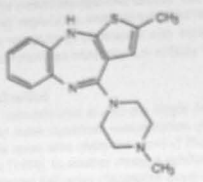
DESCRIPTION

SYMBYAX® (olanzapine and fluoxetine HCl capsules) combines 2 psychotropic agents, olanzapine (the active ingredient in Zyprexa®, and Zyprexa Zydis®) and fluoxetine hydrochloride (the active ingredient in Prozac®, Prozac Weekly™, and Sarafem®).

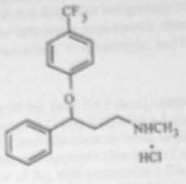
Olanzapine belongs to the thienobenzodiazepine class. The chemical designation is 2-methyl-4-(4-methyl-1-piperazinyl)-10*H*-thieno[2,3-*b*] [1,5]benzodiazepine. The molecular formula is $C_{17}H_{20}N_4S$, which corresponds to a molecular weight of 312.44.

Fluoxetine hydrochloride is a selective serotonin reuptake inhibitor (SSRI). The chemical designation is (±)-N-methyl-3-phenyl-3-[(α,α,α-trifluoro-*p*-tolyl)oxy]propylamine hydrochloride. The molecular formula is $C_{17}H_{18}F_3NO{\cdot}HCl$, which corresponds to a molecular weight of 345.79.

The chemical structures are:



olanzapine



fluoxetine hydrochloride

Olanzapine is a yellow crystalline solid, which is practically insoluble in water.

Fluoxetine hydrochloride is a white to off-white crystalline solid with a solubility of 14 mg/mL in water.

SYMBYAX capsules are available for oral administration in the following strength combinations:

	3 mg/25 mg	6 mg/25 mg	6 mg/50 mg	12 mg/25 mg	12 mg/50 mg
olanzapine equivalent	3	6	6	12	12
fluoxetine base equivalent	25	25	50	25	50

Each capsule also contains pregelatinized starch, gelatin, dimethicone, titanium dioxide, sodium lauryl sulfate, edible black ink, red iron oxide, yellow iron oxide, and/or black iron oxide.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Although the exact mechanism of SYMBYAX is unknown, it has been proposed that the activation of 3 monoaminergic neural systems (serotonin, norepinephrine, and dopamine) is responsible for its enhanced antidepressant effect. This is supported by animal studies in which the olanzapine/fluoxetine combination has been shown to produce synergistic increases in norepinephrine and dopamine release in the prefrontal cortex compared with either component alone, as well as increases in serotonin.

Olanzapine is a psychotropic agent with high affinity binding to the following receptors: serotonin $5HT_{2A/2C}$, $5HT_6$ (K_i=4, 11, and 5 nM, respectively), dopamine D_{1-4} (K_i=11 to 31 nM), histamine H_1 (K_i=7 nM), and adrenergic α_1 receptors (K_i=19 nM). Olanzapine is an antagonist with moderate affinity binding for serotonin $5HT_3$ (K_i=57 nM) and muscarinic M_{1-5} (K_i=73, 96, 132, 32, and 48 nM, respectively). Olanzapine binds weakly to $GABA_A$, BZD, and β-adrenergic receptors (K_i>10 μM). Fluoxetine is an inhibitor of the serotonin transporter and is a weak inhibitor of the norepinephrine and dopamine transporters.

Antagonism at receptors other than dopamine and $5HT_2$ may explain some of the other therapeutic and side effects of olanzapine. Olanzapine's antagonism of muscarinic M_{1-5} receptors

may explain its anticholinergic-like effects. The antagonism of histamine H_1 receptors by olanzapine may explain the somnolence observed with this drug. The antagonism of α_1-adrenergic receptors by olanzapine may explain the orthostatic hypotension observed with this drug. Fluoxetine has relatively low affinity for muscarinic, α_1-adrenergic, and histamine H_1 receptors.

Pharmacokinetics

Fluoxetine (administered as a 60-mg single dose or 60 mg daily for 8 days) caused a small increase in the mean maximum concentration of olanzapine (16%) following a 5-mg dose, an increase in the mean area under the curve (17%) and a small decrease in mean apparent clearance of olanzapine (16%). In another study, a similar decrease in apparent clearance of olanzapine of 14% was observed following olanzapine doses of 6 or 12 mg with concomitant fluoxetine doses of 25 mg or more. The decrease in clearance reflects an increase in bioavailability. The terminal half-life is not affected, and therefore the time to reach steady state should not be altered. The overall steady-state plasma concentrations of olanzapine and fluoxetine when given as the combination in the therapeutic dose ranges were comparable with those typically attained with each of the monotherapies. The small change in olanzapine clearance, observed in both studies, likely reflects the inhibition of a minor metabolic pathway for olanzapine via CYP2D6 by fluoxetine, a potent CYP2D6 inhibitor, and was not deemed clinically significant. Therefore, the pharmacokinetics of the individual components is expected to reasonably characterize the overall pharmacokinetics of the combination.

Absorption and Bioavailability

SYMBYAX — Following a single oral 12-mg/50-mg dose of SYMBYAX, peak plasma concentrations of olanzapine and fluoxetine occur at approximately 4 and 6 hours, respectively. The effect of food on the absorption and bioavailability of SYMBYAX has not been evaluated. The bioavailability of olanzapine given as Zyprexa, and the bioavailability of fluoxetine given as Prozac were not affected by food. It is unlikely that there would be a significant food effect on the bioavailability of SYMBYAX.

Olanzapine — Olanzapine is well absorbed and reaches peak concentration approximately 6 hours following an oral dose. Food does not affect the rate or extent of olanzapine absorption when olanzapine is given as Zyprexa. It is eliminated extensively by first pass metabolism, with approximately 40% of the dose metabolized before reaching the systemic circulation.

Fluoxetine — Following a single oral 40-mg dose, peak plasma concentrations of fluoxetine from 15 to 55 ng/mL are observed after 6 to 8 hours. Food does not appear to affect the systemic bioavailability of fluoxetine given as Prozac, although it may delay its absorption by 1 to 2 hours, which is probably not clinically significant.

Distribution

SYMBYAX — The in vitro binding to human plasma proteins of the olanzapine/fluoxetine combination is similar to the binding of the individual components.

Olanzapine — Olanzapine is extensively distributed throughout the body, with a volume of distribution of approximately 1000 L. It is 93% bound to plasma proteins over the concentration range of 7 to 1100 ng/mL, binding primarily to albumin and α_1-acid glycoprotein.

Fluoxetine — Over the concentration range from 200 to 1000 ng/mL, approximately 94.5% of fluoxetine is bound in vitro to human serum proteins, including albumin and α_1-glycoprotein. The interaction between fluoxetine and other highly protein-bound drugs has not been fully evaluated (*see* PRECAUTIONS, Drugs tightly bound to plasma proteins).

Metabolism and Elimination

SYMBYAX — SYMBYAX therapy yielded steady-state concentrations of norfluoxetine similar to those seen with fluoxetine in the therapeutic dose range.

Olanzapine — Olanzapine displays linear pharmacokinetics over the clinical dosing range. Its half-life ranges from 21 to 54 hours (5th to 95th percentile; mean of 30 hr), and apparent plasma clearance ranges from 12 to 47 L/hr (5th to 95th percentile; mean of 25 L/hr). Administration of olanzapine once daily leads to steady-state concentrations in about 1 week that are approximately twice the concentrations after single doses. Plasma concentrations, half-life, and clearance of olanzapine may vary between individuals on the basis of smoking status, gender, and age (*see* Special Populations).

Following a single oral dose of ^{14}C-labeled olanzapine, 7% of the dose of olanzapine was recovered in the urine as unchanged drug, indicating that olanzapine is highly metabolized. Approximately 57% and 30% of the dose was recovered in the urine and feces, respectively. In the plasma, olanzapine accounted for only 12% of the AUC for total radioactivity, indicating significant exposure to metabolites. After multiple dosing, the major circulating metabolites were the 10-*N*-glucuronide, present at steady state at 44% of the concentration of olanzapine, and 4′-*N*-desmethyl olanzapine, present at steady state at 31% of the concentration of olanzapine. Both metabolites lack pharmacological activity at the concentrations observed.

Direct glucuronidation and CYP450-mediated oxidation are the primary metabolic pathways for olanzapine. In vitro studies suggest that CYP1A2, CYP2D6, and the flavin-containing monooxygenase system are involved in olanzapine oxidation. CYP2D6-mediated oxidation appears to be a minor metabolic pathway in vivo, because the clearance of olanzapine is not reduced in subjects who are deficient in this enzyme.

Fluoxetine — Fluoxetine is a racemic mixture (50/50) of *R*-fluoxetine and *S*-fluoxetine enantiomers. In animal models, both enantiomers are specific and potent serotonin uptake inhibitors with essentially equivalent pharmacologic activity. The *S*-fluoxetine enantiomer is eliminated more slowly and is the predominant enantiomer present in plasma at steady state.

Fluoxetine is extensively metabolized in the liver to its only identified active metabolite, norfluoxetine, via the CYP2D6 pathway. A number of unidentified metabolites exist.

In animal models, *S*-norfluoxetine is a potent and selective inhibitor of serotonin uptake and has activity essentially equivalent to *R*- or *S*-fluoxetine. *R*-norfluoxetine is significantly less potent than the parent drug in the inhibition of serotonin uptake. The primary route of elimination appears to be hepatic metabolism to inactive metabolites excreted by the kidney.

Clinical Issues Related to Metabolism and Elimination — The complexity of the metabolism of fluoxetine has several consequences that may potentially affect the clinical use of SYMBYAX.

Variability in metabolism — A subset (about 7%) of the population has reduced activity of the drug metabolizing enzyme CYP2D6. Such individuals are referred to as "poor metabolizers" of drugs such as debrisoquin, dextromethorphan, and the tricyclic antidepressants (TCAs). In a study involving labeled and unlabeled enantiomers administered as a racemate, these individuals metabolized *S*-fluoxetine at a slower rate and thus achieved higher concentrations of *S*-fluoxetine. Consequently, concentrations of *S*-norfluoxetine at steady state were lower. The metabolism of *R*-fluoxetine in these poor metabolizers appears normal. When compared with normal metabolizers, the total sum at steady state of the plasma concentrations of the 4 enantiomers was not significantly greater among poor metabolizers. Thus, the net pharmacodynamic activities were essentially the same. Alternative nonsaturable pathways

(non-CYP2D6) also contribute to the metabolism of fluoxetine. This explains how fluoxetine achieves a steady-state concentration rather than increasing without limit.

Because the metabolism of fluoxetine, like that of a number of other compounds including TCAs and other selective serotonin antidepressants, involves the CYP2D6 system, concomitant therapy with drugs also metabolized by this enzyme system (such as the TCAs) may lead to drug interactions (see PRECAUTIONS, Drug Interactions).

Accumulation and slow elimination — The relatively slow elimination of fluoxetine (elimination half-life of 1 to 3 days after acute administration and 4 to 6 days after chronic administration) and its active metabolite, norfluoxetine (elimination half-life of 4 to 16 days after acute and chronic administration), leads to significant accumulation of these active species in chronic use and delayed attainment of steady state, even when a fixed dose is used. After 30 days of dosing at 40 mg/day, plasma concentrations of fluoxetine in the range of 91 to 302 ng/mL and norfluoxetine in the range of 72 to 258 ng/mL have been observed. Plasma concentrations of fluoxetine were higher than those predicted by single-dose studies, because the metabolism of fluoxetine is not proportional to dose. However, norfluoxetine appears to have linear pharmacokinetics. Its mean terminal half-life after a single dose was 8.6 days and after multiple dosing was 9.3 days. Steady-state levels after prolonged dosing are similar to levels seen at 4 to 5 weeks.

The long elimination half-lives of fluoxetine and norfluoxetine assure that, even when dosing is stopped, active drug substance will persist in the body for weeks (primarily depending on individual patient characteristics, previous dosing regimen, and length of previous therapy at discontinuation). This is of potential consequence when drug discontinuation is required or when drugs are prescribed that might interact with fluoxetine and norfluoxetine following the discontinuation of fluoxetine.

Special Populations

Geriatric — Based on the individual pharmacokinetic profiles of olanzapine and fluoxetine, the pharmacokinetics of SYMBYAX may be altered in geriatric patients. Caution should be used in dosing the elderly, especially if there are other factors that might additively influence drug metabolism and/or pharmacodynamic sensitivity.

In a study involving 24 healthy subjects, the mean elimination half-life of olanzapine was about 1.5 times greater in elderly subjects (>65 years of age) than in non-elderly subjects (≤65 years of age).

The disposition of single doses of fluoxetine in healthy elderly subjects (>65 years of age) did not differ significantly from that in younger normal subjects. However, given the long half-life and nonlinear disposition of the drug, a single-dose study is not adequate to rule out the possibility of altered pharmacokinetics in the elderly, particularly if they have systemic illness or are receiving multiple drugs for concomitant diseases. The effects of age upon the metabolism of fluoxetine have been investigated in 260 elderly but otherwise healthy depressed patients (≥60 years of age) who received 20 mg fluoxetine for 6 weeks. Combined fluoxetine plus norfluoxetine plasma concentrations were 209.3 ± 85.7 ng/mL at the end of 6 weeks. No unusual age-associated pattern of adverse events was observed in those elderly patients.

Renal Impairment — The pharmacokinetics of SYMBYAX has not been studied in patients with renal impairment. However, olanzapine and fluoxetine individual pharmacokinetics do not differ significantly in patients with renal impairment. SYMBYAX dosing adjustment based upon renal impairment is not routinely required.

Because olanzapine is highly metabolized before excretion and only 7% of the drug is excreted unchanged, renal dysfunction alone is unlikely to have a major impact on the pharmacokinetics of olanzapine. The pharmacokinetic characteristics of olanzapine were similar in patients with severe renal impairment and normal subjects, indicating that dosage adjustment based upon the degree of renal impairment is not required. In addition, olanzapine is not removed by dialysis. The effect of renal impairment on olanzapine metabolite elimination has not been studied.

In depressed patients on dialysis (N=12), fluoxetine administered as 20 mg once daily for 2 months produced steady-state fluoxetine and norfluoxetine plasma concentrations comparable with those seen in patients with normal renal function. While the possibility exists that renally excreted metabolites of fluoxetine may accumulate to higher levels in patients with severe renal dysfunction, use of a lower or less frequent dose is not routinely necessary in renally impaired patients.

Hepatic Impairment — Based on the individual pharmacokinetic profiles of olanzapine and fluoxetine, the pharmacokinetics of SYMBYAX may be altered in patients with hepatic impairment. The lowest starting dose should be considered for patients with hepatic impairment (*see* PRECAUTIONS, Use in Patients with Concomitant Illness *and* DOSAGE AND ADMINISTRATION, Special Populations).

Although the presence of hepatic impairment may be expected to reduce the clearance of olanzapine, a study of the effect of impaired liver function in subjects (N=6) with clinically significant cirrhosis (Childs-Pugh Classification A and B) revealed little effect on the pharmacokinetics of olanzapine.

As might be predicted from its primary site of metabolism, liver impairment can affect the elimination of fluoxetine. The elimination half-life of fluoxetine was prolonged in a study of cirrhotic patients, with a mean of 7.6 days compared with the range of 2 to 3 days seen in subjects without liver disease; norfluoxetine elimination was also delayed, with a mean duration of 12 days for cirrhotic patients compared with the range of 7 to 9 days in normal subjects.

Gender — Clearance of olanzapine is approximately 30% lower in women than in men. There were, however, no apparent differences between men and women in effectiveness or adverse effects. Dosage modifications based on gender should not be needed.

Smoking Status — Olanzapine clearance is about 40% higher in smokers than in nonsmokers, although dosage modifications are not routinely required.

Race — No SYMBYAX pharmacokinetic study was conducted to investigate the effects of race. In vivo studies have shown that exposures to olanzapine are similar among Japanese, Chinese and Caucasians, especially after normalization for body weight differences. Dosage modifications for race, therefore, are not routinely required.

Combined Effects — The combined effects of age, smoking, and gender could lead to substantial pharmacokinetic differences in populations. The clearance of olanzapine in young smoking males, for example, may be 3 times higher than that in elderly nonsmoking females. SYMBYAX dosing modification may be necessary in patients who exhibit a combination of factors that may result in slower metabolism of the olanzapine component (*see* DOSAGE AND ADMINISTRATION, Special Populations).

CLINICAL STUDIES

The efficacy of SYMBYAX for the treatment of depressive episodes associated with bipolar disorder was established in 2 identically designed, 8-week, randomized, double-blind, controlled studies of patients who met Diagnostic and Statistical Manual 4th edition (DSM-IV) criteria for Bipolar I Disorder, Depressed utilizing flexible dosing of SYMBYAX (6/25, 6/50, or

12/50 mg/day), olanzapine (5 to 20 mg/day), and placebo. These studies included patients (≥18 years of age) with or without psychotic symptoms and with or without a rapid cycling course.

The primary rating instrument used to assess depressive symptoms in these studies was the Montgomery–Asberg Depression Rating Scale (MADRS), a 10-item clinician-rated scale with total scores ranging from 0 to 60. The primary outcome measure of these studies was the change from baseline to endpoint in the MADRS total score. In both studies, SYMBYAX was statistically significantly superior to both olanzapine monotherapy and placebo in reduction of the MADRS total score. The results of the studies are summarized below (Table 1).

Table 1: MADRS Total Score
Mean Change from Baseline to Endpoint

	Treatment Group	Baseline Mean	Change to Endpoint Mean[1]
Study 1	SYMBYAX (N=40)	30	-16[a]
	Olanzapine (N=182)	32	-12
	Placebo (N=181)	31	-10
Study 2	SYMBYAX (N=42)	32	-18[a]
	Olanzapine (N=169)	33	-14
	Placebo (N=174)	31	-9

[1] Negative number denotes improvement from baseline.
[a] Statistically significant compared to both olanzapine and placebo.

INDICATIONS AND USAGE

SYMBYAX is indicated for the treatment of depressive episodes associated with bipolar disorder. The efficacy of SYMBYAX was established in 2 identically designed, 8-week, randomized, double-blind clinical studies.

Unlike with unipolar depression, there are no established guidelines for the length of time patients with bipolar disorder experiencing a major depressive episode should be treated with agents containing antidepressant drugs.

The effectiveness of SYMBYAX for maintaining antidepressant response in this patient population beyond 8 weeks has not been established in controlled clinical studies. Physicians who elect to use SYMBYAX for extended periods should periodically reevaluate the benefits and long-term risks of the drug for the individual patient.

CONTRAINDICATIONS

Hypersensitivity — SYMBYAX is contraindicated in patients with a known hypersensitivity to the product or any component of the product.

Monoamine Oxidase Inhibitors (MAOI) — There have been reports of serious, sometimes fatal reactions (including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, and mental status changes that include extreme agitation progressing to delirium and coma) in patients receiving fluoxetine in combination with an MAOI, and in patients who have recently discontinued fluoxetine and are then started on an MAOI. Some cases presented with features resembling neuroleptic malignant syndrome.

Lilly

www.lilly.com

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.

Phone 317 276 2000

October 5, 2007

Re: Safety data on Zyprexa® (olanzapine) and Symbyax® (olanzapine and fluoxetine HCl capsules) – Hyperglycemia, Weight Gain, and Hyperlipidemia

Dear Health Care Professional,

Eli Lilly and Company would like to inform you of important information being added to the Zyprexa® (olanzapine) and Symbyax® (olanzapine and fluoxetine HCl) labels. These labeling updates include new WARNINGS for Weight Gain and Hyperlipidemia and updated information in the WARNING for Hyperglycemia. These changes reflect results of recently completed pooled analyses of clinical trials in adults and adolescents as well as information from two published large studies of atypical antipsychotics, CATIE[1] and CAFE[2].

The new labeling language is detailed below. Monitoring of glucose, weight, and lipids is recommended during olanzapine and olanzapine/fluoxetine combination treatment. Guidelines published by the American Diabetes Association (ADA) following the consensus development conference[3] provide recommendations for the monitoring of blood glucose, weight, and lipid levels in those treated with atypical antipsychotics. Other highlights of the updated labeling include:

- Abnormal or borderline glucose levels at baseline are an important risk factor for further glucose increase.
- While relative risk estimates are inconsistent, the association between atypical antipsychotics and increases in glucose levels appears to fall on a continuum and olanzapine appears to have a greater association than some other atypical antipsychotics.
- Significantly greater mean increases in total cholesterol, LDL cholesterol, and triglycerides were observed in Zyprexa-treated patients compared with placebo-treated patients both with and without evidence of dyslipidemia at baseline.
- Labeling provides information on magnitude and distribution of weight gain over a two year period in Zyprexa-treated patients.
- Labeling also provides information on glucose, weight gain, and lipids from studies of Zyprexa for adolescent patients. Please note that Zyprexa and Symbyax are not approved currently for use in children and adolescents aged less than 18 years old.

Eli Lilly and Company remains committed to providing you with the most current product information available for the management of your patients and we will continue our ongoing research and analyses in these areas.

Please refer to the full prescribing information for Zyprexa and Symbyax included with this letter.

Should you have any questions or would like additional information regarding this important safety information, please contact the Lilly medical department at 1-800-Lilly-Rx or your Eli Lilly and Company sales representative.

The Medical Community can further our understanding of adverse events by reporting all cases to the Agency via the MedWatch program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, via the MedWatch website at www.fda.gov/medwatch or by mail:

MEDWATCH
Food and Drug Administration
5515 Security Lane
Suite 5100, HFD-001
Rockville, MD 20852

Sincerely,

Tim Garnett, M.D.
Vice President,
Global Patient Safety
Eli Lilly and Company

The following are the updated Hyperglycemia WARNINGS and the new Hyperlipidemia and Weight WARNINGS included in the Zyprexa label.

WARNINGS:

Zyprexa:
The following is updated language in the WARNINGS section of the Zyprexa package insert, and will be reflected in other materials.

Hyperglycemia — Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including olanzapine. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. While relative risk estimates are inconsistent, the association between atypical antipsychotics and increases in glucose levels appears to fall on a continuum and olanzapine appears to have a greater association than some other atypical antipsychotics.

Mean increases in blood glucose have been observed in patients treated (median exposure of 9.2 months) with olanzapine in phase I of the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE). The mean increase of serum glucose (fasting and nonfasting samples) from baseline to the average of the two highest serum concentrations was 15.0 mg/dl.

Olanzapine Monotherapy in Adults — In an analysis of 5 placebo-controlled adult olanzapine monotherapy studies with treatment duration up to 12 weeks, olanzapine was associated with a greater mean change in fasting glucose levels compared to placebo (2.76 mg/dL versus 0.17 mg/dL). The difference in mean changes between olanzapine and placebo was greater in patients with evidence of glucose dysregulation at baseline (patients diagnosed with diabetes mellitus or related adverse events, patients treated with antidiabetic agents, patients with a baseline random glucose level ≥200 mg/dL, and/or a baseline fasting glucose level ≥126 mg/dL). These patients had a statistically significantly greater mean increase in HbA_{1c} compared to placebo. In patients with baseline normal fasting glucose levels (<100 mg/dL), 2.2% (N= 543) of those treated with olanzapine were found to have high glucose levels (≥126 mg/dL) during olanzapine treatment versus 3.4% (N= 293) of those treated with placebo. In patients with baseline borderline fasting glucose levels (≥100 mg/dL and <126 mg/dL), 17.4% (N=178) of those treated with

olanzapine were found to have high glucose levels (>126 mg/dL) during olanzapine treatment versus 11.5% (N=96) of those treated with placebo.

Olanzapine Monotherapy in Adolescents — The safety and efficacy of olanzapine have not been established in patients under the age of 18 years. In an analysis of 3 placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with schizophrenia (6 weeks) or bipolar disorder (manic or mixed episodes) (3 weeks), olanzapine was associated with a statistically significantly greater mean change in fasting glucose levels compared to placebo (2.68 mg/dL versus -2.59 mg/dL). In patients with baseline normal fasting glucose levels (<100 mg/dL), zero out of 124 (0%) of those treated with olanzapine were found to have high glucose levels (≥126 mg/dL) during olanzapine treatment versus 1 out of 53 (1.9%) of those treated with placebo. In patients with baseline borderline fasting glucose levels (≥100 mg/dL and <126 mg/dL), 2 out of 14 (14.3%) of those treated with olanzapine were found to have high glucose levels (≥126 mg/dL) during olanzapine treatment versus zero out of 13 (0%) of those treated with placebo.

Physicians should consider the risks and benefits when prescribing olanzapine to patients with an established diagnosis of diabetes mellitus or having borderline increased blood glucose level (fasting 100–126 mg/dL, non-fasting 140–200 mg/dL). Patients taking olanzapine should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Hyperlipidemia — Undesirable alterations in lipids have been observed with olanzapine use. Clinical monitoring, including baseline and follow-up lipid evaluations in patients using olanzapine, is advised.

Significant, and sometimes very high (>500 mg/dL), elevations in triglyceride levels have been observed with olanzapine use. Modest mean increases in total cholesterol have also been seen with olanzapine use.

Olanzapine Monotherapy in Adults — In an analysis of 5 placebo-controlled olanzapine monotherapy studies with treatment duration up to 12 weeks, olanzapine-treated patients had statistically significant increases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 5.3 mg/dL, 3.0 mg/dL, and 20.8 mg/dL respectively compared to decreases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 6.1 mg/dL,

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C D E F G

4.3 mg/dL, and 10.7 mg/dL for placebo-treated patients. For fasting HDL cholesterol, no statistically significant differences were observed between olanzapine-treated patients and placebo-treated patients. Mean increases in fasting lipid values (total cholesterol, LDL cholesterol, and triglycerides) were greater in patients without evidence of lipid dysregulation at baseline, where lipid dysregulation was defined as patients diagnosed with dyslipidemia or related adverse events, patients treated with lipid lowering agents, or patients with high baseline lipid levels. Table 1 shows categorical changes in fasting lipid values.

Table 1. Changes in Fasting Lipids Values from Adult Placebo-Controlled Olanzapine Monotherapy Studies with Treatment Duration up to 12 Weeks

Laboratory Analyte	Category Change from Baseline	Treatment Arm	N	Patients
Fasting Triglycerides	Increase by 150 mg/dL	Olanzapine	745	39.6%*
		Placebo	402	26.1%
	Normal to High (<150 mg/dL to ≥200 mg/dL)	Olanzapine	457	9.4%*
		Placebo	251	4.4%
	Borderline to High (≥150 mg/dL and <200 mg/dL to ≥200 mg/dL)	Olanzapine	135	39.3%*
		Placebo	65	20.0%
Fasting Total Cholesterol	Increase by 240 mg/dL	Olanzapine	745	21.6%*
		Placebo	402	9.5%
	Normal to High (<200 mg/dL to ≥240 mg/dL)	Olanzapine	392	2.8%
		Placebo	207	2.4%
	Borderline to High (≥200 mg/dL and <240 mg/dL to ≥240 mg/dL)	Olanzapine	222	23.0%*
		Placebo	112	12.5%
Fasting LDL Cholesterol	Increase by 130 mg/dL	Olanzapine	536	23.7%*
		Placebo	304	14.1%
	Normal to High (<100 mg/dL to ≥160 mg/dL)	Olanzapine	154	0%
		Placebo	82	1.2%
	Borderline to High (≥100 mg/dL and <160 mg/dL to ≥160 mg/dL)	Olanzapine	302	10.6%
		Placebo	173	8.1%

* Statistically significant compared to placebo.

In phase 1 of the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE), over a median exposure of 9.2 months, the mean increase in triglycerides in patients taking olanzapine was 40.5 mg/dL. In phase 1 of CATIE, the mean increase in total cholesterol was 9.4 mg/dL.

Olanzapine Monotherapy in Adolescents — The safety and efficacy of olanzapine have not been established in patients under the age of 18 years. In an analysis of 3 placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with schizophrenia (6 weeks) or bipolar disorder (manic or mixed episodes) (3 weeks), for fasting HDL cholesterol, no statistically significant

differences were observed between olanzapine-treated patients and placebo-treated patients. Table 2 shows categorical changes in fasting lipid values in adolescent patients.

Table 2. Changes in Fasting Lipids Values from Adolescent Placebo-Controlled Olanzapine Monotherapy Studies

Laboratory Analyte	Category Change from Baseline	Treatment Arm	N	Patients
Fasting Triglycerides	Increase by ≥50 mg/dL	Olanzapine	138	37.0%*
		Placebo	66	15.2%
	Normal to High (<90 mg/dL to ≥130 mg/dL)	Olanzapine	67	26.9%
		Placebo	28	10.7%
	Borderline to High (≥90 mg/dL and ≥130 mg/dL to ≥130 mg/dL)	Olanzapine	37	59.5%
		Placebo	17	35.3%
Fasting Total Cholesterol	Increase by ≥40 mg/dL	Olanzapine	138	14.5%*
		Placebo	66	4.5%
	Normal to High (<170 mg/dL to ≥200 mg/dL)	Olanzapine	87	6.9%
		Placebo	43	2.3%
	Borderline to High (≥170 mg/dL and <200 mg/dL to ≥200 mg/dL)	Olanzapine	36	38.9%*
		Placebo	13	7.7%
Fasting LDL Cholesterol	Increase by ≥30 mg/dL	Olanzapine	137	17.5%
		Placebo	63	11.1%
	Normal to High (<110 mg/dL to ≥130 mg/dL)	Olanzapine	98	5.1%
		Placebo	44	4.5%
	Borderline to High (≥110 mg/dL and <130 mg/dL to ≥130 mg/dL)	Olanzapine	29	48.3%*
		Placebo	9	0%

* Statistically significant compared to placebo.

Weight Gain — Potential consequences of weight gain should be considered prior to starting olanzapine. Patients receiving olanzapine should receive regular monitoring of weight.

Olanzapine Monotherapy in Adults — In an analysis of 13 placebo-controlled olanzapine monotherapy studies, olanzapine-treated patients gained an average of 2.6 kg, which was statistically significantly different compared to an average 0.3 kg weight loss in placebo-treated patients with a median exposure of 6 weeks; 22.2% of olanzapine-treated patients gained at least 7% of their baseline weight, which was statistically significantly different compared to 3% of placebo-treated patients, with a median exposure of 8 weeks; 4.2% of olanzapine-treated patients gained at least 15% of their baseline weight, which was statistically significantly different compared to 0.3% of placebo-treated patients, with a median exposure of 12 weeks. Clinically significant weight gain was observed across all baseline Body Mass

Index (BMI) categories. Discontinuation due to weight gain occurred in 0.2% of olanzapine-treated patients and in zero placebo-treated patients.

During long-term continuation therapy with olanzapine (238 median days of exposure), 56% of olanzapine patients met the criterion for having gained greater than 7% of their baseline weight. Average weight gain during long-term therapy was 5.4 kg.

Table 3 includes data on weight gain with olanzapine pooled from 68 clinical trials. The data in each column represent data for those patients who completed treatment periods of the durations specified.

Table 3. Weight Gain with Olanzapine Use

Amount Gained kg (lb)	6 Weeks (N=2976) (%)	6 Months (N=1536) (%)	12 Months (N=778) (%)	24 Months (N=422) (%)
≥0	47	21	20	22
≥0.5 (≥1.1 lb)	37	34	25	22
≥5 (≥11 lb)	15	26	25	22
≥10 (≥22 lb)	2	12	16	18
≥15 (≥33 lb)	0	6	14	16

Olanzapine Monotherapy in Adolescents — The safety and efficacy of olanzapine have not been established in patients under the age of 18 years. In an analysis of 4 placebo-controlled olanzapine monotherapy studies of adolescent patients (ages 13 to 17 years), including those with schizophrenia (6 weeks) or bipolar disorder (manic or mixed episodes) (3 weeks), olanzapine-treated patients gained an average of 4.6 kg, which was statistically significantly different compared to an average of 0.3 kg in placebo-treated patients, with a median exposure of 3 weeks; 40.6% of olanzapine-treated patients gained at least 7% of their baseline body weight, which was statistically significantly different compared to 9.8% of placebo-treated patients, with a median exposure of 4 weeks; 7.1% of olanzapine-treated patients gained at least 15% of their baseline weight, compared to 2.7% of placebo-treated patients, with a median exposure of 19 weeks. Clinically significant weight gain was observed across all baseline Body Mass Index (BMI) categories, but mean changes in weight were greater in adolescents with BMI categories above normal at baseline. Discontinuation due to weight gain occurred in 1% of olanzapine-treated patients, compared to zero placebo-treated patients.

During long-term continuation therapy with olanzapine, 65% of olanzapine-treated patients met the criterion for having gained greater than 7% of their baseline weight. Average weight gain during long-term therapy was 7.4 kg.

Information for Patients:

Hyperglycemia — Patients should be advised of the potential risk of hyperglycemia-related adverse events. Patients should be monitored regularly for worsening of glucose control.

Weight Gain — Patients should be counseled that olanzapine is associated with weight gain. Patients should have their weight monitored regularly.

The following are the updated Hyperglycemia WARNINGS and the new Hyperlipidemia and Weight WARNINGS included in the Symbyax label.

WARNINGS:

Symbyax:
The following is updated language in the WARNINGS section of the Symbyax package insert, and will be reflected in other materials.

Hyperglycemia — Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including olanzapine alone, as well as olanzapine taken concomitantly with fluoxetine. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. While relative risk estimates are inconsistent, the association between atypical antipsychotics and increases in glucose levels appears to fall on a continuum and olanzapine appears to have a greater association than some other atypical antipsychotics.

Mean increases in blood glucose have been observed in patients treated (median exposure of 9.2 months) with olanzapine in phase 1 of the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE). The mean increase of serum glucose (fasting and nonfasting samples) from baseline to the average of the two highest serum concentrations was 15.0 mg/dL.

In an analysis of 7 controlled clinical studies, 2 of which were placebo-controlled, with treatment duration up to 12 weeks, SYMBYAX was associated with a statistically significantly greater mean change in random glucose compared to placebo (8.65 mg/dL versus -3.86 mg/dL). In patients with baseline normal random glucose levels (<140 mg/dL), 2.3% of those treated with SYMBYAX were found to have high glucose levels (≥200 mg/dL) during SYMBYAX treatment and were statistically significantly different compared to 0.3% of those treated with placebo. In patients with baseline borderline random glucose levels (≥140 mg/dL and <200 mg/dL), 34.1% of those treated with SYMBYAX were found to have high glucose levels (≥200 mg/dL) during SYMBYAX treatment and were statistically significantly different compared to 3.6% of those treated with placebo. The difference in mean changes between SYMBYAX and placebo was greater in patients with evidence of glucose dysregulation at baseline (including those patients diagnosed with diabetes mellitus or related adverse events, patients treated with anti-diabetic agents,

patients with a baseline random glucose level ≥200 mg/dL, or a baseline fasting glucose level ≥126 mg/dL). These patients had a greater mean increase in HbA_{1c}.

Controlled fasting glucose data is limited for SYMBYAX; however, in an analysis of 5 placebo-controlled olanzapine monotherapy studies with treatment duration up to 12 weeks, olanzapine was associated with a greater mean change in fasting glucose levels compared to placebo (2.76 mg/dL vs 0.17 mg/dL).

Olanzapine Monotherapy in Adolescents — The safety and efficacy of olanzapine and olanzapine and fluoxetine in combination have not been established in patients under the age of 18 years. In an analysis of 3 placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with schizophrenia (6 weeks) or bipolar disorder (manic or mixed episodes) (3 weeks), olanzapine was associated with a statistically significantly greater mean change in fasting glucose levels compared to placebo (2.68 mg/dL versus -2.59 mg/dL). In patients with baseline normal fasting glucose levels (<100 mg/dL), zero out of 124 (0%) of those treated with olanzapine were found to have high glucose levels (≥126 mg/dL) during olanzapine treatment versus 1 out of 53 (1.9%) of those treated with placebo. In patients with baseline borderline fasting glucose levels (≥100 mg/dL and <126 mg/dL), 2 out of 14 (14.3%) of those treated with olanzapine were found to have high glucose levels (≥126 mg/dL) during olanzapine treatment versus zero out of 13 (0%) of those treated with placebo.

Physicians should consider the risks and benefits when prescribing SYMBYAX to patients with an established diagnosis of diabetes mellitus or having borderline increased blood glucose level (fasting 100–126 mg/dL, nonfasting 140–200 mg/dL). Patients taking SYMBYAX should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Hyperlipidemia — Undesirable alterations in lipids have been observed with SYMBYAX use. Clinical monitoring, including baseline and follow-up lipid evaluations in patients using SYMBYAX, is advised.

Significant, and sometimes very high (>500 mg/dL), elevations in triglyceride levels have been observed with SYMBYAX use. Significant increases in total cholesterol have also been seen with SYMBYAX use.

Controlled fasting lipid data is limited for SYMBYAX.

In an analysis of 7 controlled clinical studies, 2 of which were placebo-controlled, with treatment duration up to 12 weeks, SYMBYAX-treated patients had an increase from baseline in mean random total cholesterol of 12.1 mg/dL compared to a statistically significantly different increase from baseline in mean random total cholesterol of 4.8 mg/dL for olanzapine-treated patients and a decrease in mean random total cholesterol of 5.5 mg/dL for placebo-treated patients. Table 3 shows categorical changes in nonfasting lipid values.

Table 3 Changes in Nonfasting Lipids Values from Controlled Clinical Studies with Treatment Duration up to 12 Weeks

Laboratory Analyte	Category Change from Baseline	Treatment Arm	N	Patients (%)
Nonfasting Triglycerides	Increase by 150 mg/dL	OFC	174	67.8%
		Olanzapine	172	72.7%
	Normal to High (<150 mg/dL to ≥500 mg/dL)	OFC	57	0%
		Olanzapine	58	0%
	Borderline to High (≥150 mg/dL and <500 mg/dL to ≥500 mg/dL)	OFC	106	15.1%
		Olanzapine	103	8.7%
Nonfasting Total Cholesterol	Increase by 240 mg/dL	OFC	685	35%[a,b]
		Olanzapine	749	22.7%
		Placebo	390	9%
	Normal to High (<200 mg/dL to ≥240 mg/dL)	OFC	256	8.2%[a,b]
		Olanzapine	279	2.9%
		Placebo	175	1.7%
	Borderline to High (≥200 mg/dL and <240 mg/dL to ≥240 mg/dL)	OFC	213	36.2%[a,b]
		Olanzapine	261	27.6%
		Placebo	111	9.9%

[a] Statistically significant compared to olanzapine.
[b] Statistically significant compared to placebo.

Controlled fasting lipid data is limited for SYMBYAX; however, in an analysis of 5 placebo-controlled olanzapine monotherapy studies with treatment duration up to 12 weeks, olanzapine-treated patients had statistically significant increases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 5.3 mg/dL, 3.0 mg/dL, and 20.8 mg/dL respectively compared to decreases from baseline in mean fasting total cholesterol, LDL cholesterol, and triglycerides of 6.1 mg/dL, 4.3 mg/dL, and 10.7 mg/dL for placebo-treated patients. For fasting HDL cholesterol, no statistically significant differences were observed between olanzapine-treated patients and placebo-treated patients. Mean increases in fasting lipid values (total cholesterol, LDL cholesterol, and triglycerides) were greater in

patients without evidence of lipid dysregulation at baseline, where lipid dysregulation was defined as patients diagnosed with dyslipidemia or related adverse events, patients treated with lipid lowering agents, patients with high baseline lipid levels. Table 4 shows categorical changes in fasting lipid values.

Table 4. Changes in Fasting Lipids Values from Adult Placebo-Controlled Olanzapine Monotherapy Studies with Treatment Duration up to 12 Weeks

Laboratory Analyte	Category Change from Baseline	Treatment Arm	N	Patients
Fasting Triglycerides	Increase by 150 mg/dL	Olanzapine	745	39.6%*
		Placebo	402	26.1%
	Normal to High (<150 mg/dL to ≥200 mg/dL)	Olanzapine	457	9.2%*
		Placebo	253	4.4%
	Borderline to High (≥150 mg/dL and <200 mg/dL to ≥200 mg/dL)	Olanzapine	135	39.3%*
		Placebo	65	20.0%
Fasting Total Cholesterol	Increase by 240 mg/dL	Olanzapine	745	21.6%*
		Placebo	402	9.5%
	Normal to High (<200 mg/dL to ≥240 mg/dL)	Olanzapine	392	2.8%
		Placebo	207	2.4%
	Borderline to High (≥200 mg/dL and <240 mg/dL to ≥240 mg/dL)	Olanzapine	222	23.0%*
		Placebo	112	12.5%
Fasting LDL Cholesterol	Increase by 130 mg/dL	Olanzapine	536	23.7%*
		Placebo	304	14.1%
	Normal to High (<100 mg/dL to ≥160 mg/dL)	Olanzapine	154	0%
		Placebo	82	1.2%
	Borderline to High (≥100 mg/dL and <160 mg/dL to ≥160 mg/dL)	Olanzapine	302	10.6%
		Placebo	173	8.1%

* Statistically significant compared to placebo.

In phase 1 of the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE), over a median exposure of 9.2 months, the mean increase in triglycerides in patients taking olanzapine was 40.5 mg/dL. In phase 1 of CATIE, the median increase in total cholesterol was 9.4 mg/dL.

Olanzapine Monotherapy in Adolescents — The safety and efficacy of olanzapine and olanzapine and fluoxetine in combination have not been established in patients under the age of 18 years. In an analysis of 3 placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with schizophrenia (6 weeks) or bipolar disorder (manic or mixed episodes) (3 weeks), for fasting HDL cholesterol, no statistically significant differences were observed between olanzapine-treated patients and placebo-treated patients. Table 5 shows categorical changes in fasting lipid values in adolescent patients.

Table 3. Changes in Fasting Lipids Values from Adolescent Placebo-Controlled Olanzapine Monotherapy Studies

Laboratory Analyte	Category Change From Baseline	Treatment Arm	N	Patients
Fasting Triglycerides	Increase by 150 mg/dL	Olanzapine	138	37.0%*
		Placebo	66	15.2%
	Normal to High (<90 mg/dL to ≥130 mg/dL)	Olanzapine	87	26.4%
		Placebo	38	10.5%
	Borderline to High (≥90 mg/dL and <130 mg/dL to ≥130 mg/dL)	Olanzapine	37	59.5%
		Placebo	17	35.3%
Fasting Total Cholesterol	Increase by 240 mg/dL	Olanzapine	138	14.5%*
		Placebo	66	4.5%
	Normal to High (<170 mg/dL to ≥200 mg/dL)	Olanzapine	87	5.9%
		Placebo	43	2.3%
	Borderline to High (≥170 mg/dL and <200 mg/dL to ≥200 mg/dL)	Olanzapine	30	36.9%*
		Placebo	13	7.7%
Fasting LDL Cholesterol	Increase by 130 mg/dL	Olanzapine	137	17.5%
		Placebo	63	11.1%
	Normal to High (<110 mg/dL to ≥130 mg/dL)	Olanzapine	98	5.1%
		Placebo	44	4.5%
	Borderline to High (≥110 mg/dL and <130 mg/dL to ≥130 mg/dL)	Olanzapine	29	48.3%*
		Placebo	9	0%

* Statistically significant compared to placebo.

Weight Gain — Potential consequences of weight gain should be considered prior to starting SYMBYAX. Patients receiving SYMBYAX should receive regular monitoring of weight.

In an analysis of 7 controlled clinical studies, 2 of which were placebo-controlled, the mean weight increase for SYMBYAX-treated patients was statistically significantly greater than placebo-treated (4 kg vs -0.3 kg). Twenty-two percent of SYMBYAX-treated patients gained at least 7% of their baseline weight, with a median exposure of 6 weeks. This was statistically significantly greater than in placebo-treated patients (1.8%). Approximately 3% of SYMBYAX-treated patients gained at least 15% of their baseline weight, with a median exposure of 8 weeks. This was statistically significantly greater than in placebo-treated patients (0%). Clinically significant weight gain was observed across all baseline Body Mass Index (BMI) categories. Discontinuation due to weight gain occurred in 2.5% of SYMBYAX-treated patients and zero placebo-treated patients.

Table 6 includes data on weight gain with olanzapine pooled from 68 clinical trials. The data in each column represent data for those patients who completed treatment periods of the durations specified.

Table 4. Weight Gain with Olanzapine Use

Amount Gained kg (lb)	4 Weeks (N=1976) (%)	6 Months (N=1536) (%)	12 Months (N=778) (%)	24 Months (N=422) (%)
≥7	37	41	40	22
≥7 (≥15 lb)	37	34	25	22
≥7 (≥15 lb)	13	26	25	22
≥7 (≥15 lb)	2	12	16	18
≥7 (≥15 lb)	0	6	14	16

During long-term continuation therapy with olanzapine monotherapy (238 median days of exposure), 36% of olanzapine patients met the criterion for having gained greater than 7% of their baseline weight. Average weight gain during long-term therapy was 5.4 kg.

Olanzapine Monotherapy in Adolescents — The safety and efficacy of olanzapine and olanzapine and fluoxetine in combination have not been established in patients under the age of 18 years. In an analysis of 4 placebo-controlled olanzapine monotherapy studies of adolescent patients (ages 13 to 17 years), including those with schizophrenia (6 weeks) or bipolar disorder (manic or mixed episodes) (3 weeks), olanzapine-treated patients gained an average of 4.6 kg, which was statistically significantly different compared to an average of 0.3 kg in placebo-treated patients, with a median exposure of 3 weeks; 40.6% of olanzapine-treated patients gained at least 7% of their baseline body weight, which was statistically significantly different compared to 9.8% of placebo-treated patients, with a median exposure of 4 weeks; 7.1% of olanzapine-treated patients gained at least 15% of their baseline weight, compared to 2.7% of placebo-treated patients, with a median exposure of 19 weeks. Clinically significant weight gain was observed across all baseline Body Mass Index (BMI) categories, but mean changes in weight were greater in adolescents with BMI categories above normal at baseline. Discontinuation due to weight gain occurred in 1% of olanzapine-treated patients, compared to zero placebo-treated patients.

During long-term continuation therapy with olanzapine, 65% of olanzapine-treated patients met the criterion for having gained greater than 7% of their baseline weight. Average weight gain during long-term therapy was 7.4 kg.

Information for Patients:

Hyperglycemia — Patients should be advised of the potential risk of hyperglycemia-related adverse events. Patients should be monitored regularly for worsening of glucose control.

Weight Gain — Patients should be counseled that SYMBYAX is associated with weight gain. Patients should have their weight monitored regularly.

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3. American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, and North American Association for Study of Obesity. 2004. Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes. Diabetes Care 27: 596-601. http://care.diabetesjournals.org/cgi/content/full/27/2/596

Zyprexa® (olanzapine) is indicated for the short-term and maintenance treatment of schizophrenia. Zyprexa is also indicated as monotherapy or in combination with lithium or valproate for the short-term treatment of acute mixed or manic episodes associated with Bipolar I Disorder and as maintenance treatment in bipolar disorder. Symbyax® (olanzapine and fluoxetine HCl capsules) is indicated for treatment of depressive episodes associated with bipolar disorder.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

PLAINTIFF'S FIRST AMENDED RESPONSES TO DEFENDANT'S FIRST SET OF INTERROGATORIES

Pursuant to Rules 26(e)(2) and 33 of the Alaska Rules of Civil Procedure, Plaintiff hereby amends it's Responses to Defendant's First Set of Interrogatories as follows. Plaintiff specifically reserves the right to further supplement and or amend these responses as discovery continues and as provided for by the applicable rules of procedure.

INTERROGATORIES

INTERROGATORY NO. 1: Identify each Medicaid State Plan in effect for the State of Alaska since 1996, and for each plan:

a. state whether pharmacy benefits are offered as part of the coverage;

b. state whether pharmacy benefits are offered for Zyprexa prescriptions; and

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EXHIBIT C
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001888 001889

D E F G

g. identify the prescriber;

h. state whether the prescriber continues to prescribe Zyprexa;

i. identify any misrepresentations you allege caused the physician to prescribe Zyprexa;

j. identify the injury you allege was caused by Zyprexa for which you seek damages;

k. identify the physician that diagnosed the injury;

l. identify all physicians that treated the injury; and

m. state the dollar amount that Alaska is claiming against Lilly in damages.

ANSWER: See responses to Interrogatory Nos. 10 and 11 above.

INTERROGATORY NO. 25: Identify any communications since 1996 by Alaska to Medicaid recipients concerning Zyprexa.

ANSWER: The State has no documents or communications responsive to this request.

INTERROGATORY NO. 26: Identify any communications since 1996 by Alaska to physicians concerning Zyprexa.

ANSWER: The State objects to this interrogatory in that it seeks information that is irrelevant to the claims and defenses of the parties, is not reasonably calculated to lead to the discovery of admissible evidence, and is vague and ambiguous. Subject to and without

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waiving these objections, the State has no documents or communications responsive to this request.

INTERROGATORY NO. 27: Identify any Drug Utilization Reviews and/or Drug Class Reviews done by Alaska since 1996 concerning Zyprexa.

ANSWER: The State did a review of atypical antipsychotic medications in approximately 2005 with respect to their propensity to cause diabetes. The minutes of this review meeting are being produced with the State's responses to Lilly's Requests for Production.

INTERROGATORY NO. 28: Identify any algorithms or protocols adopted by Alaska for treatment of schizophrenia, bipolar disorder, and/or any other algorithms or protocols that include Zyprexa.

ANSWER: The State of Alaska has used a protocol for the use of atypical antipsychotic medications, although it does not specifically address Zyprexa. This protocol was developed by a grant from Eli Lilly. It is generally known as the BPMS program and is run by a contractor, CNS.

INTERROGATORY NO. 29: Identify any studies or analyses performed by Alaska to assess the effect on overall costs to the state of prescribing atypical anti-psychotics to mental health patients.

ANSWER: The State objects to this interrogatory in that it is vague and ambiguous. Subject to and without waiving this objection, and assuming this interrogatory is limited to

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EXHIBIT C
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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

VIDEOTAPED DEPOSITION OF

LUCY LJUBICICH CURTISS, M.D.

December 13, 2007
1:35 p.m.

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

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

EXHIBIT D
PAGE 1 OF 3

E F G

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Also Present: STEVE MIEDZWIADEK, VIDEOGRAPHER

I-N-D-E-X

KARLEEN JACKSON DECEMBER 12, 2007

EXAMINATION

PROCEEDINGS

THE VIDEOGRAPHER: One moment, please.

We're on the record, today is December 13th, 2007. The time is approximately 8:56 a.m.

This is tape 1 of the videotaped deposition of Lucy Curtiss, M.D. being taken on behalf of the Defendant in the matter of the State of Alaska versus Eli Lilly & Company filed in the Superior Court for the State of Alaska, Third Judicial District at Anchorage, Case No. 3AN-06-05630 Civil.

We're in the office of Dr. Curtiss, located at 4020 Folker Street in Anchorage, Alaska.

My name is Steve Miedzwiadik, and I'm the videographer. My business is 545 East 12th Avenue in Anchorage, Alaska.

The court reporter is Sandra M. Mierop with Northern Lights Realtime & Reporting.

Would counsel identify themselves for the record, please?

MR. STEELE: My name is Joe Steele. I represent the State of Alaska.

MR. JAMIESON: Brewster Jamieson with Lane Powell. I represent Eli Lilly & Company.

MR. ROGOFF: Andrew Rogoff with Pepper Hamilton; and I also represent Eli Lilly.

MS. MANDALA: Cheryl Mandala with Jermain, Dunnagan & Owens. And I represent Anchorage Community Mental Health Services and Dr. Curtiss.

LUCY LJUBICICH CURTISS, M.D.

having been duly sworn, testified as follows:

EXAMINATION

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

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

A. Yes.

Q. How did you hear about it?

A. I'm not sure whether it was the newspaper or from colleagues.

Q. Do you know how long ago?

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preference. Patients have been on medications for a long period of time. They know what works, they know what they trust.

Q. Any other factors that would militate in favor of using perphenazine besides patient preference?

A. Well, it has anti-psychotic effect. You know, I'm looking for effectiveness of a medication, and acceptability to a patient.

Q. For new patients who have not used perphenazine and therefore wouldn't have a preference for it, do you, nevertheless, from time to time prescribe perphenazine for such patients?

A. At times.

Q. And what are the factors you consider in those cases?

A. The patients that come here, it is very rare that I would see a patient who has -- is treatment naive. That, by definition, the people that we take are people that are coming out of other treatment facilities, and generally have been started on an agent. And so I'm not the first one that is prescribing for somebody. They typically have experience with treatment.

And so often people will have come here after having failed other treatments.

Q. For a treatment-naive patient, have you used perphenazine?

A. Not since my residency, no.

Q. Why is that?

A. Well, first, I don't see very many treatment-naive patients. But in terms of options that are available, I do preferentially use the newer anti-psychotics.

Q. Have you ever received -- do you recall ever receiving a letter from the State regarding the use of anti-psychotics?

A. I don't. I don't know.

Q. Are you familiar with the Behavioral Pharmacy Management Steering Committee?

A. I am aware of the process.

Q. What do you know about it?

A. That there is -- the BPMS, it is -- I believe it is sponsored, paid for, by Eli Lilly, and they have a number of indicators that they review, and they send out notification to prescribers every other month when patients that we're -- for whom we're prescribing meet certain indicators. If they're on three or more

psychotropics, if they're on a subtherapeutic dose, if they're on a higher-than-recommended dose, if they're not filling their prescriptions, if they're getting prescriptions from more than one provider, we get those lists every two months.

Q. Have you personally received them?

A. Yes, I have.

Q. Have any of those notifications affected your practice with any of these patients?

A. There have been times when I have learned that patients are seeing more than one provider; that's useful information.

Q. And receiving more medication than you're aware of?

A. Yes.

Q. Any other times it's affected your practice?

A. Overall, I'd say not.

Q. Dr. Curtiss, are you ever involved in treating patients who are involuntarily committed?

A. Yes, I am.

Q. Where do you treat them?

A. I treat them here as outpatients. We do

get patients who are on -- it's called an early release. It is an outpatient commitment that -- it starts as an inpatient commitment, and then patients can agree that they will adhere to treatment recommendations specified in the early release. We as an agency would accept responsibility for their care. And if they don't follow through with what they've agreed to, then -- well, then, it's our responsibility to seek rehospitalization. So, yes, I have treated patients like that.

Q. Are those patients coming out from API?

A. Yes.

Q. Are any --

A. There -- I'm sorry, there are also patients who are in court-ordered treatment who as conditions of their parole or probation are mandated to -- to follow treatment recommendations, in which case I would recommend to someone this is -- this is what I think you should do; if you disagree, go to your P.O. about it. That's involuntary. Coercive.

Q. The folks who are coming out of API, are any of them, when you receive them, on Zyprexa?

A. Some.

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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

VIDEOTAPED DEPOSITION OF DUANE HOPSON, M.D.

December 11, 2007
10:18 a.m.

Taken at:
The Offices of Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

Reported by: Leslie J. Knisley
Shorthand Reporter

EXHIBIT E
PAGE 1 OF 3

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Also Present: STEVE MIEDZWIADOK, VIDEOGRAPHER

3-N-O-E-X

DUANE HOPSON, M.D. DECEMBER 11, 2007

EXAMINATION

EXHIBITS

NUMBER	DESCRIPTION	PAGE
1	E-mail, 5/1/07 Bates Nos. ZYP-AK-05302 to 05305	96
2	E-mail, 1/24/07 Bates Nos. ZYP-AK-05218 to 05241	101

PROCEEDINGS

THE VIDEOGRAPHER: One moment, please.

We're on the record. Today is December 11th, 2007, and the time is approximately 10:18 a.m. This is Tape 1 of the videotaped deposition of Duane Hopson, being taken on behalf of the defendant, in the matter of State of Alaska versus Eli Lilly and Company, filed in the Superior Court for the State of Alaska, Third Judicial District at Anchorage, Case No. 3AN-06-05630 Civil. We're in the offices of Lane Powell, LLC, located at 301 West Northern Lights Boulevard, Suite 301 in Anchorage, Alaska.

My name is Steve Miedzwiadok,and I'm the videographer. My business address 545 East 12th Avenue, Anchorage, Alaska. The court reporter is Leslie Knisley with Northern Lights Realtime & Reporting.

Would counsel identify themselves for the record, please?

MR. SNIFFEN: Ed Sniffen, assistant attorney general for the State of Alaska.

MR. STEELE: Joe Steele, assistant

attorney general for the State of Alaska as well, sort of special assistant attorney general to be exact.

MR. JAMIESON: Brewster Jamieson with Lane Powell on behalf of Eli Lilly and Company.

MR. ROGOFF: Andrew Rogoff, Pepper Hamilton, on behalf of Eli Lilly and Company.

Did you get sworn in?

MR. STEELE: No, but I get a badge.

MR. ROGOFF: Let's you ride the Anchorage subway for free.

MR. STEELE: Well, you can use it in public restrooms actually. We can get you one if you want one.

THE VIDEOGRAPHER: We ask now that the court reporter please swear the witness.

DUANE HOPSON, M.D.,

having been sworn, testified as follows:

EXAMINATION

Q (BY MR. ROGOFF) Dr. Hopson, as you heard, I represent Eli Lilly and Company. I'm going to be asking you some questions about the lawsuit that the State has brought against our client.

psychiatric drugs?
A. Well, I think the way they were introduced and marketed and presented to the physicians was that it revolutionized treatment, particularly for schizophrenia, and that it treated the positive and the negative symptoms of schizophrenia. So I think that was with lower risk of tardive dyskinesia. That was usually in the -- in the scheme of presentation, too.
Q. Have you seen patients with tardive dyskinesia?
A. Yes.
Q. Can you describe what that is?
A. It's generally a permanent and can be a very disabling disorder caused by dopamine block A from the older atypical -- from the older typical antipsychotics. And there are tremors involved, some muscular rigidity, a lot of oral dyskinesias, oral abnormal movements of the tongue. And it's not only socially embarrassing, but it can be very impairing to some individuals.
Q. And in weighing the risks and benefits of using the typicals against the atypicals, why is it that you come down on the side of the atypicals?

A. I think I believe and I think a lot of docs believe that if -- I've heard discussion about this -- is that we, if we're properly informed about the risks associated with a medication, we can monitor those risks. And it's all in the process of being adequately informed and then us monitoring for it. The problem with tardive dyskinesia is it can come on even with just one dose. There have been reported cases. So it's not kind of a progressive thing that we might see with the atypicals, so we have more time to intervene with it.
Q. So it's your practice, then, to monitor your patients on atypicals for those side effects that you're concerned about?
A. As we've become more aware and educated about the risks, yes.
Q. And as you said, though, you were aware of the weight gain and blood sugar issues really from the start; is that right?
A. Yes.
Q. You described earlier the use of Zyprexa in an involuntary situation -- or the involuntary use of Zyprexa. How is the medication administered when it's administered

involuntarily?
A. Well, ideally, orally. And, interestingly, you can convince a patient after they've gone before a judge and a judge has told them, you know, this doctor is going to give you this medication, you can usually tell the patient, you need to take this, the judge has said you have to take it, and they usually will. If not, then it can be administered to them with a shot, intramuscular.
Q. That includes Zyprexa?
A. Yes.
Q. Have you seen the intramuscular injection of Zyprexa work for these patients?
A. Yes. I would say as much as, you know, any other intramuscular.
Q. Have you ever read the Complaint that the State has filed against Eli Lilly?
A. No.
Q. Did anyone in the attorney general's office consult with you before filing the Complaint?
A. No.
Q. Did you ever receive a letter from a drug utilization review committee regarding the

use of Zyprexa here in Alaska?
A. Not that I recall, no.
Q. Are you able to say that there are -- there is -- as a blanket statement, a drug that's equally as effective as Zyprexa in all situations, but with a better safety profile?
A. In all situations? No.
Q. Why is that?
A. Because I think patients are unique and illnesses are unique, and you can't -- I think you would be in error to say that one particular medication in all instances is going to be superior.
Q. When you prescribe Zyprexa, do you talk to your patients about the risks and benefits?
A. Yes.
Q. Have you always done that?
A. Yes.
Q. What are the risks that you've told your patients about Zyprexa?
A. Well, there again, I think it's been a -- it's been a process of changing how we do informed consent over time with Zyprexa, as we've learned more about it. But now it includes the weight gain, increase in lipids, blood sugar,

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IN THE SUPERIOR COURT OF THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630

VIDEOTAPED 30(b)(6) DEPOSITION OF
STATE OF ALASKA
DESIGNEE: DAVID CAMPANA

Wednesday, September 19, 2007
9:30 a.m.
Volume II

Taken by Counsel for Defendant
at
Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

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G

this on prior authorization? Why don't we get every drug we want?"

Also, psychiatrists are one group of physicians that, in my opinion, think that every drug should be available on their armoral to every patient, and they have a stronger opinion of that than other practicing physicians.

Q. Do you understand why they hold that opinion?

A. No, I don't.

Q. Clozapine was subject to a prior authorization process?

A. It is subject to a prior authorization process.

Q. And what is the reason that Clozapine is subject to a prior authorization process?

A. Safety issue for Clozapine causes blood dyscrasias.

Q. So that's an example of a mental health medication which, notwithstanding the political pressure, the state has implemented a prior authorization process?

A. Correct.

Q. Has the state instituted a prior authorization process for Zyprexa?

A. No.

Q. Why not?

A. We haven't.

Q. Is it the same reasons that you haven't done a step-edit?

A. Correct.

Q. So the state is capable of doing it for safety reasons, but has chosen not to for Zyprexa?

A. Correct.

Q. And you have been able to resist the pressure from the mental health community and psychiatrists in keeping Clozapine on prior authorization?

A. Correct.

Q. And you have experienced that pressure?

A. I have experienced that pressure.

VIDEOGRAPHER: Off record. The time is 12:08.

(There was a lunch break.)

VIDEOGRAPHER: On the record. The time is 1:01.

Q. Good afternoon, Mr. Campana.

A. Hello.

Q. Your counsel has given me two disks. One of them has just a tape label on it that says "gender control". One has a label, and the other one has a label that says "gender tally and gender zyp".

I have looked at those disks, and I'm just going

to give you some representations about the numbers, unique Medicaid recipients that I saw there just to confirm that's consistent with your understanding of what was expected.

On the disc that includes the gender tally file, that appears to just be a duplicate of the gender file that we looked at earlier today which had relatively small numbers, 700 or so Zyprexa users and about 8,300 other users.

Then there is a file "gender Zyp" and it has 6,455 unique recipients. Is that number consistent with your recollection about the number of Zyprexa users who you received gender data for?

A. That's closer to consistent to my number.

Q. I mean, is there anything about that number that sounds wrong to you or you just don't have a perfect recollection of the number?

A. I don't have a perfect recollection of that number, but it's more than 700, and 6,000 sounds better.

Q. Other than that, you can't -- you don't know whether it was 8,000 or 4,000?

A. Right.

Q. It was in the thousands?

A. Thousands.

Q. The other disk, which is "gender control," has

256,772 unique recipients. Does that sound roughly consistent with the information you pulled for the gender of what you would label the control group?

A. That sounds like a number more consistent with the control group.

Q. Thank you. For the prior authorization of Clozapine, I understood your testimony to be that that prior authorization was already in effect when you became part of the Department of Health and Social Services; is that correct?

A. That is correct.

Q. Has that treatment, reimbursement treatment of Clozapine, been up for review during your tenure?

A. We have reviewed it. I have reviewed it and I changed the criteria set for that and developed a specific form for authorization of Clozapine.

Q. It's been up for review and you have made changes. Is that subject to any kind of public proceeding or comment period or anything like that?

A. No.

Q. You have indicated that you felt political pressure regarding that treatment of Clozapine.

What was the context where you would receive pressure?

A. I have met at different times with different

psychiatrists in the community and we have been -- this was at a time when Dr. Porter and I worked together on the program. We met with psychiatrists, and they requested we take the prior authorization off of Clozapine.

I have met with different psychiatrists at different times and there have been requests to take the prior authorization off of that.

Q. And you have always declined that request?

A. Basically, I have declined that request.

Q. And in the course over the years where you have been dealing with issues of prior authorization for Clozapine, have you had any interactions with representatives of the mental community or their advocacy groups regarding the prior authorization of Clozapine?

A. No.

Q. Have you felt political pressure from those groups regarding the issue?

A. No.

Q. Have you had any dialogue or heard from the mental health community advocates regarding possible changes to the reimbursement treatment of Zyprexa?

A. No.

Q. Before lunch, you were talking quite a bit about

the issue of political pressure from these groups as it related to possible changes in the treatment of Zyprexa, and I'm trying to understand where you would have received that from if you are not meeting with them or hearing from them.

A. As far as the pressure would be is discussion with psychiatrists or phone calls. They may call in and say, "You know, we would like to make sure you don't put prior authorization on that."

As far as the mental health drugs, in looking at states across the country, very few states have any of the mental health drugs on prior authorization.

Q. Does that include Clozapine?

A. That could include Clozapine. Some of the states have legislation that prevents them from having any of the mental health or any of the atypical anti-psychotics on prior authorization.

Q. So Alaska distinguishes itself to some extent from other states by having Clozapine on prior authorization?

A. Correct. There are states that do have Clozapine under prior authorization still.

Q. But it's not the norm?

A. I can't answer that.

Q. The name Thomas Porter has come up in our

dialogue and, in fact, his name appears in some of the interrogatory answers. I think I need a better understanding of where he fits in the picture.

He was the medical director?

A. He was the medical director for Medicaid.

Q. For what time period?

A. Approximately to '90 or late '89 through to 2001, I believe.

Q. And what was -- what roles or functions or responsibilities did he have regarding medications, and particularly anti-psychotic medications?

A. Well, he basically reviewed the prior authorization for Clozapine. He also reviewed the prior authorization requests for growth hormone.

And then he reviewed prior authorization requests for gastric bypass, different hospitalization, different issues that would come up under the surveillance utilization review program.

Q. Who replaced Mr. Porter?

A. There was no replacement for him until this year, this spring. Dr. Maher was hired as the medical director.

Q. Did somebody fill Dr. Porter's responsibilities during this period where there was no medical director?

A. I took over the prior authorization for growth

hormone and Clozapine.

Q. If I'm understanding you correctly, during Dr. Porter's tenure, he worked with you on some medication issues, and, after his departure, you didn't have a counterpart to work on medication issues?

A. Correct.

Q. Another way that you described that the state could address safety issues with the medication is to review the medication for the PDL, correct?

A. Correct.

Q. And the outcome of a review for that reason could be that the medication is put on -- is treated as non-preferred, correct?

A. Correct.

Q. And -- or the outcome could be that all the atypicals are preferred?

A. Sure.

Q. And, again, as you said before lunch, becoming non-preferred wouldn't stop any prescriber from prescribing the medication, it would just mean that the prescriber has to explain the medical necessity?

A. Correct.

Q. And as we have discussed, you have not reviewed Zyprexa or any of the other anti-psychotics for the PDL, correct?

EXHIBIT F
PAGE 3 OF 4

A. The typical or atypical anti-psychotics have not been reviewed for the preferred drug list.
Q. Why didn't you review Zyprexa after you learned the information you have described about Zyprexa's relationship to diabetes?
A. We did review it as far as under the drug utilization review program.
Q. Why didn't you review it for the PDL?
A. We didn't take over that class or didn't review that therapeutic class in the preferred drug list.
Q. And that was the decision of you and your First Health counterpart?
A. Correct. And as reasons I had previously stated, and also the mental health community is under terrific pressure here due to low funding and due to over-abundance of patients and small infrastructure to take care of those patients, so why do we want to add one more hoop to that whole overrun entity?
Q. So was that resource issue the reason? I want to be very precise about my question here. There came a point in time when you had gathered information about Zyprexa's relationship to diabetes, correct?
A. Correct.
Q. And you interpreted that information to be communicating that Zyprexa actually caused diabetes?

A. Correct.
Q. And that was sometime around fall of 2004, correct?
A. Correct.
Q. And could have been even earlier?
A. Could have been even earlier.
Q. And one of the things you could have done about that is reviewed Zyprexa for the PDL?
A. Correct.
Q. And the P&T committee might have come to the conclusion that the safety issues warranted Zyprexa being non-preferred, correct?
A. Correct.
Q. As you said, putting a drug -- making a drug non-preferred has actually been fairly effective in causing prescribers to prescribe those medications less than they previously did?
A. Correct.
Q. But you elected not to do that?
A. Correct.
Q. I want to make sure I understand. Why in this juncture, after you have come to these conclusions about Zyprexa's relationship with diabetes, did you not take that step?
A. Well, we didn't take that step at the time.

There were political issues about that. And as I mentioned just a minute ago, the over-burdened community, mental health and mental health community, and lack of psychiatrists out there, lack of practitioners for the mentally ill.
Q. So are those the two reasons that after determining that Zyprexa causes diabetes you didn't elect to review Zyprexa for the PDL?
Those are the only two reasons, the political pressure and the resource issue?
A. Those are the main two I can think of right now.
Q. Can you think of anything else?
A. At this point. I might have a brain storm in a minute, but that's the two.
Q. I'll put up the umbrella. Just let me know.
So let's break those down. One issue is lack of resources. In what way does the lack of mental health resources bear on the issue of whether a drug you have concluded has a safety issue should not be reviewed for that safety issue for the PDL?
A. Well, as far as making it any more onerous for those prescribers to prescribe the drug. Even though writing -- the only requirement we have is to write "medically necessary," do we want to impact that resource with another hoop or another restriction to

getting that -- getting the services for the mentally ill.
Q. Are there any mental health medications that are on the PDL?
A. There are mental health as far as drugs that are used in the treatment of mental health conditions.
Anti-depressants are on there. The anti-convulsants, the sedative hypnotics, and the ADHD drugs.
Q. That's actually most of the mental health drugs, isn't it?
A. Well, that's most of the other mental health drugs that are used in the treatment of mental illness other than the atypical or typical anti-psychotics.
Q. The people who prescribe all of those drugs you just described, anti-depressants and anti-convulsants, they pretty well overlap with the group that prescribes anti-psychotics, correct?
A. Correct.
Q. And you have nevertheless put those drugs on the PDL, correct?
A. Correct.
Q. And made those prescribers jump through those hoops, correct?
A. Correct.

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

STATUS CONFERENCE
BEFORE THE HONORABLE M. RINDNER

Pages 1 - 56
Wednesday, October 24, 2007
2:00 P.M.
Anchorage, Alaska

Court Reporter and Transcriptionist:
Diane M. Bondeson
PACIFIC RIM REPORTING
711 M Street, Suite 4
Anchorage, Alaska 99501

EXHIBIT G
PAGE 1 OF 4

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

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(272-3538)

Clyde "Ed" Sniffen, Jr.
STATE OF ALASKA
DEPARTMENT OF LAW, CIVIL DIVISION
1031 West Fourth Avenue, Suite 200
Anchorage, Alaska 99501-1994
(269-5200)

For the Defendant:
Brewster H. Jamieson
LANE POWELL
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
(277-9511)

Eric J. Rothschild
PEPPER HAMILTON
3000 Logan Square
Philadelphia, Pennsylvania 19103-2799

EXHIBIT 6
PAGE 2 OF 4

deadline. If that happens and then experts have to be deposed, we're going to lose even a bifurcated date that we've got possibilities for now.

MR. ROTHSCHILD: Your Honor, I haven't heard from Mr. Sanders that the reports they'll file on November 12 from Broncotti and Goff and Wershing, who were their MDL witnesses, are going to be the same as what they filed in the MDL. In the MDL, we got a chance to respond to what they actually filed.

THE COURT: Everybody should file their reports by the deadlines I've established on liability. You don't have to file damages reports because it's unclear to me that you can't really do that with missing information and stuff. But on the liability issues, everybody should file their report. If somebody feels that a report is different in quality or quantity or whatever that requires some additional supplementation, they can request -- I don't even -- we may have even got supplementation built in, I'm not sure. But if there isn't, people can come back and explain to me why they need more time to do something different than has already been done in the MDL cases.

But everybody should file their reports that they were expecting to file on liability by

EXHIBIT 6
PAGE 3 OF 4

it, you know, December 12, December 5, you know, a reasonable time. You know, I hope you're right; it's not a whole lot of extra work for all of us, but this is -- this is not asking for extraordinary relief.

MR. SANDERS: What are they going to rebut if I produce the MDL reports?

THE COURT: Maybe nothing.

MR. SANDERS: So let's --

THE COURT: But I didn't hear you say it will be the MDL report and nothing else. If I heard you say that, I'd understand what your point is.

MR. SANDERS: If they want to rebut -- okay. The question is do they -- are they going to be permitted -- are the parties going to be permitted to rebut information that is not part of their existing reports that have already been exchanged in another proceeding? Is that -- if that's the question, that's fine.

THE COURT: I'll give everybody until December 3 to file rebuttal reports, but I will expect that the rebuttal reports will truly be rebuttal.

MR. ROTHSCHILD: The other scheduling issue is that we have deadlines in place aside from the expert reports that I think we could all fairly agree

EXHIBIT 6
PAGE 1 OF 1

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

MOTION AND APPLICATION OF NON-RESIDENT ATTORNEY KENNETH T. FIBICH FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska Rule of Civil Procedure 81(a)(2), attorney Kenneth T. Fibich of the law firm of Fibich, Hampton & Leebron, L.L.P., whose mailing address is 1401 McKinney, Suite 1800, Houston, Texas 77010 (Telephone: (713) 751-0025), applies for permission to appear and participate as co-counsel for plaintiff State of Alaska in this action.

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

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

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

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

DATED this 25 day of January, 2008.

FELDMAN ORLANSKY & SANDERS
Attorneys for State of Alaska

By _____
Eric T. Sanders
Alaska Bar No. 7510085

CONSENT OF LOCAL COUNSEL

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

Dated this 27 day of January, 2008.

FELDMAN ORLANSKY & SANDERS

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

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

Certificate of Service

I hereby certify that a true and correct copy of the foregoing **Motion and Application of Non-Resident Attorney Kenneth T. Fibich for Permission to Appear and Participate and (proposed) Order** was served by messenger on:

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

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

By Peggy S Crowe
Date 1/30/08

Feldman Orlansky & Sanders
500 L Street
Fourth Floor
Anchorage, AK 99501
Tel: 907.272.3538
Fax: 907.274.0819

STATE BAR OF TEXAS

Office of The Chief Disciplinary Counsel

January 14, 2008

RE: **Mr. Kenneth T. Fibich**
State Bar Number - **06952600**

To Whom it May Concern:

This is to certify that Mr. Kenneth T. Fibich was licensed to practice law in Texas on April 29, 1974 and is an active member in good standing with the State Bar of Texas.

Good Standing means that the attorney is current on payment of Bar dues and attorney occupation tax; has met Minimum Continuing Legal Education requirements; and is not presently under either administrative or disciplinary suspension.

No disciplinary action involving professional misconduct has been taken against the attorney's law license. This certification expires 30 days from this date, unless sooner revoked or rendered invalid by operation of rule or law.

John A. Neal
Chief Disciplinary Counsel

JN/dh

001908

Exhibit A
Motion to Participate – Fibich
Case No. 3AN-06-5630 CI

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

Customer's Order No. | Phone No. 843-727-6940 | Date 1-30-07

Sold to: Richardson, Patrick, Westbrook, Brickman
Address: 1037 Chuck Dawley Blvd Bldg. A Box 1007
City: Mount Pleasant SC 29465 1007

Book No.	Date	C.O.D.	Charge	Call Back	Mdse. Retd.	Paid Out	

Qty	Description	Price	Amount
	Rule 81		410 00
	Kenneth Fibich AA		
	assoc w/ Eric Saunders 7510085		
	case # 3AN-06-5630		
	check # 105333		
	2007		

All claims and returned goods MUST be accompanied by this bill. | Tax

Rec'd By: Denise Richardson | Total 410 00

029748 Thank You!

001909

Exhibit B
Motion to Participate – Fibich
Case No. 3AN-06-5630 CI

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

IT IS HEREBY ORDERED that defendant Eli Lilly and Company's Unopposed Motion for Extension of Time is GRANTED. The parties shall file objections to deposition designations and counter-designations on Monday, February 4, 2008. The objections to counter-designations would also be extended by one week for both parties on Monday, February 11, 2008.

ORDERED this 29 day of January, 2008.

The Honorable Mark Rindner
Superior Court Judge

I certify that on January 28, 2008, a copy of the foregoing was served by fax and mail on:

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

009867.0038/162868.1

I certify that on 1/29/08 a copy of the above was personally handed to each of the following: D JAMISON / BANKS

Mark Bonneman
Deputy Clerk

001910

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

UNOPPOSED MOTION FOR EXTENSION OF TIME

Defendant Eli Lilly and Company, by and through counsel of record, Lane Powell LLC, hereby moves the Court to grant a one week extension from Monday, January 28 to Monday, February 4, 2008, for the parties to file objections to deposition designations and their counter-designations. The objections to counter-designations would also be extended by one week, from Monday, February 4, to Monday, February 11, 2008.

Defendant's counsel has spoken with plaintiff's counsel and they are in agreement; plaintiff's counsel does not oppose this Motion for Extension of Time.

DATED this 28th day of January, 2008.

PEPPER HAMILTON LLP
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 January 28, 2008, a copy of The foregoing was served by fax + mail on:

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

009867:0038/162866.1

LANE POWELL LLC
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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 PLAINTIFF'S OBJECTIONS TO DEFENDANT'S PAGE/LINE DESIGNATIONS AND EXHIBITS UNDER SEAL

On this date the State of Alaska is filing a pleading titled "Plaintiff's Objections to Defendant's Page/Line Designations." 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 28 day of January, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

NOTICE OF FILING PLAINTIFF'S COUNTER DESIGNATIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS AND EXHIBITS UNDER SEAL

On this date the State of Alaska is filing a pleading titled "Plaintiff's Counter Designations to Defendant's Deposition Designations for Trial." 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 28 day of January, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
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TEL: 907.272.3538
FAX: 907.274.0819

001913

A B C D E F

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 LEAVE TO FILE SUPPLEMENTAL BRIEF

Defendant Eli Lilly and Company moves this Court for leave to supplement its Summary Judgment Motion to address new material placed into the summary judgment record by the State on Friday, January 25, 2008, ten days after Lilly filed its Reply Brief. Lilly submits its Motion for Leave on shortened time, in order to provide the Court with relevant legal argument on the new material as promptly as possible. Lilly is prepared to file its supplemental briefing by the end of this week.

When Lilly filed its Reply Brief in Support of Summary Judgment, the State had not identified any evidence supporting its Unfair Trade Practice Consumer Protection Act (UTPCPA) claim. On Friday, the State submitted a Supplemental Exhibit to its Opposition to Summary Judgment, comprised of supplemental responses to interrogatories, in which the State discloses for the first time in any pleading that it is claiming that every single Zyprexa prescription in Alaska violates the Act because of the content of the FDA approved warning. This formulation of the State's UTPCPA claim raises constitutional and statutory preemption issues that must be addressed by this Court. The State has also identified, as evidence relating to summary judgment, the interactions between Lilly sales representatives and physicians that it alleges are violations of the Act. Lilly is entitled to respond to this new matter as well.

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

For the foregoing reasons, Lilly seeks leave to file supplemental briefing in support of its Summary Judgment Motion.

DATED this 28th day of January, 2008.

PEPPER HAMILTON LLP
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 January 28, 2008, a copy of the foregoing was served by hand-delivery on:

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

_____
Nabci L. Briggs-Taff, CPS, PLS
009867.0038/162848.1

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

MOTION FOR EXPEDITED CONSIDERATION

COMES NOW defendant, by and through counsel, and hereby moves, pursuant to Civil Rule 77(g), for expedited consideration of its Motion to File Supplemental Brief. Defendant respectfully requests that the Court rule on the underlying Motion to File Supplemental Brief no later than January 30, 2008. This Motion is supported by the attached affidavit of Brewster H. Jamieson.

DATED this 28th day of January, 2008.

PEPPER HAMILTON LLP
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

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

I certify that on January 28, 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

_____
Nancy L. Burgstaff, CP, PLS
009867.0038/162848.1

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

AFFIDAVIT OF BREWSTER H. JAMIESON

STATE OF ALASKA)
) ss.
THIRD JUDICIAL DISTRICT)

I, Brewster H. Jamieson, being first duly sworn, states as follows:

1. I am an attorney with Lane Powell LLC, counsel for defendant Eli Lilly and Company, and have personal knowledge of the contents of this affidavit. This affidavit is filed in support of the Motion for Expedited Consideration, as well as defendant's underlying Motion for Leave to File Supplemental Brief.

2. For the reasons stated in the Motion for Leave to File Supplemental Brief, the need for supplemental briefing first became apparent on Friday, January 25, 2008 upon receipt of the State of Alaska's Supplemental Exhibit to its Opposition to Summary Judgment, in which the State discloses for the first time in any pleading that it is claiming that every single Zyprexa prescription in Alaska violates the Act because of the content of the FDA approved warning. This formulation of the State's UTPCPA claim raises constitutional and statutory preemption issues that must be addressed by this Court.

3. Lilly's Motion for Leave to File Supplemental Brief must be heard and decided on shortened time, since there is insufficient time to proceed on this motion, as well as the supplemental briefing that Lilly intends to file, in the approximately five weeks

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
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Telephone 907.277.9511 Facsimile 907.276.2631

remaining before trial. For this reason, Lilly respectfully moves this court to allow Lilly to file is supplemental brief, and to set an expedited briefing schedule on this issue no later than January 30, 2008.

4. I have this date provided telephonic notice of this motion to Eric T. Sanders prior to its filing, and service of this motion has been made by hand and email.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Brewster H. Jamieson

SUBSCRIBED AND SWORN TO this 28th day of January, 2008.

Notary in and for the State of Alaska
My commission expires August 15, 2010

I certify that on January 28 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 99501-2911

Robert L. Bigger[illegible], CP[illegible], PLS
009867.0058/162855.1

NANCY L. BIGGERSTAFF NOTARY PUBLIC STATE OF ALASKA My Commission Expires Aug 15, 2010

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

NOTICE OF FILING SUPPLEMENTAL PAGE 77 UNDER SEAL

On this date the State of Alaska is filing a pleading titled "Supplemental Page 77 to Plaintiff's Trial Deposition Designations." Because this page may be confidential under the Court's April 6, 2007 oral ruling, the State of Alaska is submitting this page under seal.

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

Filed in the Trial Courts
STATE OF ALASKA, THIRD DISTRICT
JAN 25 2008
Clerk of the Trial Courts
By _____ Deputy

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

NOTICE OF FILING SUPPLEMENTAL EXHIBITS IN OPPOSITION TO LILLY'S MOTION FOR SUMMARY JUDGMENT UNDER SEAL

On this date the State of Alaska is filing a pleading titled "Notice of Filing Supplemental Exhibits in Opposition to Lilly's Motion for Summary Judgment." Because the exhibits filed with these pleadings may be confidential documents under the Court's April 6, 2007 oral ruling, the State of Alaska is submitting the attached exhibits under seal.

/

/

/

Separate Envelope / Separate

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

001920

A B C D E F

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

NOTICE OF FILING SUPPLEMENTAL EXHIBITS IN OPPOSITION TO LILLY'S MOTION FOR SUMMARY JUDGMENT

Lilly's Reply to Plaintiff's Opposition to Defendant's Motion for Summary Judgment, filed last week, devotes the first seven pages to allegations that the State has failed to provide meaningful discovery concerning the UTPA claim. The Reply makes reference to a recent ruling by the Discovery Master, which occurred after the State filed its Opposition.

As the State's Opposition asserted, Lilly's allegations about discovery problems, even if true, would not be a basis for summary judgment. Moreover, recent discovery responses by the State to Lilly, due and served yesterday in response to the Discovery Master's Order, demonstrate that Lilly's assertions are untrue: The State has provided substantial detailed information to Lilly to explain the factual bases for its UTPA claims.

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

As supplemental exhibits to its opposition to Lilly's summary judgment motion, the State provides a copy of its Supplemental Responses to Defendant's Fourth Set of Interrogatories, which were due and served on Lilly yesterday, along with a very small sample of the more than 500 pages of "call notes" that the State provided to Lilly with its interrogatory responses, each of which is evidence of a contact between a Lilly representative promoting Zyprexa to an Alaska physician.

DATED this 22 day of January, 2008.

FELDMAN ORLANSKY & SANDERS

By _____
Eric T. Sanders
Alaska Bar No. 7510085

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
5664 South Green Street
Salt Lake City, UT 84123
(801) 266-0999

RICHARDSON, PATRICK, WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
Christiaan A. Marcum
P.O. Box 1007
Mt. Pleasant, SC 29465
(843) 727-6500
Counsel for Plaintiff

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

Certificate of Service

I hereby certify that a true and correct copy of the foregoing **Notice of Filing Supplemental Exhibits in Opposition to Lilly's Motion for Summary Judgment** was served by messenger on:

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

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

By Annette R. Carter
Date 1.25.08

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

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 reviewed the defendant's Motion for Nonresident Attorney for Permission to Appear and Participate, as well as all responses thereto;

HEREBY ORDERS that George A. Lehner of Pepper Hamilton LLP, 600 Fourteenth Street, Washington, DC 20005-2004, phone number 202-220-1416, may appear and participate as attorney for defendant in the above-captioned action in association with Brewster H. Jamieson.

DATED this 24 day of January/~~February~~, 2008.

Mark Rindner

The Honorable Mark Rindner

I certify that on January 22, 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 99501-1911

Nanci L. Bjorkstaff, ABA, PLS
009867.0038/162778.1

I certify that on 1-25-08 a copy of the above was mailed to each of the following at their addresses of record:

Jamieson Sanders

Administrative Assistant

001924

JAN 23 2008

JAN 23 2008

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

A B C D E F

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 NONRESIDENT ATTORNEY FOR PERMISSION TO APPEAR AND PARTICIPATE

THIS COURT having reviewed the defendant's Motion for Nonresident Attorney for Permission to Appear and Participate, as well as all responses thereto;

HEREBY ORDERS that Nina M. Gussack of Pepper Hamilton LLP, Two Logan Square, Suite 3000, Philadelphia, Pennsylvania 19103-2799, phone 215-981-4000, may appear and participate as attorney for defendant in the above-captioned action in association with Brewster H. Jamieson.

DATED this 24 day of January/~~February~~, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on January 22, 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

Nanci L. Bigenstaff, CPC, PLS
009867.0038\158004.1

I certify that on 1-25-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

001925

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

THIS COURT having reviewed the defendant's Motion for Nonresident Attorney for Permission to Appear and Participate, as well as all responses thereto;

HEREBY ORDERS that Andrew Edward Kantra of Pepper Hamilton LLP, Two Logan Square, Suite 3000, Philadelphia, Pennsylvania 19103-2799, phone number 215-981-4186, may appear and participate as attorney for defendant in the above-captioned action in association with Brewster H. Jamieson.

DATED this 24 day of January/~~February~~, 2008.

Mark Rindner

The Honorable Mark Rindner

I certify that on January 22 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

Nancy L. Bigelstaff, CP, FLS
009867.0038/162780.1

I certify that on 1-25-08 a copy of the above was mailed to each of the following at their addresses of record:

Sanders Jamieson

Administrative Assistant

001926

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

JAN 23 2008

A B C D E F

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 OF NONRESIDENT ATTORNEY FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska R. Civ. P. 81(a)(2), defendant moves to permit Andrew Edward Kantra of Pepper Hamilton LLP, Two Logan Square, Suite 3000, Philadelphia, Pennsylvania 19103-2799, phone number 215-981-4186, to appear and participate as attorney for defendant in the above-captioned action. Mr. Kantra, as shown by the attached certificate, is a member in good standing of the Bar of the Commonwealth of Pennsylvania and is not otherwise disqualified from practicing law in the State of Alaska.

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

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

DATED this 22nd day of January, 2008.

LANE POWELL LLC
Attorneys for Defendant

By _____
for Brewster H. Jamieson, ASBA No. 8411122

I certify that on January 22, 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

_____
Nanci L. Bruggestaf, CP, PLS
009867.0038/162779.1

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

A B C D E F

Supreme Court of Pennsylvania

CERTIFICATE OF GOOD STANDING

Andrew Edward Kantra, Esq.

DATE OF ADMISSION

August 10, 1992

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

Witness my hand and official seal
Dated: January 11, 2008

Patricia A. Johnson
Chief Clerk

001928

A B C D E F

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	Assoc. w/ Brewster Jamieson #8411122		
	Case#3AN-06-05630		
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NRESIDENT
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By /Brewster Jamieson/
for Brewster H. Jamieson, ASBA No. 8411122

I certify that on January 22, 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

/Nancy L. Bigenwald/
Nancy L. Bigenwald, CPS to JGS
009867.0038/158004.1

001929

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Clerk of the Trial Courts

ALASKA BAR ASSOCIATION
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George A. Lehner NA Assoc w/ Brewster Jamieson #8411122		
Case#3AN-06-05630		
CK# 663980		
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C. Feltman

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THE STATE OF ALASKA
T AT ANCHORAGE

e No. 3AN-06-05630 CI

MOTION OF NONRESIDENT ATTORNEY FOR PERMISSION TO APPEAR AND PARTICIPATE

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Northern Lights Boulevard, Suite 301,
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Jamieson consents to this association.
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POWELL LLC
eys for Defendant

By
for Brewster H. Jamieson, ASBA No. 8411122

I certify that on January 22, 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

Nanci L. Bigenstaff, CP, PLS
009867.0038/162779.1

001930

A B C D E F

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 OF NONRESIDENT ATTORNEY FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska R. Civ. P. 81(a)(2), defendant moves to permit George A. Lehner of Pepper Hamilton LLP, 600 Fourteenth Street, Washington, DC 20005-2004, phone number 202-220-1416, to appear and participate as attorney for defendant in the above-captioned action. Mr. Lehner, as shown by the attached certificate, is a member in good standing of the of the District of Columbia Court of Appeals, and is not otherwise disqualified from practicing law in the State of Alaska.

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

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

DATED this 22nd day of January, 2008.

LANE POWELL LLC
Attorneys for Defendant

By
Brewster H. Jamieson, ASBA No. 8411122

I certify that on January 22, 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

Nancy L. Bumgardner, CPS
009867.0038/162776.1

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

District of Columbia Court of Appeals
Committee on Admissions
500 Indiana Avenue, N.W. — Room 4200
Washington, D. C. 20001
202 / 879-2710

I, GARLAND PINKSTON, JR., Clerk of the District of Columbia Court of Appeals, do hereby certify that

George A. Lehner

was on the 28th day of September, 1979 duly qualified and admitted as an attorney and counselor and entitled to practice before this Court and is, on the date indicated below, an active member in good standing of this Bar.

In Testimony Whereof, I have hereunto subscribed my name and affixed the seal of this Court at the City of Washington, D.C., on January 8, 2008.

GARLAND PINKSTON, JR., CLERK

By: _____
Deputy Clerk

001932

A B C D E F

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 OF NONRESIDENT ATTORNEY FOR PERMISSION TO APPEAR AND PARTICIPATE

Pursuant to Alaska R. Civ. P. 81(a)(2), defendant moves to permit Nina M. Gussack of Pepper Hamilton LLP, Two Logan Square, Suite 3000, Philadelphia, Pennsylvania 19103-2799, phone 215-981-4950, to appear and participate as attorney for defendant in the above-captioned action. Ms. Gussack, as shown by the attached certificate, is a member in good standing of the Bar of the Commonwealth of Pennsylvania, and is not otherwise disqualified from practicing law in the State of Alaska.

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

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

DATED this 22nd day of January, 2008.

LANE POWELL LLC
Attorneys for Defendant

By _____
for Brewster H. Jamieson, ASBA No. 8411122

I certify that on January 22, 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

_____
Nancy L. Bigelow, CPS, RPS
009867.0038/158004.1

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

CERTIFICATE OF GOOD STANDING

UNITED STATES OF AMERICA

EASTERN DISTRICT OF PENNSYLVANIA }.

I, Michael E. Kunz, Clerk of the United States District Court for the Eastern District of Pennsylvania,

DO HEREBY CERTIFY That Nina M. Gussack, Bar #31054 was duly admitted to practice in said Court on July 2, 1980, and is in good standing as a member of the bar of said Court.

DATED at Philadelphia, Pennsylvania

on January 14, 2008

MICHAEL E. KUNZ
Clerk of Court

BY _____
Sheila M. Jeffers
Deputy Clerk

001934

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JAN 23 2008

Clerk of the Trial Courts

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**F NONRESIDENT
FOR PERMISSION
AND PARTICIPATE**

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	Case# 3AN-06-05630		
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...Defendant

By
Sar Brewster H. Jamieson, ASBA No. 8411122

I certify that on January 22, 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

Nanci L. Bigenstaff, CPS/PLS
009867.0038/162776.1

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

001935

A B C D E F

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 PLEADING AND EXHIBITS UNDER SEAL

On this date the State of Alaska is filing a pleading titled "Plaintiff's Trial Deposition Designations." 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 22 day of January, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

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

A B C D E F

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

RICHARDSON, PATRICK, WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
David L. Suggs
Christiaan A Marcum
Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Notice of Filing Pleading and Exhibits Under Seal** was served by messenger on:

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

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

By Annette R. Carter
Date 1-22-08

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

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

Filed in the Trial Courts
STATE OF ALASKA, THIRD DISTRICT
JAN 22 2008
Clerk of the Trial Courts
By _____ Deputy

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ELI LILLY'S NOTICE OF FILING DEPOSITION DESIGNATIONS UNDER SEAL

Defendant Eli Lilly, by and through counsel of record, files its deposition designation pages, Exhibits A-J, under seal, attached to this notice. Portions of the deposition designations may be confidential under the Court's April 6, 2007 oral ruling.

DATED this 22 day of January, 2008.

PEPPER HAMILTON LLP
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 January 22, 2008, a copy of the foregoing was served by hand-delivery on:

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

_____

009867.0038/162792.1

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
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Telephone 907.277.9511 Facsimile 907.276.2631

A B C D E F

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

Upon consideration of Defendant Eli Lilly and Company ("Lilly")'s Motion for Leave to File Overlength Reply, and any response thereto, it is hereby ORDERED that:

Defendant's Motion for Leave to File Overlength Reply is GRANTED.

ORDERED this 18 day of January, 2008.

The Honorable Mark Rindner
Superior Court Judge

I certify that on January 17, 2008, a copy of the foregoing was served by and hand-delivery on:

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

009867.0038/162746.1

I certify that on 1-18-07 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

001939

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

DEFENDANT'S MOTION FOR LEAVE TO FILE OVERLENGTH REPLY

COMES NOW defendant Eli Lilly and Company ("Lilly"), by and through counsel of record, Lane Powell LLC, and hereby moves the Court for leave to file Lilly's overlength (15 pages) Reply to its Motion for Summary Judgment, filed herewith.

The Uniform Pretrial Order limits replies to oppositions to 10 pages. The Reply filed herewith exceeds the 10 pages based on a combination of the many arguments raised for the first time in the State's Opposition, the recent (January 14, 2008) Order from the Discovery Master confirming the State's lack of production of evidence to support its UTPA claim, and the State's recent dismissal of its defective design claim, apparently in response to Lilly's motion for summary judgment.

In particular, the two developments (dismissal of defective design claim and Discovery Master's Order) post-filing of Lilly's Motion for Summary Judgment have required additional discussion and analysis in the Reply. Based on these reasons and the omnipresent reason that this case includes numerous and complex legal issues, Lilly has good

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cause to request an overlength reply. Therefore, Lilly respectfully requests that the Court accept its overlength reply.

DATED this 17th day of January, 2008.

PEPPER HAMILTON LLP
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 January 17, 2008, a copy of the foregoing was served by hand-delivery on:

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

_____

605867.0038/162745.1

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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 REPLY TO PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

COMES NOW Defendant Eli Lilly and Company ("Lilly"), by and through counsel of record, Lane Powell LLC, and hereby submits its reply to plaintiff's opposition to defendant's motion for summary judgment as follows:

I. INTRODUCTION

Throughout this case, the State of Alaska (the "State") has avoided matching its allegations with evidence. Time has run out on that strategy.

In its summary judgment motion, Lilly urged the Court to dismiss the State's Unfair Trade Practice Act (UTPA) claims because the State could not even describe Lilly's alleged violations, much less point to admissible evidence demonstrating that they had occurred. The State's failure to adduce admissible evidence was underscored this week by Discovery Master Hensley's finding that the State has not, in its discovery responses, identified any communications that violated the Act.[1] Nor has the State produced any evidence of such communications in its response to Lilly's summary judgment motion. Although it strenuously argues that Lilly violated the State's UTPA by promoting Zyprexa for non-indicated (off-label) uses in Alaska, the State has failed to identify even one piece of

[1] Exhibit A, Discovery Master Order re Lilly's Motion to Compel 12/13/07 (Fourth Set of Int's and RFP's), January 14, 2008 ("Discovery Master Order.")

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evidence – not one deposition excerpt, affidavit, or document – that demonstrates that this occurred.

Lilly's motion also challenges the State to demonstrate how it will prove that alleged UTPA violations or inadequate warnings caused Alaska physicians to prescribe Zyprexa when they otherwise would not have. The State continues to insist that this element of its case can be satisfied with some form of aggregate evidence, a position rejected recently in *In re Rezulin*, the most relevant case cited by either party in this proceeding. On this basis alone, these claims should be dismissed. But because this is summary judgment, this Court must move beyond the theoretical, and examine the actual "aggregate" evidence that the State intends to present to a jury as proof of Alaska prescribers' behavior. The State has identified just two documents – a Lilly document relating to physicians in Japan, and one expert's report – as its evidence of record to meet its burden that Alaska physicians fell victim to allegedly inadequate warnings and off-label promotion to prescribe Zyprexa instead of other medications. This evidence is not even relevant to the behavior of Alaska prescribers, much less sufficient to meet the State's burden of causation across all Zyprexa prescriptions written for Alaska Medicaid recipients.

While rushing this case to trial, the State has never mustered the evidence it promised. It still has not produced its Medicaid database, the purported centerpiece of its case that Zyprexa harmed Alaska Medicaid recipients. It began this case by alleging that Lilly introduced "the *defective drug Zyprexa* into the State's Medicaid population,"[2] and urged a phased proceeding, where the first phase would address whether Zyprexa was a

[2] State's Memorandum Describing Its Claims and Proofs at 1 (emphasis added).

LANE POWELL LLC
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Anchorage, Alaska 99503-2648
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defective product.[3] However, once Lilly challenged the State in its summary judgment motion to identify the *evidence* that supported this central claim of the State's lawsuit, the State voluntarily dismissed its design defect claim.[4] Similarly, after repeatedly asserting that Lilly had defrauded prescribers, the State dismissed its fraudulent and negligent misrepresentation claims.

The State has failed to support its two remaining claims, failure to warn and UTPA claims, with evidence and they should be dismissed. The State has insisted from the start that it could prove that physicians were misled and patients were harmed, without ever calling individual patients and physicians as witnesses. On the eve of trial, however, it has become clear that the State has nothing to take their place. In the absence of competent, admissible evidence creating a genuine issue of material fact that Lilly promoted Zyprexa for non-indicated uses to Alaska physicians, or that such promotion or the content of Lilly's warnings caused Alaska physicians to prescribe Zyprexa when they otherwise would not have, this Court should grant summary judgment on the State's remaining causes of actions.

II. ARGUMENT

A. Lilly Has Demonstrated That There Is No Genuine Issue of Material Fact as to Whether It Violated the State's Unfair Trade Practices Act.

The State has failed to identify admissible evidence regarding even one Lilly action in Alaska that would satisfy its burden of demonstrating a genuine issue of material

[3] Exhibit B, Transcript of October 24, 2007 Status Conference at 11, 15 and 18.
[4] State's Opposition to Summary Judgment at 1.

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fact regarding whether Lilly violated Alaska's UTPA.[5] The Discovery Master's ruling confirmed that "the State has not identified the particular sales calls or other communications that it alleges violated the Act."[6] The State had the opportunity and obligation to produce evidence of these communications in response to Lilly's summary judgment motion; having failed to do so, its UTPA claim should be dismissed.

The civil penalties sought by the State are a "drastic remedy."[7] The imposition of such penalties – or even a trial on the issue – when the State has not demonstrated that its claims have a basis in admissible evidence "would transgress due process and fundamental fairness."[8] Alaska courts have awarded penalties where the jury has heard specific evidence of each violation alleged by the State. For example, in *Lee v. State*, the State established UTPA violations with evidence of specific advertisements the defendant placed in the *Anchorage Daily News*, specific representations on the defendant's website, and specific

---

[5] *Martech Constr. Co. v. Ogden Envtl. Servs*, 852 P.2d 1146, 1149 n.7 (Alaska 1993). The State makes the spurious assertion that it can continue to avoid pointing to any evidence in support of its claims because, it argues, Lilly has not met its initial burden of proving the absence of genuine factual disputes. State's Opposition at 19 n.48 (citing to *Shade v. Co & Anglo Alaska Serv. Corp.*, 901 P.2d 434, 437 (Alaska 1995)). Lilly has met the necessary burden, by citing the State's discovery responses, in which the State failed to identify any specific conduct that occurred in Alaska supporting a UTPA claim. Lilly's Motion for Summary Judgment at 13, a failing confirmed by the Discovery Master's Order. In the *Shade* case relied upon by the State, it was undisputed that equipment manufactured by the defendant had malfunctioned, injuring the plaintiff. *Id.* at 435. Nothing equivalent has been established here. Absent even a basic description of the conduct at issue in this case, Lilly is not required to prove a negative.

[6] Exhibit A, Discovery Master Order at 2.

[7] *First Amer. Bank v. Dole*, 763 F.2d 644, 651 (4th Cir. 1985) ("The quasi-criminal nature of civil penalties counsels caution and pause before we resort to such a drastic remedy.").

[8] *Smith v. Maryland*, 46 Md. App. 78, 90 415 A.20 651, 658 (1980) (vacating finding of eighty violations of Consumer Protection Act for lack of admissible evidence).

statements contained in handouts for a specific presentation.[9] In *State v. Anchorage-Nissan, Inc.*, the State based its UTPA claims on evidence of specific representations and omissions by the defendant to certain individuals in connection with the purchase of specific automobiles – for example, that Anchorage-Nissan employee Shawn Gibbons sold a 1985 Chevrolet Blazer to Monte Parish in April 1992 with an odometer altered from 98,887 miles to approximately 59,000 miles.[10]

The State has not mustered anything comparable to the evidence that supported UTPA violations in *Lee* and *Anchorage-Nissan*. The State alleges that Lilly violated the act through off-label promotion "such as promoting Zyprexa to treat depression and insomnia."[11] Faced with this motion, the State's burden was, for each alleged violation, to submit witness affidavits, deposition testimony, or documents demonstrating that, on a particular date, a Lilly sales representative told an Alaska physician that Zyprexa effectively treats those non-indicated uses, or equivalent evidence of some other Lilly conduct that constituted the alleged off-label promotion. The State insists that it "plainly has evidence to satisfy the basic elements of a UTPA violation,"[12] but does not identify a single piece of evidence that

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[9] *Lee v. State*, 141 P.3d 342, 345-46, 351 (Alaska 2006).

[10] *State v. Anchorage-Nissan, Inc.*, 941 P.2d 1229, 1231-32 (Alaska 1997).

[11] State's Opposition to Summary Judgment at 10. The precise language used by the State is that its claims will "focus" on off-label promotion. That State should not be allowed any semantic reservoir to maintain claims that it is not "focusing" on, including any claims of promotion relating to on-label use. *See also* State's Memorandum in Support of Bifurcation at 5 ("The essence of the State's Unfair Trade Practices Act claim will be that, in addition to the failings already described, Lilly improperly promoted Zyprexa for uses which were not appropriate or approved by the FDA.").

[12] State's Opposition to Summary Judgment at 9.

demonstrates promotional activity, of any kind, in Alaska. Accordingly, the Court should dismiss the State's claims.

The only documents that the State does refer to in its response are the following:

- Excerpts of Lilly employee Robin Wojcieszek's deposition (Exh. 1 to State's Opposition);
- March 28, 2007 letter from FDA to Lilly (Exh. 2 to State's Opposition);
- October 5, 2007 "Dear Doctor" letter (Exh. 3 to State's Opposition);
- Expert witness Report and Declaration of William Wirshing, M.D. (Exh. 4 to State's Opposition);
- February 2004 article in Diabetes Care (Exh. 5 to State's Opposition);
- July 1, 2002 Lilly memorandum regarding label change in Japan (Exh. 6 to State's Opposition);
- January 2007 article in Pharmacotherapy (Exh. A to State's Memorandum Describing Its Claims and Proofs); and
- Excerpt from Reference Manual on Scientific Evidence (Exh. B to State's Memorandum Describing Its Claims and Proofs).[13]

The State provides no explanation of how these documents demonstrate promotional activities *in Alaska*, and, in fact, they do not.[14] These exhibits address Zyprexa's safety profile and the content of the Zyprexa warning, which, as the Discovery Master recognized, is a distinct factual issue from whether Lilly made "particular sales calls or other

[13] State's Opposition at 20 n.50.

[14] The October 5, 2007 Dear Doctor letter, communicating changes to the Zyprexa label, is the only exhibit that has any relation to Alaska – it went to prescribers throughout the country – but the State does not argue that that letter constitutes a promotional or marketing action or is a violation of the Act. Nor could it, as the content of prescription drug labels is vested to the sole jurisdiction of the FDA, and any State statute purporting to control the content of the label would be preempted. *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 789 (8th Cir. 2001) ("[T]he FDA has continuing authority and responsibility to control the content of any information or warnings…"). Such a claim would also be preempted under the UTPA, AS § 45.50.481.

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communications that [allegedly] violated the Act."[15] None of the documents address this essential component of the State's UTPA claim. A party cannot just attach *anything* to its summary judgment response, and claim that it should avoid summary judgment.

This case is long past the point when the State should be allowed to rest on vague generalities about the types of things Lilly allegedly did wrong. The jury can only make the determination that Lilly violated Alaska's UTPA based on evidence of who did what to whom (and where and when). The jury must be presented evidence that would allow a separate verdict for each alleged violation for which the State seeks a penalty, and for which it will seek to recover actual damages in the second phase.[16] Having failed to identify such evidence, the State has no basis to contend that there is a material issue of fact that Lilly engaged in improper off-label promotion giving rise to a UTPA violation.

B. The State Cannot Demonstrate That a Failure to Warn or UTPA Violation Proximately Caused Its Injuries.

In its Opposition to Lilly's Motion, the State agrees with Lilly that in order to recover actual damages under either surviving claim (failure to warn or UTPA), it must prove that absent the alleged improper warning or off-label promotion, the physician would not have written the prescription;[17] the only dispute between the parties is what evidence will satisfy this burden. The State's plan to rely on aggregate evidence rather than evidence of

[15] Exhibit A, Discovery Master Order at 2.

[16] *See, e.g., Anchorage Nissan*, 941 P.2d at 1240-41 (court issued nine separate jury instructions for the nine separate transactions giving rise to the alleged UTPA violations).

[17] State's Opposition to the Motion for Summary Judgment at 4, 9-10 ("The State's ascertainable losses include the costs it paid for prescriptions for off-label uses that *were written as a result of Lilly's deceptive promotions…*") (emphasis added).

any particular physician's testimony[18] embodies the type of "collective reliance" rejected by courts in other pharmaceutical cases, including the newly issued case cited in Lilly's motion.[19] In addition, even if this novel form of proof were valid, the actual evidence the State brings forth to establish proximate causation is insufficient to survive summary judgment.

1. State Asserts a Collective Reliance Theory Analogous to a Fraud-on-the-Market Theory to Prove Causation

In its motion for summary judgment, Lilly argued that the State's method for proving that Lilly's alleged misconduct proximately caused physicians to write prescriptions was based on a "fraud on the market" theory, rejected by numerous courts, including most recently the Southern District of New York in *In re Rezulin*. In response, the State argues that fraud-on-the-market damage theories should only be rejected in actions involving prescription drug overpricing.[20] This argument is wrong.

Rezulin was not an overpricing case, but, instead, involved claims for "extra prescriptions" and medical costs, the same injuries the State asserts it suffered here.[21] The State complains that the *Rezulin* decision is "poorly reasoned,"[22] and that Judge Kaplan "went astray"[23] in finding that the State of Louisiana's claims for extra prescriptions and

[18] State's Opposition to Summary Judgment at 13-14.

[19] *See, e.g., In re Rezulin Products Liability Litigation*, No. 05 Civ 8397, 2007 U.S. Dist. LEXIS 86451, at *12 (S.D.N.Y. Nov. 26, 2007).

[20] State's Opposition to Motion for Summary Judgment at 11-12.

[21] *In re Rezulin*, 2007 U.S. Dist. LEXIS 86451, at *1 ("Plaintiff here seeks to recover amounts paid to fill Rezulin prescriptions for Louisiana Medicaid recipients and to treat their illnesses allegedly caused by Rezulin.").

[22] State's Opposition to Motion for Summary Judgment at 10.

[23] State's Opposition to Motion for Summary Judgment at 17.

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medical costs depended on a fraud-on-the-market theory to prove that the alleged misconduct caused physicians to write Rezulin prescriptions. This Court will make its own judgment about Judge Kaplan's reasoning.[24] In any event, the State does not dispute that *Rezulin* stands as the only reported case where a court evaluated whether a state can recover damages for medical costs without proof of why specific physicians chose to prescribe a drug to specific patients, the very question the Court must resolve here.

The only case that the State has identified that *allowed* aggregate evidence of physician prescribing behavior – *In re Zyprexa* -- was an overpricing case.[25] Accordingly, that decision "has no bearing on this case, since the State is not contending that Lilly's misrepresentations and concealments artificially inflated the price of Zyprexa."[26] In holding that the plaintiffs could proceed with aggregate evidence of causation, Judge Weinstein made clear that the plaintiffs' overpricing claims were "not dependent on any physician's decision or injury suffered by those who ultimately ingested Zyprexa."[27]

By contrast, the State's claims for actual damages are entirely dependent on establishing that physicians' decisions to write Zyprexa prescriptions occurred "as a result of Lilly's deceptive promotions" and led to medical injuries.[28] Whatever utility aggregate evidence has for establishing whether the price paid for a medication was too high, it cannot

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[24] Fraud-on-the-market causation was also rejected in *Coleman v. Danek Medical*, 43 F. Supp. 2d 629, 634 n.4 (S.D. Miss. 1998), where an individual plaintiff sought personal injury damages.

[25] *In re Zyprexa Products Liability Litigation*, 493 F. Supp. 2d 571, 578 (E.D.N.Y. 2007).

[26] State's Opposition to Motion for Summary Judgment at 12.

[27] *In re Zyprexa Products Liability Litigation*, 493 F. Supp. 2d at 577.

[28] State's Opposition to Motion for Summary Judgment at 9.

account for the physician-specific knowledge or patient-specific factors that bear on the determination of what effect the FDA-mandated warning or the company's promotional behavior had on the decision to write particular prescriptions.[29] The evidence of record in this case shows that, as new information about the medication developed, and the FDA-approved label was changed, Zyprexa has continued to be prescribed in Alaska, including to Medicaid recipients,[30] by the Alaska physicians who have been deposed in this case,[31] and to patients *involuntarily medicated* with Zyprexa at the State mental health hospital.[32]

In the only other case cited by the State, *In re Neurontin Marketing & Sales Practices Litigation,* the court did not accept the aggregate evidence proffered by the plaintiffs to demonstrate causation.[33] That court observed that the aggregate causation methodology proffered by the plaintiffs at the class certification stage could not distinguish between physicians that prescribed Neurontin based on off-label promotion "as opposed to lawful off-label prescribing by a doctor who is exercising his own medical judgment," and

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[29] *See United Food & Commercial Workers Central Pennsylvania v. Amgen, Inc.*, 2007 WL 4144676, *6 (N.D. Cal. Nov. 13, 1997)("in order to show causation, Plaintiff will have to prove, for each prescription for which it seeks a refund, that the prescription was for an off-label use, and that the prescribing physician based his or her decision to prescribe for an off-label use on a communication from Amgen, rather than his or her clinical experience, training and independent medical judgment").

[30] Exhibit C, Deposition of David Campana at 304.

[31] Exhibit D, Deposition of Duane Hopson, M.D., at 39, 58 and 65-66; Exhibit E, Deposition of Lucy Ljubicich Curtiss, M.D., at 31.

[32] Exhibit D, Deposition of Duane Hopson, M.D., at 28.

[33] 244 F.R.D. 84 (D. Mass. 2004). The *Neurontin* court did provide the plaintiffs a second chance to develop expert evidence that would allow the case to proceed. That, as yet unrealized, opportunity does not provide legal support for the State's case.

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could not "distinguish between payments for on- and off-label prescriptions, or among indications,"[34] the same problems the State confronts in this case.

2. The State's Offer of Proof on Causation Is Insufficient to Survive Summary Judgment

Even if the Court were disposed to allow some form of aggregate evidence to prove that Lilly's conduct caused Alaska physicians to write Zyprexa prescriptions that they otherwise would not have, the evidence proffered by the State to avoid summary judgment has no evidentiary relationship to the behavior of Alaska prescribers in response to the warnings or Lilly's promotional practices. The only evidence that the State plans to present to the jury are a memorandum written by Lilly employees regarding Zyprexa sales in Japan, and excerpts from an expert's report.[35] Neither document creates a material issue of fact on the issue of whether Lilly's conduct caused physicians to write prescriptions that they otherwise would not have.

The memorandum, Exhibit 6 to the State's Motion, merely summarizes one Lilly employee's perception of Japanese physicians' reaction to a label change in Japan that was different from any label change made in the United States. Even if this document was competent evidence of actual events in Japan (as opposed to one lay individual's perception),

[34] *Id.* at 113, 115.

[35] State's Opposition to Motion for Summary Judgment at 5-6 and n.14 and n.15.

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it hardly proves how Alaska physicians made prescribing decisions under a different set of circumstances.[36] The concept of relevance is not nearly that elastic, in any jurisdiction.

Dr. Wirshing's speculation about what a "reasonable physician" would have done if the warning had been different[37] is also irrelevant to this inquiry. The State does not argue, and there is no case law supporting the assertion, that the determination of whether the content of a warning or an off-label promotional activity caused a physician to prescribe a medication is controlled by an objective or reasonable physician standard, which could be established by expert testimony. Case after case holds that this is a subjective physician-specific, patient-based determination.[38] While there is no case law in Alaska directly addressing this question, there is also no case law suggesting that Alaska would reject this common sense proposition.[39] The law demands an individualized determination of what proximately caused each physician to prescribe a medication because a physician's prescription behavior rests on myriad factors, including what the physician knew aside from

[36] *See, e.g., Alizal v. MVM, Inc.*, 40 F. Supp. 2d 752, 756 n.2 (E.D. Va. 1998) (declining to take judicial notice of a wide-spread reaction to an event because such evidence would be inadmissible to prove the reaction of a specific group or individual); *see also State v. McQuillen*, 689 P.2d 822, 828 (Kan. 1984) ("[E]vidence of reactions of other people does not assist the jury in its fact finding task."); *State v. Saldana*, 324 N.W.2d 227, 230 (Minn. 1982) (same).

[37] Exh. 4 to State's Opposition at 49-50.

[38] *See, e.g., Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 383-84 (D.N.J. 2004); *Kernke v. Menniger Clinic, Inc.*, 173 F. Supp. 2d 1117, 1123 (D. Kan. 2001); *Huntman v. Danek Med., Inc.*, No. 97-2155, 1998 U.S. Dist. LEXIS 13431, at *19 (S.D. Cal. July 27, 1998); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1161 (D. Or. 1989); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 349-50 (Minn. Ct. App. 2001).

[39] The State interprets *Shanks* to apply an objective standard for the adequacy of the warning, but not for the determination of whether an inadequate warning proximately caused a prescription to be written. State's Opposition to Motion for Summary Judgment at 13-14.

what the company communicated, and the unique circumstances of the patient being treated.[40]

Even if one could theoretically apply generalized evidence to prove the element of proximate causation, the evidence relied upon by the State could not accomplish it. The assertion from Dr. Wirshing's expert report relied upon by the State, that a "reasonably prudent physician wouldn't use Zyprexa as a first line treatment if all information had been disclosed," was discarded by Doctor Wirshing at his deposition:

> **Question:** And so there is a class of patients or at least people who may present to you for whom you would prescribe Zyprexa as sort of the first line treatment. Is that correct?
>
> **Answer:** Sure.[41]

Furthermore, Dr. Wirshing's expert report says nothing about how to determine causation when Zyprexa was used by a physician as a second- or third-line treatment, which surely describes many of the prescriptions at issue in this case. Numerous Alaska Medicaid recipients used Zyprexa after trying other drugs. The following Medicaid recipients' claims

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[40] *See, e.g., Strumph v. Schering Corp.*, 626 A.2d 1090, 1090 (N.J. 1993) (adopting dissenting opinion from intermediate appellate court which argued for summary judgment for defendant pharmaceutical manufacturer because a lack of proximate cause evidenced by the physician's testimony that his knowledge of the drug at issue came from "his formal education in psychiatry, his review of literature in pharmacology and psychiatry and his own clinical practice" 606 A.2d 1140 (N.J. Sup. Ct. 1992) (Skillman, J. dissenting)); *Nelson v. Wyeth*, No. 1670, 2007 Phila. Ct. Com. Pl. LEXIS 316, at *11 (Pa. Ct. Com. Pl. Dec. 5, 2007) ("Where the prescribing physician bases her decision to prescribe a drug based on clinical experience and medical literature rather than any information supplied by a drug manufacturer, a reasonable jury could not find that the alleged failure to warn was the proximate cause of the plaintiff's injuries."); *see also Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 996 (C.D. Cal. 2001) ("Dr. Trostler's recollection of how he learned about Zoloft is vague. But he did state unequivocally that in making that decision, he did not rely either on any statements Pfizer representatives made to him nor any written materials they may have provided to him.").

[41] Exhibit F, Deposition of William C. Wirshing, M.D., at 162.

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data, for example, show sustained use of Zyprexa after changing from other drugs, an indication that their physicians did not use Zyprexa as a first-line treatment, but may have turned to Zyprexa after the patient failed on a different agent:

Patient ID[42]	Risperdal Start/End		Zyprexa Start/End	
0600440951	3/14/00	6/12/00	8/01/01	11/29/05
0600088939	3/15/00	7/04/00	1/25/01	12/27/06
0600093672	11/02/98	3/27/99	5/17/99	11/14/03

The two meager pieces of evidence supporting the State's collective reliance model cannot address this phenomenon, and provide no explanation for the numerous prescriptions that fit this pattern.

The theory of collective reliance the State plans to use to prove proximate causation, whether labeled as fraud-on-the-market or not, should be rejected. Moreover, even if this theory is theoretically sound, the State has presented no competent evidence to support it. Thus, summary judgment for Lilly is appropriate.

III. CONCLUSION

For the foregoing reasons, and the reasons set forth in Lilly's original motion, Lilly requests that this Court grant summary judgment in favor of Lilly on all of the State's remaining claims.

[42] These examples were extracted from the Medicaid claims data that the State produced to Lilly in this action.

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DATED this 17th day of January, 2008.

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I certify that on January 17, 2008, a copy of the foregoing was served by hand-delivery on:

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January 14, 2008

DISCOVERY MASTER ORDER
LILLY'S MOTION TO COMPEL 12/13/07 (Fourth Set of Int's and RFP's)

The State alleges that "each prescription [of Zyprexa] without an adequate warning" and each "sales call in which the sales representative minimized the hazards [of Zyprexa]" was a separate violation of the Alaska Unfair Trade Practices and Consumer Protection Act. Plaintiff's Response to Defendant's Motion to Compel Discovery at 10. Lilly asked the State to "enumerate each instance in which it alleges that Lilly violated [the Act] and to state the factual bases for each instance, and the resulting ascertainable loss." Lilly Motion to Compel, p. 2. The State argues that it has answered adequately, that it may answer more fully upon completion of discovery, that Lilly will be able to discern the factual bases when the State files its deposition designations and exhibit lists, and that Lilly is not entitled to this detailed information.

McKibben v. Mohawk, 667 P.2d 1223 (Alaska 1983) controls. A party is entitled to discover the factual bases of each of his opponent's claims. Thus, to be responsive to Lilly's request the State must identify each Unfair Trade Practices Act violation it alleges, and describe the nature of the violation, including any communication from Lilly that forms the basis of the alleged violation.

B C D E F

The State's responses, including all incorporated materials, adequately identify the factual bases for inadequate warnings and Lilly's knowledge of the alleged hazards of Zyprexa. But the State has not identified the particular sales calls or other communications that it alleges violated the Act.

The State must answer Lilly's interrogatories on the basis of information the state currently possesses within 10 days. The State must supplement the answers when discovery is complete.

The State's objections to Lilly's Requests for Production are sustained. The State's answers to Lilly's interrogatories will provide Lilly the same information it seeks in the RFP's. The State is not obligated to tell Lilly which documents it believes are relevant to the case. McKibben v. Mohawk, 667 P.2d 1223 (Alaska 1983).

MOTION FOR SANCTIONS, ALLOCATION OF FEES

The State's request for sanctions is DENIED. The parties shall share the Discovery Master Fees for the two recent motions equally. Total fees are $1100.00. Invoice will follow with hard copy.

Dan A. Hensley
Discovery Master

CC: Jamieson, Sanders by E-mail 1/14/08, hard copy to follow

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

STATUS CONFERENCE
BEFORE THE HONORABLE M. RINDNER

Pages 1 - 56
Wednesday, October 24, 2007
2:00 P.M.
Anchorage, Alaska

Court Reporter and Transcriptionist:
Diane M. Bondeson
PACIFIC RIM REPORTING
711 M Street, Suite 4
Anchorage, Alaska 99501

MR. ROTHSCHILD: The data that we're talking about that hasn't been produced yet and will be the subject of later expert reports is not, in the State's case, limited solely to damages. We know that from reading their own explanation in a briefing that went on this summer.

The issues of causation and reliance which Lilly argued had to be proved, you know, patient by patient, prescriber by prescriber, which we still maintain, the State proposes to displace that evidence with the statistical aggregate data. And your ruling was, "Well, they can try that, but that is not limited to damages."

The question of whether Zyprexa caused an increased incidence of certain diseases in the Alaska Medicaid population, that's not an issue simply of damages. That is -- that's the heart of the case.

THE COURT: Right. But as I understand it, what Mr. Sanders is proposing is the bifurcation would be -- again, these are my words, and correct me if I'm putting words in your mouth. But that phase 1 which he proposes to try when we've got our current trial date, would be: Was the product defective? That's what I think your shorthand is for liability.

MR. SANDERS: Can I just tell you what I

THE COURT: What I really hear you slicing it -- Mr. Sanders proposing you slicing it is liability and then causation and damages, perhaps with a causation not in an epidemiological individual case, but I assume -- maybe I'm wrong to assume this, but I'm not sure why you couldn't, in a liability phase, determine if this drug is defective, what kinds of harms generically does it determine and why you'd need information from the State that already isn't gathered in the MDL to be able to -- why you couldn't determine all those things in the first place, because I assume that's what all the MDL cases are all about.

MR. ROTHSCHILD: The MDL cases, as contemplated, are one trial of, you know, the published literature and what's been --

THE COURT: Right, but I assume that the discovery in that case is the same discovery that would be what we're -- is being discussed as a first phase of this case.

MR. ROTHSCHILD: I think you're right, Your Honor, that the evidence sort of -- at this general level is similar case to case, and -- I mean, you can slice a case -- I'm not sure what -- how we're advantaging both the parties and the court system to

version of the case in March and then, you know, maybe, I don't know, June, July, that same jury, a different jury, hear --

THE COURT: I recognize the procedural issues we'll have to discuss if we go this way.

MR. SANDERS: Right.

THE COURT: I don't want to get into those until I know that I'm going to go this way.

MR. SANDERS: Right.

THE COURT: Mr. Sanders gives me an answer to my question. He says if you try this first case, you can do the liability, and if you're right, it's not a defective product and you didn't do anything under the Consumer Protection Act, all of this other need to produce this other information, all this need to get into how damages are going to be proved and stuff completely goes away because there is no liability, so I don't need to worry about damages. Why isn't he right about that?

MR. ROTHSCHILD: Well, it would make me happy if that's the way the case was resolved in the end and we can avoid some of this, but that doesn't, as I see it, sort of warrant sort of rushing ahead to trial with half a case only to have to do -- potentially to do more work later. And just to

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

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630

VIDEOTAPED 30(b)(6) DEPOSITION OF
STATE OF ALASKA
DESIGNEE: DAVID CAMPANA

Wednesday, September 19, 2007
9:30 a.m.
Volume II

Taken by Counsel for Defendant
at
Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

EXHIBIT C
PAGE 1 OF 2

D E F

A. They hinged on safety and effectiveness, at least as far as the FDA looked at all the data, and have they determined that it is safe and effective, if it is safe and effective, if there is a drug rebate then Alaska covers it.

Q. And what you are saying is if the FDA determines it's safe and effective such that it can accept a rebate, then Alaska agrees with that?

A. Alaska covers it.

Q. Alaska covers it. Okay. And you have told me that your understanding is that the package insert did not accurately represent the safety of Zyprexa, correct?

A. Correct.

Q. And you have felt that way for some period of time, correct?

A. Correct.

Q. At least since 2004, correct?

A. Correct.

Q. And since 2004, the reimbursement policies of Alaska towards Zyprexa is exactly the same as it was before you came to the conclusion that the representations about safety weren't true, correct?

A. Correct.

Q. The next allegation in the complaint says, "That as a result of ingesting Zyprexa, Alaska Medicaid

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
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STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

VIDEOTAPED DEPOSITION OF DUANE HOPSON, M.D.

December 11, 2007
10:18 a.m.

Taken at:
The Offices of Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

Reported by: Leslie J. Knisley
Shorthand Reporter

Q How many of those patients, if you can state, are being medicated involuntarily at any given time?

A It's a very small number. We don't do that many unvoluntary medication commitments at API. So at any one time there might be 4, 5.

Q And over a year, that might be how many people?

A Let me see. I've seen those stats. Over the course of a year, it may be 20 or so people.

Q And that's pretty consistent year over year?

A Those numbers have actually been dropping, of the number of involuntary medication, in part, an effort for us to better educate patients about medications and things like that.

Q So that through the education they become voluntary takers of those medications?

A Yes.

Q Are patients at API involuntarily treated ever with Zyprexa?

A Yes.

Q Right through today?

Q Nevertheless, you and your fellow psychiatrists at API continued to prescribe Zyprexa for individual patients?

A Yes. We tend to -- doctors continued to do that despite the --

Q Despite?

A Despite risks with all classes -- all types of medications.

Q Why is it that you would continue to prescribe Zyprexa given that higher risk of weight gain, lipids and diabetes?

A Well, I think one -- one treatment approach is you try other medications perhaps first. You go with those with a less risk profile, and if perhaps those are not effective, patients had perhaps side effects to them, didn't tolerate them, and then you would make a change in your approach and try Zyprexa. Some docs might do that, you know, rather than put it on as first line.

Q But there were also some doctors in your group who treated with Zyprexa first line; is that correct?

A That's possible, yes.

Q That's because they were making

Q That would include Zyprexa?
A Sure.
Q You have not instituted any restrictions on Zyprexa, have you?
A No.
Q When you fill in for doctors or are the attending psychiatrist at API, are there patients for whom you still prescribe Zyprexa?
A Yes.
Q For what types of conditions?
A Typical schizophrenia, perhaps bipolar. Those would be the top type of patient that would -- you would prescribe for.
Q That you would prescribe for?
A Yes, uh-huh. That I would prescribe for. That one would prescribe for.
Q Can you describe circumstances in which you would choose Zyprexa over another antipsychotic medication?
A Well, a typical scenario might be someone who has been treatment resistant perhaps to one with less side effects. And so, you know, you move up to a bigger gun, so to speak. And doctors are pretty accomplished at doing that, taking into account prior performance of a

medication, and so then you would consider something like Zyprexa for them.

Q Do you have a personal viewpoint regarding the efficacy of Zyprexa?

A Efficacy. I think it is efficacious. It is efficacious, I think, in lower doses than some of the others. Some of the others are equally as efficacious if you adjust their dosage accordingly.

Q And is there a problem that you see with adjusting doses?

A Well, sometimes you also run into side effects from that and getting your patients to take higher doses, even though you try to explain to them, you know, it's apples and oranges, it's not the same thing.

Q There's no formula that you can come up with for when you'd prescribe Zyprexa and when you wouldn't, is there?

A There isn't.

Q Have you ever used Zyprexa off label?

A I would say yes. Psychiatrists are keen at doing that on occasion.

Q Keen at off-label uses?

A Yes.

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

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

VIDEOTAPED DEPOSITION OF LUCY LJUBICICH CURTISS, M.D.

December 13, 2007
1:35 p.m.

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

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

patient against his or her will?
A. Not directly. No.
Q. Have you ever sought a court order to medicate somebody?
A. No. We don't do that in the outpatient setting. If we think that someone is at imminent risk, we seek hospitalization; we would never seek a court order to medicate someone in the community.
Q. And the hospitalization would be typically in this community at API?
A. At API.
Q. For what kinds of conditions do you use Zyprexa in your practice today?
A. In my practice today, I have patients that take Zyprexa for schizophrenia, schizoaffective disorder, bipolar disorder, PTSD, and behavioral disturbances associated with dementia.
Q. And for several of those illnesses, the treatment with Zyprexa would be off label; is that correct?
A. Yes.
Q. Why do you use Zyprexa off label?
A. Well, in psychiatry there is very much

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION	MDL No. 1596 04 MD 1596
THIS DOCUMENT RELATES TO: ALL CASES	
UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, et al. v. ELI LILLY AND COMPANY	
LOCAL 28 SHEET METAL WORKERS, et al. v. ELI LILLY AND COMPANY	
SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, et al. v. ELI LILLY AND COMPANY	

DEPOSITION OF: WILLIAM C. WIRSHING, M.D.

DATE: May 1, 2007

TIME: 9:38 a.m.

LOCATION: 22122 Victory Boulevard
Pacific Room
Woodland Hills, CA 91367

TAKEN BY: Counsel for Eli Lilly and Company

REPORTED BY: K.C. Belden, RPR, CRR
Certified Shorthand
Reporter No. 6728

once your horse has got to the finish line, you know, don't be changing in the off season kind of thing. I stick with that horse.

And it takes a lot to convince me that a drug which previously has demonstrated itself doesn't work. The usual explanations are "I forgot to take it." "I have been out of town for like three weeks," you know, "I started using crystal meth." Go figure; it doesn't help schizophrenia. Whatever. But not the drug itself. The drug that worked first in schizophrenia, not in other illnesses, but in schizophrenia, tends to be the drug I like to try to work with.

Occasionally 15 percent or so, yeah, treatment-refractory patients do get made. It's unfortunate, tragic, it's terrible. But usually there are other more prosaic explanations.

Q And so there is a class of patients or at least people who may present to you for whom you would prescribe Zyprexa as sort of the first-line treatment. Is that correct?

A Sure.

Q Same thing with all of the other drugs; you may look at a particular patient and you may decide that this particular drug for this particular patient, given the circumstances they present, "I would go with

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

STIPULATION FOR EXTENSION OF TIME

COME NOW the parties, by and through counsel, and stipulate that the deadline for Eli Lilly to file a reply to its Motion for Summary Judgment shall be extended from January 15, 2008, to January 17, 2008.

1/14/08
Date

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

By _____
Eric T. Sanders, ASBA No. 75100085

1/14/08
Date

PEPPER HAMILTON LLP
Andrew R. Rogoff, *pro hac vice*
Eric J. Rothschild, *pro hac vice*
and
LANE POWELL LLC
Attorneys for Defendant

By _____
Brewster H. Jamieson, ASBA No. 8411122

ORDER

IT IS SO ORDERED.

1/16/08
Date

_____
The Honorable Mark Rindner
Judge of the Superior Court

I certify that on 1-16-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

_____
Administrative Assistant

001974

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

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

STATE OF ALASKA,
Plaintiff,

v.

ELI LILLY AND COMPANY,
Defendant.

Case No. 3AN-06-05630 CI

STIPULATION FOR PARTIAL DISMISSAL WITH PREJUDICE

COME NOW, the parties, by and through their respective counsel, pursuant to Rule 41(a) of the Alaska Rules of Civil Procedure, and stipulate that the Second Claim for Relief (Strict Products Liability: Design Defect) asserted by plaintiff in its Complaint against defendant Lilly in paragraphs 35-40, may be dismissed with prejudice.

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

Dated: January 10, 2008

By _____
Eric T. Sanders, ASBA No. 75100085

LANE POWELL LLC
Attorneys for Defendant

Dated: January 10th, 2008

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

ORDER

IT IS HEREBY ORDERED that plaintiff's Second Claim for Relief (Strict Products Liability: Design Defect) is hereby dismissed with prejudice.

ORDERED this 11th day of January, 2008.

_____
The Honorable Mark Rindner

I certify that on 1-11-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

_____
Administrative Assistant

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

Filed in the Trial Courts
STATE OF ALASKA, THIRD DISTRICT
JAN 08 2008
Clerk of the Trial Courts
By _____ Deputy

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

NOTICE OF FILING PLEADINGS UNDER SEAL

The State of Alaska's Opposition to Lilly's Motion for Summary Judgment and the exhibits attached thereto, filed on January 8, 2008, contain CONFIDENTIAL information. Thus, the parties request that the pleading be filed under seal in the attached envelope.

RESPECTFULLY SUBMITTED this 8 day of January, 2008.

FELDMAN, ORLANSKY & SANDERS
Counsel for Plaintiff

BY Susan Orlansky
Susan Orlansky
Alaska Bar No. 8106042
Eric T. Sanders
Alaska Bar No. 7510085

Send Envelope / Separate

3MAN ORLANSKY
& SANDERS
500 L STREET
OURTH FLOOR
CHORAGE, AK
99501
L: 907.272.353
X: 907.274.0819

001976

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 & COMPANY'S SUPPLEMENT TO ITS PRELIMINARY WITNESS LIST

COMES NOW, Defendant Eli Lilly and Company ("Lilly") and hereby supplements its Preliminary Witness List as follows:

1. Lucy Curtiss, M.D.
   3127 Wesleyan Drive
   Anchorage, AK 99508
   (907) 563-1000

   Dr. Curtiss is a physician practicing in the State of Alaska, and is expected to testify regarding the treatment of mentally ill patients, including use of antipsychotic medications.

2. Joey Eski **Attorney-Client Privilege**
   c/o Pepper Hamilton LLP
   3000 Two Logan Square
   18th & Arch Streets
   Philadelphia, PA 19103
   (215) 981-4000

   Ms. Eski is a representative of Eli Lilly & Company and is expected to testify in response to allegations in Plaintiff's Complaint.

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

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

Attorney-Client Privilege

3. Tim Franson
c/o Pepper Hamilton LLP
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

Mr. Franson is a representative of Eli Lilly & Company and is expected to testify in response to allegations in Plaintiff's Complaint.

4. R. Duane Hopson, M.D.
Alaska Psychiatric Institute
2800 Providence Drive
Anchorage, AK 99508
(907) 269-7100

Dr. Hopson is the Medical Director of the Alaska Psychiatric Institute, and a physician practicing in the State of Alaska, and is expected to testify regarding the treatment of mentally ill patients, including use of antipsychotic medications.

5. Jeffrey S. Magee, M.D.
36251 Mere Circle
Sterling, AK 99672
(907) 283-7501

Dr. Magee is a physician practicing in the State of Alaska, and is expected to testify regarding the treatment of mentally ill patients, including use of antipsychotic medications.

6. Ramzi Nassar, M.D.
2221 Vanderbilt Circle
Anchorage, AK 99508
(907) 212-6900

Dr. Nassar is a physician practicing in the State of Alaska, and is expected to testify regarding the treatment of mentally ill patients, including use of antipsychotic medications.

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

7. Carolyn Rader, M.D.
5314 Sillary Circle
Anchorage, AK 99508
(907) 212-6900

Dr. Rader is a physician practicing in the State of Alaska, and is expected to testify regarding the treatment of mentally ill patients, including use of antipsychotic medications.

8. Robert Schults, M.D.
613 Alta Court
Douglas, AK 99824
(907) 463-3303

Dr. Schults is a physician practicing in the State of Alaska, and is expected to testify regarding the treatment of mentally ill patients, including use of antipsychotic medications.

9. Verner Stillner, M.D.
12555 Auke Nu Drive
Juneau, AK 99801
(907) 796-8498

Dr. Stillner is a physician practicing in the State of Alaska, and is expected to testify regarding the treatment of mentally ill patients, including use of antipsychotic medications.

10. Alexander von Hafften, M.D.
11540 Trails End Road
Anchorage, AK 99507
(907) 212-6900

Dr. von Hafften is a physician practicing in the State of Alaska, and is expected to testify regarding the treatment of mentally ill patients, including use of antipsychotic medications.

DATED this 4th day of January, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric Rothschild, admitted *pro hac vice*
3000 Two Logan Square
18th & Arch Streets
Philadelphia, PA 19103
(215) 981-4000

LANE POWELL LLC

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

I certify that on January 4, 2008, a copy of the foregoing was served by mail on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-2911

_____

092857.0038/162627.1

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
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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

STIPULATION FOR EXTENSION OF TIME

COME NOW the parties, by and through counsel, and stipulate that the deadline to file expert admissibility motions shall be extended from January 7, 2008, to January 15, 2008.

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

1/3/08.
Date

By
Eric T. Sanders, ASBA No. 75100085

PEPPER HAMILTON LLP
Andrew R. Rogoff, *pro hac vice*
Eric J. Rothschild, *pro hac vice*
and
LANE POWELL LLC
Attorneys for Defendant

1/3/08
Date

By
for Brewster H. Jamieson, ASBA No. 8411122

ORDER

IT IS SO ORDERED.

1/4/08
Date

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on 1-4-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

001981

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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 CI

ORDER

Lilly's Motion to Compel dated December 13, 2007 and plaintiff's Renewed Motion to Compel dated December 11, 2007 are referred to the Discovery Master.

DATED at Anchorage, Alaska, this 3rd day of January 2008.

MARK RINDNER
Superior Court Judge

I certify that on January 3, 2008 a copy was mailed to:
E. Sanders B. Jamieson
D. Hensley

Administrative Assistant

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 CI

ORDER

Oral argument on Eli Lilly's pending Motion for Summary Judgment is scheduled for January 29, 2008 at 9:00 a.m. One hour is allocated to the argument divided equally between the parties.

DATED at Anchorage, Alaska, this 3rd day of January 2008.

Mark Rindner

MARK RINDNER
Superior Court Judge

I certify that on January 3, 2008 a copy was mailed to:
E. Sanders B. Jamieson
D. Hensley

Administrative Assistant

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

ORDER REGARDING PLAINTIFF'S RENEWED MOTION TO COMPEL AND MOTION FOR SANCTIONS

The State of Alaska ("the State") has filed a renewed Motion to compel responses to several of its Requests for Production of Documents and Interrogatories upon which the Discovery Master previously held a hearing on September 11, 2007 and issued an order dated September 24, 2007. The Court finds Eli Lilly and Company ("Lilly") should provide further responses to those requests as follows:

1. Interrogatory Nos. 1 and 3, and Request for Production Nos. 1 and 3 – Lilly shall produce the custodial files of Trina Clark and Jeff Hill within 10 days of this order, including all related documents and emails from those witnesses, and shall produce the witnesses for deposition within 20 days of this order.

2. Request for Production No. 7 – Lilly shall immediately supplement its call note production to include a random sampling consistent with the Discovery

FELDMAN ORLANSKY & SANDERS
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Master's prior ruling of 10 percent of all call notes generated between August 2004 and the present. In addition, Lilly shall also produce all call notes relating to interactions with Drs. Carolyn Rader, Lucy Curtiss, Alexander Von Hafften, Jeffrey Magee, Ramzi Nassar, Robert Schults, and Verner Stillner.

3. Interrogatory Nos. 12 and 13 – Lilly shall produce within 10 days the financial information consistent with the Discovery Master's prior order for the years 2005 to the present.

The State has requested sanctions in connection with its Renewed Motion to Compel, in particular, with the expense and time associated with the depositions of Nathaniel Miles and Kevin Walters, and the expense and time associated with the filing of this motion. The State shall submit a proposed order with the specific attorney fees and expenses sought for the Court's consideration.

Dated this ___ day of _____, 2007.

BY THE COURT

_____
Mark Rindner
Superior Court Judge

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

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

Upon consideration of Plaintiff's Renewed Motion to Compel and Motion for Sanctions, defendant's opposition thereto, and being fully advised in the premises,

IT IS HEREBY ORDERED that Plaintiff's Renewed Motion to Compel and Motion for Sanctions is DENIED.

ORDERED this ____ day of _____, 2007.

The Honorable Mark Rindner
Superior Court Judge

I certify that on December 21, 2007, a copy of the foregoing was served by e-mail and hand-delivery on:

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

009867-0038/162575.1

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

Not used
returned to Master 1-3-08

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

ORDER

Upon consideration of Defendant Eli Lilly and Company ("Lilly")'s Motion to Compel Discovery and Memorandum in Support, and any response thereto, it is hereby ORDERED that:

1. The plaintiff State of Alaska will immediately provide complete responses to Lilly's Interrogatory Nos. 66-72, and

2. The plaintiff State of Alaska will immediately produce documents in response to Lilly's Request for Production No. 60.

ORDERED this ____ day of _____, 2007.

The Honorable Mark Rindner
Superior Court Judge

I certify that on December 13, 2007, a copy of the foregoing was served by e-mail and hand-delivery on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-2911

[signature]

009867-0038/162509.1

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

Not used referred to Master 1-3-08

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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

PROPOSED SCHEDULE FOR DISCOVERY UNRELATED TO LIABILITY

Pursuant to this Court's Order of November 27, 2007, requiring the parties to provide the Court with a stipulation or their respective positions as to "how discovery unrelated to liability should proceed," the parties submit the following proposed deadlines:

State's Production of Medicaid Database ..... January 31, 2008[1]

State's Production of Expert Reports ..... May 14, 2008

Depositions of State's Experts ..... July 3, 2008

Fact Discovery Deadline ..... July 14, 2008[2]

Lilly's Production of Expert Reports ..... July 21, 2008

Depositions of Lilly's Experts..... September 10, 2008

[1] In its Status Report filed December 7, 2007, the State committed to producing its Medicaid database by no later than January 31, 2008. The parties agree that the deadlines proposed below are contingent on a satisfactory production of the Medicaid database by that date. Lilly will promptly advise the Court of any delays or deficiencies in the database production that may affect the agreed deadlines.

[2] Lilly has advised the State that during this fact discovery period it may take the depositions of Alaska prescribers that were allegedly misled by the Zyprexa warning or other communications by Lilly. The State has indicated that it may object to some or all of these depositions. To the extent the State's objections relate to the time needed to take this discovery, Lilly has no objection to extending the fact discovery deadline to complete this discovery.

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

The parties also contemplate that the Court will set deadlines for expert admissibility and dispositive motions in conjunction with setting a trial date. The parties request that the Court set the deadline for dispositive motions on or after the deadlines for expert admissibility motions.

By agreeing to the deadlines proposed above, Lilly does not withdraw or waive its objections to the bifurcated proceeding ordered by the Court, which are set forth in other pleadings.

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

1/2/08
Date

By _____
Eric T. Sanders, ASBA No. 75100085

PEPPER HAMILTON LLP
Andrew R. Rogoff, *pro hac vice*
Eric J. Rothschild, *pro hac vice*
and
LANE POWELL LLC
Attorneys for Defendant

1/2/08
Date

By _____
for Brewster H. Jamieson, ASBA No. 8411122

ORDER

IT IS SO ORDER.

1/4/08
Date

_____
The Honorable Mark Rindner
Judge of the Superior Court

I certify that on 1-4-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

_____
Administrative Assistant

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

A B

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

CORRECTED
ORDER GRANTING MOTIONS FOR EXTENSION

IT IS HEREBY ORDERED that the parties' Joint Motions for Extension of Time are GRANTED. The State's opposition to Eli Lilly's Motion for Summary Judgment is due January 8, 2008; Eli Lilly's reply to the State's Opposition to Lilly's Motion to Compel is due January 4, 2008.

DATED this 2 day of January, 2008.

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on 1-2-08 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

001990

DEC 28 2007

FELDMAN ORLANSKY & SANDERS
500 L STREET
FOURTH FLOOR
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FAX: 907.274.0819

A B

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
CORRECTED ORDER GRANTING MOTIONS FOR EXTENSION

PLEASE TAKE NOTICE that the State of Alaska is filing herewith a Corrected Order Granting Motions for Extension. In its motion, the State stated that Lilly was requesting an extension to reply to the State's Renewed Motion to Compel. That statement is incorrect. Lilly is requesting an extension to reply to the State's Opposition to Lilly's Motion to Compel. The attached order correctly allows Lilly to January 4, 2007, to reply to the State's Opposition to Lilly's Motion to Compel.

DATED this 27 day of Dec, 2007.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
AK Bar No. 7510085

FELDMAN ORLANSKY
& SANDERS
500 L STREET
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ANCHORAGE, AK
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TEL: 907.272.3538
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001991

A B

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
5664 South Green Street
Salt Lake City, UT 84123
(801) 266-0999
Counsel for Plaintiff

RICHARDSON, PATRICK, WESTBROOK & BRICKMAN, LLC
H. Blair Hahn
Christiaan A. Marcum
P.O. Box 1007
Mt. Pleasant, SC 29465
(843) 727-6500
Counsel for Plaintiff

Certificate of Service
I hereby certify that true and correct copies of **Notice of Filing Corrected Order Granting Motions for Extension and Corrected Order Granting Motions for Extension** were 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 JJSummers

Date 12/28/07

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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

ORDER GRANTING MOTIONS FOR EXTENSION

IT IS HEREBY ORDERED that the parties' Joint Motions for Extension of Time are GRANTED. The State's opposition to Eli Lilly's Motion for Summary Judgment is due January 8, 2008; Eli Lilly's reply to the State's Renewed Motion to Compel is due January 4, 2008.

DATED this 26 day of Dec, 2008.

BY THE COURT

Mark Rindner
Superior Court Judge

I certify that on 12-31-07 a copy of the above was mailed to each of the following at their addresses of record:
Sanders Jamieson

Administrative Assistant

001993

DEC 27 2007

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99501
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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

JOINT MOTIONS FOR EXTENSION OF TIME

Plaintiff, State of Alaska, requests an extension of time until January 8, 2007, to file its opposition to Eli Lilly's Motion for Summary Judgment. The parties have conferred and defendant's counsel does not object to this extension.

Defendant, Eli Lilly and Company, requests an extension of time until January 4, 2007, to file its reply to the State's Renewed Motion to Compel. The parties have conferred and plaintiff's counsel does not object to this extension.

DATED this 27 day of December, 2007.

FELDMAN ORLANSKY & SANDERS
Attorneys for Plaintiff

BY_____
Eric T. Sanders
AK Bar No. 7510085

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

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

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

Certificate of Service
I hereby certify that a true and correct copy of the foregoing **Joint Motions for Extension and (proposed) Order** were 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 S Crowe
Date 12/27/07

FELDMAN ORLANSKY
& SANDERS
500 L STREET
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ANCHORAGE, AK
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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'S OPPOSITION TO PLAINTIFF'S RENEWED MOTION TO COMPEL AND MOTION FOR SANCTIONS

COMES NOW, Defendant Eli Lilly and Company ("Lilly"), through counsel of record, and hereby submits its opposition to Plaintiff's Renewed Motion to Compel and Motion for Sanctions as follows:

In its rush to trial, the State has abandoned appropriate discovery methods, and instead has attempted to take new discovery under the guise of a Renewed Motion to Compel.

None of the documents that are the subject of the State's motion are the subject of outstanding requests, or any order by the discovery master Judge Hensley or this Court. By its motion the State seeks, for the first time, documents from certain Lilly employees that it has never previously requested – documents that should be the subject of a new discovery request to the extent they are relevant at all. The State also seeks call notes for physicians noticed for depositions, and call notes generated after September 2004, neither of which are required by Judge Hensley's Order, which resolved Lilly's obligations regarding call note production. Rather than attempt to resolve these issues collaboratively, or through proper discovery requests, the State has resorted to recrimination and misrepresentation. This Court should deny the State's motion and any request for sanctions and costs.

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A B

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I. ARGUMENT

A. Interrogatories Nos. 1 And 3 and Corresponding Requests for Production Nos. 1 and 3.

The State seeks to force Lilly to produce, in an expedited manner, documents of Lilly employees not previously sought by any request for production. The State argues that these documents are responsive to earlier requests, but, as set forth below, that assertion is incorrect. The State's Motion demands sanctions against Lilly regarding this issue, even though it has never initiated any dialogue with Lilly about the desired documents, a violation of Rule 37 (a)(2)'s requirement that the movant confer with the opposing party in an effort to secure the disclosure without court action.

In its first set of interrogatories and requests for production the State sought the identities of Lilly employees "responsible for communicating with any employee or representative of Alaska's Medicaid program regarding efficacy, benefits, risks or costs associated with Zyprexa" and also "any organization, committee or authority responsible for determining what prescription drugs will be on any Alaska formulary, pharmaceutical and therapeutics list or preferred drug list" as related to Zyprexa.[1] The State also sought documents relating to and embodying the communications between Lilly employees and the above mentioned individuals.[2] Lilly responded to these requests by identifying two of its employees, Nathaniel Miles and Kevin Walters, and producing their documents.[3] These

[1] Exhibit A, Pltf's First Set of Interrogatories, Nos. 1 and 3.

[2] Exhibit B, Pltf's First Set of Requests for Production, Nos. 1 and 3.

[3] These documents were produced to the State on September 11, 2007, well in advance of the depositions at issue in this motion. If the State had a question about whether they should depose these individuals, they had ample time to make that assessment by reviewing the documents that had been produced.

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individuals were identified because they interacted with the Alaska Medicaid program as part of their job responsibilities – a fact borne out by the testimony of the State's own employees.

The State now suggests that "Lilly has failed to meaningfully respond to the State's discovery requests,"[4] arguing that Walters' testimony proves that Lilly ought to have identified Lilly Outcomes Liaisons, Trina Clark and Jeff Hille,[5] and produced their files. The State bases this assertion largely on the misinterpretation of answers given by Kevin Walters in his deposition. The testimony relied upon by the State for its abrupt demand for production of the Outcomes Liaisons' documents is the following:

> **Question:** You told me earlier that the customers you met with typically were Medicaid Department officials.
>
> **Answer:** Correct.
>
> **Question:** Physicians?
>
> **Answer:** Prescribers. And CMHCs [community mental health centers].
>
> **Question:** And corrections facilities. Those were your primary customers?
>
> **Answer:** Correct.
>
> .....
>
> **Question:** Okay. Who discussed Zyprexa with your customers?
>
> **Answer:** That responsibility would fall to others within our company.

[4] Pltf's Renewed Motion to Compel at 3.

[5] Jeff Hille was incorrectly identified as Jeff Hill in Kevin Walters' deposition.

.....

Question: What others in your company would have responsibility for discussing Zyprexa with customers in Alaska?

.....

Answer: Outcome liaisons.[6]

The State argues that this testimony proves that Lilly Outcomes Liaisons communicated with the State Medicaid program. As is apparent from this sequence, however, the questions that elicited the reference to Outcome Liaisons did not distinguish among customers, and do not establish that Outcomes Liaisons discussed Zyprexa with representatives of the Alaska Medicaid agency. Similarly, while Kevin Walters and Nathaniel Miles testified that Outcomes Liaisons *might be* responsible for communicating with a Pharmaceutical and Therapeutics Committee or a Drug Utilization Review Board, they did not testify that such communications actually occurred with such bodies in Alaska,[7] and

[6] Exhibit C, Deposition of Kevin R. Walters at 84-86.

[7] Nathaniel Miles testified that Lilly's normal practice was to bring in Outcomes Liaisons to present to a Drug Utilization Review Board, but he did not testify that any presentations occurred in Alaska:

> **Question**: Okay. Who among these groups would communicate with – if, for example, in Alaska – well in Alaska I believe there was a drug utilization review board?
>
> **Answer**: Uh-huh. Usually in a case like that it – we – they'd bring in the OL, the outcomes liaison to –
>
> **Question**: Okay.
>
> **Answer**: -- do the – to do the presentation.

(continued . . .)

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the record evidence strongly suggests that no such interactions took place. The Alaska Pharmaceutical and Therapeutics Committee has never addressed antipsychotics[8] and no Lilly employee presented at either meeting of the Alaska Drug Utilization Review Board on the use of antipsychotics.[9]

Moreover, the witnesses produced by Lilly are exactly the ones that State witnesses identified as their Lilly contacts. Lilly has asked the State to identify all the particulars regarding Lilly's communications with the State, and neither Outcomes Liaison was identified as having interacted with the State. In addition, Lilly asked the State to identify the Alaska employees or representatives who communicated with Lilly about Zyprexa since 1996. The State identified two individuals, David Campana and Tom Porter, M.D.,[10] both of whom Lilly has deposed. Mr. Campana testified that the only Lilly employee who had had any contact with regarding Zyprexa was Kevin Walters:

(. . . continued)
Exhibit D, Deposition of Nathaniel R. Miles at 217-18 (emphasis added). Similarly, Kevin Walters testified that the Outcomes Liaisons might have responsibility for making formulary presentations, but he did not testify that any presentations occurred in Alaska:

> **Question:** You did not, okay. Never did any formulary presentations on a Lilly product?
>
> **Answer:** No.
>
> **Question:** And would that have been the responsibility of the an outcomes liaison?
>
> **Answer:** It could have been.

Exhibit C, Deposition of Kevin R. Walters at 90-91 (emphasis added).

[8] Exhibit E, Deposition of David Campana at 265-66.

[9] The State produced to Lilly all Drug Utilization Review Board meeting minutes for meetings on antipsychotics. *Id.* at 333. Those meeting minutes show no presentations by Lilly employees. *Id.* at Exhibits 16 & 17 (meeting minutes for 10/22/04 and 11/19/04).

[10] Exhibit F, Pltf's First Amended Responses to Def's First Set of Interrogatories, No.4.

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Question: Is Kevin Walters the only Lilly employee who you have met with, who you discussed Zyprexa with?

Answer: To my knowledge, he is the only one I have discussed that with.[11]

Dr. Porter testified that he could not recall ever communicating with any Lilly employee.[12] In addition, Joel Gilbertson, the former Commissioner of Health and Social Services, testified that he interacted with Mr. Miles.[13] In this case about alleged misrepresentations, if it were the case that Lilly's Outcomes Liaisons had communicated with the State, one would expect that the State would know it, and that information would have been disclosed by the State in its discovery responses, or at the depositions of State employees.

The suggestion that Lilly failed to disclose potential witnesses or failed to produce relevant documents is fully contradicted by the testimony of the State's own witnesses, and the suggestion that Lilly should be sanctioned in this instance, is in itself sanctionable.[14] If the State came to the conclusion, in the midst of discovery, that additional individuals might have relevant documents, its attorneys should have picked up the phone and initiated a

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[11] Exhibit E, Deposition of David Campana at 290-91.

[12] Exhibit G, Deposition of Thomas Porter, M.D. at 53-54.

[13] Exhibit H, Deposition of Joel Gilbertson at 26.

[14] The State's Motion is particularly egregious when viewed in the context of its own identification of witnesses. The State identified Thomas Porter, the former medical director for Alaska's Department of Health and Social Services, as a trial witness, and as one of two witnesses with knowledge about the events alleged in the Complaint and interactions with Lilly. At his deposition, however, Dr. Porter revealed that he knew about none of the events in the Complaint, nor did he have any recollection about interactions with Lilly, or, in fact, any knowledge about Zyprexa. Exhibit G, Deposition of Thomas Porter at 19, 46-47, 53-54.

discussion with Lilly.[15] The State should not have rushed to file an unsupported motion seeking sanctions and costs.

B. Request For Production 7.

In his Order of September 24, 2007, the Discovery Master, Judge Hensley, held that "Lilly shall produce a random sample of 4,000 Alaska call notes referencing Zyprexa."[16] Lilly has complied with that order. The State now argues that Lilly should be sanctioned because it failed to include two additional categories of call notes: (1) those relating to specific physicians noticed for deposition; and (2) those to which Lilly objected based on date scope. The State's argument is meritless, as Lilly was not required by Judge Hensley's Order to produce either set of call notes.

1. Call Notes for Specific Physicians.

The State originally made a discovery request for all Alaska call notes dealing with Zyprexa.[17] Lilly objected to this burdensome request.[18] At the September 11 hearing before Discovery Master Hensley, Lilly explained the history of call note production in the Zyprexa litigation and raised the possibility of producing call notes for specific physicians noticed for depositions as one reasonable solution of the parties' dispute.[19] The State argued **against** such a proposal, stating that its request "cannot be conditioned upon or limited by its identification of specific prescribing physicians in Alaska,"[20] and it continued to argue for

[15] Consistent with its ongoing obligations, Lilly will review documents and produce documents, if any exist, which are responsive.

[16] Exhibit I, Discovery Master Order on State's First Motion to Compel at 11.

[17] Exhibit B, Pltf's First Requests for Production to Def, No. 7.

[18] Exhibit J, Eli Lilly and Company's Objections and Responses to Pltf's First Requests for Prod., No. 7.

[19] Exhibit K, Transcript of Motion Argument Before Discovery Master at 86-91.

[20] Exhibit L, Memorandum in Support of Plaintiff's Motion to Compel Discovery at 8.

(continued . . .)

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full production of all call notes. Judge Hensley resolved the dispute by ordering that "Lilly shall produce a random sample of 4,000 Alaska call notes referencing Zyprexa."[21] Lilly has complied with this Order.

Now, the State attempts to convert a Lilly proposal about call note discovery that it rejected into an obligation that is stated nowhere in Judge Hensley's Order. Judge Hensley's Order did not obligate Lilly to produce any additional call notes beyond the 4,000 random call notes, and the State elected not to appeal the Order to this Court.

If the State believes it must receive these call notes, it should serve the appropriate discovery requests. An informal request seeking these call notes, made by Alaska to Lilly during the first week of December, is under consideration by Lilly, but Lilly is not obligated to produce these call notes pursuant to any outstanding discovery request, any agreement between the parties, or by Judge's Hensley's Order.

2. Date Scope.

The State initially requested all Zyprexa related call notes from Alaska created from 1996 until the present.[22] In its response, Lilly objected to the State's request for call notes from the period covering September 2004 to the present.[23] The State never moved to compel production of the call notes withheld by Lilly pursuant to this objection.[24] Accordingly, Lilly's date scope objection was not an issue at the September 11 hearing before Judge Hensley. In fact, the only time the Discovery Master has considered date scope

(. . . continued)

[21] Exhibit I, Discovery Master Order on State's First Motion to Compel at 11.

[22] Exhibit B, Pltf's First Requests for Prod., No. 7.

[23] Exhibit J, Eli Lilly and Company's Objections and Responses to Pltf's First Requests for Prod., No. 7.

[24] Exhibit L, Memorandum in Support of Plaintiff's Motion to Compel Discovery at 7-8.

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is when the State moved to compel production of documents related to Symbyax, another medication sold by Lilly. In that context, Judge Hensley overruled Lilly's date scope objection because he found "the request focuses on a discrete issue," but explicitly held that "allowing this discovery will not automatically open Lilly up to ongoing discovery of information generated at later times."[25]

If the State had timely moved to compel production of these additional call notes, Lilly would have opposed such discovery on relevancy grounds. The State seeks call notes to prove specific conduct relevant to its common law counts and specific violations of the Unfair Trade Practices Act.[26] The alleged fraud complained of by the State, that Lilly withheld information on Zyprexa's possible association with diabetes,[27] was known by David Campana, the responsible official for Alaska's Medicaid Program, in the fall of 2004.[28] Accordingly, call notes generated after that time are not relevant to establishing that Lilly deceived anyone.

If the State believed Lilly's objection to date scope was improper, it should have moved to compel production in a timely manner. It did not, and this Court should not entertain such arguments now – especially given such discovery is not relevant.

C. Interrogatories Nos. 12 And 13.

The State also seeks publicly available financial data relating to sales of Zyprexa in Alaska and globally from 2005 to the present. Lilly objected to producing this data after 2004 because it is not relevant to this litigation, [29] as explained above.[30] The State did not

[25] Exhibit M, Discovery Master Order on State's Second Motion to Compel at 2.

[26] Exhibit L, Memorandum in Support of Plaintiff's Motion to Compel Discovery at 8.

[27] Compl. ¶¶ 24-26.

[28] Exhibit E, Deposition of David Campana at 335.

[29] Exhibit N, Eli Lilly and Company's Objections and Responses to Plaintiff's First Interrogatories, Nos. 12 and 13.

(continued . . .)

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move to compel against Lilly's date scope objection,[31] and, as a result, Lilly is under no obligation to produce this information. Moreover, Judge Hensley only ordered that Lilly produce publicly available data regarding Zyprexa sales,[32] which are, by definition, equally accessible to the State.

II. CONCLUSION

For the foregoing reasons, Lilly requests that this Court deny the State's Renewed Motion to Compel and Motion for Sanctions.

DATED this 21st day of December, 2007.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square, Suite 3000
Philadelphia, Pennsylvania 19103-2711
(215) 981-4000

LANE POWELL LLC

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

I certify that on December 21, 2007, a copy of the foregoing was served by hand-delivery and e-mail on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-3911

009867.0038/162574.1

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(. . . continued)

[30] As noted in section B.2., the State was aware of a possible association of Zyprexa with diabetes in Fall 2004. Exhibit E, Deposition of David Campana at 335.

[31] Exhibit L, Memorandum in Support of Plaintiff's Motion to Compel Discovery at 9-11.

[32] Exhibit I, Discovery Master Order on State's First Motion to Compel at 11-12.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

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

PLAINTIFF'S FIRST INTERROGATORIES TO DEFENDANT

Pursuant to Rule 33 of the Alaska Rules of Civil Procedure, plaintiff State of Alaska submits the following interrogatories to defendant Eli Lilly and Company ("Lilly"), each of which is to be answered separately and fully in writing, under oath, within thirty (30) days of the date of service hereof.

INSTRUCTIONS FOR INTERROGATORIES

The Interrogatories set forth below are served upon you in accordance with Rule 33 of the Alaska Rules of Civil Procedure. Each Interrogatory must be answered fully and separately, under oath, in the spaces provided, using additional sheets as needed.

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

INTERROGATORIES

INTERROGATORY NO. 1. Identify any and all Lilly employees responsible for communicating with any employee or representative of Alaska's Medicaid program regarding the efficacy, benefits, risks or costs associated with the use of Zyprexa from October 1996 to the present and describe the "chain of command" or order of authority of reporting relationships from the level of such employees to the Chief Executive Officer of Lilly.

RESPONSE:

INTERROGATORY NO. 2. Identify any and all Lilly employees responsible for communicating with any employee or representative of any public payer in Alaska other than Alaska's Medicaid program regarding the efficacy, benefits, risks or costs associated with the use of Zyprexa from October 1996 to the present and describe the "chain of command" or order of authority of reporting relationships from the level of such employees to the Chief Executive Officer of Lilly.

RESPONSE:

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

INTERROGATORY NO. 3. Identify the Lilly employees responsible for communicating with any member of any organization, committee or authority responsible for determining what prescription drugs will be on any formulary, pharmaceutical and therapeutics list, or any preferred drug list in Alaska from October 1996 to the present regarding the use of Zyprexa and describe the "chain of command" or order of authority of reporting relationships from the level of such employees to the Chief Executive Officer of Lilly.

RESPONSE:

INTERROGATORY NO. 4. Identify any and all employees of Lilly who acted as sales representatives in promoting the sale and use of Zyprexa in Alaska from October 1996 to the present and describe the "chain of command" or order of authority of reporting relationships from the level of such employees to the Chief Executive Officer of Lilly.

RESPONSE:

INTERROGATORY NO. 5. Identify any and all employees of Lilly or any other organization, including but not limited to any third party marketing entities, responsible for the development and implementation of Zyprexa marketing programs for use by sales

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B

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

PLAINTIFF'S FIRST REQUESTS FOR PRODUCTION TO DEFENDANT

Pursuant to Rule 34 of the Alaska Rules of Civil Procedure, plaintiff State of Alaska requests that defendant Eli Lilly and Company ("Lilly") produce the following documents within thirty (30) days of the date of service hereof.

INSTRUCTIONS FOR REQUESTS FOR PRODUCTION

The Requests for Production set forth below are served upon you pursuant to Rule 34 of the Alaska Rules of Civil Procedure. Each document requested should be produced for inspection and copying at the offices of Feldman Orlansky & Sanders, 500 L Street, Fourth Floor, Anchorage, Alaska 99501 within thirty (30) days after the date of

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

E. "Identify" with regard to documents means to state the title or name of the document, the date prepared, identify the author and all who assisted in its preparation, identify those who have possession, custody or control of the document, and identify those to whom the document was addressed or distributed.

REQUESTS FOR PRODUCTION

REQUEST FOR PRODUCTION NO. 1. Produce any and all documents relating to, referring to or embodying any communications between Lilly or any employee or representative of Lilly and any employee or representative of Alaska's Medicaid program regarding the efficacy, benefits, risks or costs associated with the use of Zyprexa from October 1996 to the present.

RESPONSE:

REQUEST FOR PRODUCTION NO. 2. Produce any and all documents relating to, referring to or embodying any communications between Lilly or any employee or representative of Lilly and any employee or representative of any public payer in Alaska other than Alaska's Medicaid program regarding the efficacy, benefits, risks or costs associated with the use of Zyprexa from October 1996 to the present.

RESPONSE:

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500 L STREET
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ANCHORAGE, AK 99501
TEL: 907.272.3538
FAX: 907.274.0819

EXHIBIT B
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REQUEST FOR PRODUCTION NO. 3. Produce any and all documents relating to, referring to or embodying any communications between Lilly or any employee or representative of Lilly and any member of any committee, group or other authority which determines what prescription drugs may be on any formulary or pharmaceutical and therapeutics list, or preferred drug list in Alaska from October 1996 to the present regarding the use of Zyprexa.

RESPONSE:

REQUEST FOR PRODUCTION NO. 4. Produce any and all documents relating to, referring to or embodying any communications between Lilly's sales representatives and healthcare providers in Alaska from October 1996 to the present relating or referring to the efficacy, benefits, risks or costs associated with the use of Zyprexa, including but not limited to any and all e-mails, letters, reprints, brochures, powerpoint or computer presentations, audiotapes, videotapes, CDs and DVDs.

RESPONSE:

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

REQUEST FOR PRODUCTION NO. 7. Produce an electronic, searchable database copy of all call notes generated by any sales representative in Alaska between October 1996 to the present which relate or refer to Zyprexa.

RESPONSE:

REQUEST FOR PRODUCTION NO. 8. Produce color copy samples of any and all advertisements for Zyprexa which appeared in medical journals published in the United States between October 1996 to the present.

RESPONSE:

REQUEST FOR PRODUCTION NO. 9. Produce any and all documents relating to, referring to or embodying any communications between Lilly or any employee or representative of Lilly and any employee or representative of Alaska's executive or legislative branch of government regarding the efficacy, benefits, risks or costs associated with the use of Zyprexa from October 1996 to the present.

RESPONSE:

LAW OFFICES
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500 L STREET
FOURTH FLOOR
ANCHORAGE, AK 99501
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FAX: 907.274.0819

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EXHIBIT B
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K L C D E F G H I J

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

STATE OF ALASKA,	:	
Plaintiff,	:	
	:	
vs.	:	No. 3AN-06-05630
	:	
ELI LILLY AND COMPANY,	:	
Defendant.	:	

December 5, 2007

Videotaped Deposition of KEVIN R. WALTERS held in the law offices of Pepper Hamilton, LLP, One Logan Square, Philadelphia, Pennsylvania 19103, beginning at approximately 9:11 a.m., before Ann V. Kaufmann, a Registered Professional Reporter, Certified Realtime Reporter, Approved Reporter of the U.S. District Court, and a Notary Public.

GOLKOW TECHNOLOGIES, INC.
One Liberty Place, 51st Floor
Philadelphia, Pennsylvania 19103
877.370.3377

A. Correct.

Q. It is. Okay. And at those Alaska State Action Team meetings is there always someone present from State Government Affairs?

A. No.

Q. Okay. Frequently is there someone present from State Government Affairs?

A. Yes.

Q. Okay. So over the course of five years at no Alaska State Action Team meeting did a member of State Government Affairs ever explain to you that you were the primary contact for any of these categories or what any of these categories were?

A. Again, I'm not sure what the author was referring to in these categories. And to answer your question, no.

Q. You told me earlier that the customers you met with typically were Medicaid Department officials.

A. Correct.
Q. Okay. Physicians?
A. Prescribers.
Q. Prescribers. And CMHCs.
A. And Corrections.
Q. And Corrections facilities. Those four were your primary customers?
A. Correct.
Q. Okay. And your primary role was ensuring open access for Zyprexa in Medicaid?
A. No.
MR. BRENNER: Objection, misstates testimony.
BY MR. MARCUM:
Q. In your customers what concerns were present?
A. I don't understand the question.
Q. Okay. Well, customers typically have questions about a product you may be dealing with them on; correct?

MR. BRENNER: Objection, lacks foundation.

Q. Your customers were concerned about cost, weren't they?

A. Costs?

Q. Of Zyprexa. We'll get specific.

A. I never talked product with my customers.

Q. Never discussed Zyprexa with any of your customers?

A. No.

Q. Okay. Who discussed Zyprexa with your customers?

A. That responsibility would fall to others within our company.

Q. What others in your company would have responsibility for discussing Zyprexa with customers in Alaska?

A. Sales.

Q. Okay. Anyone else?

A. Not to my knowledge.

Q. Okay.

A. Outcome liaisons.

A. Yes.

Q. Okay. And when did -- is Jeff Hill still with the company?

A. He is not.

Q. Okay. When did he leave Eli Lilly?

A. 2007.

Q. Okay. Was he outcomes liaison for Alaska until 2007 when he left?

A. Yes --

Q. Okay.

A. -- among other responsibilities.

Q. Okay. So you never discussed any Lilly product with your customers?

A. I did not discuss product with my customers.

Q. Okay. Did you do presentations to Alaska's P&T Committee?

A. No.

Q. You did not, okay. Never did any formulary presentations on a

Lilly product?

A. No.

Q. And would that have been the responsibility of an outcomes liaison?

A. It could have been.

Q. Okay. Who else could it have been the responsibility of?

A. Are you referring to a P&T Committee meeting, public meeting? I'm not sure what --

Q. We could start there, yeah, Pharmacy & Therapeutics.

A. It would be the primary role of an outcomes liaison to present at a P&T public meeting, yes.

Q. Okay. Excuse me for one second.

A. Uh-huh.

MR. MARCUM: Let's go off the record for a second.

THE VIDEOGRAPHER: We're going off the record. The time is 10:48 a.m.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

- - - - - - - - - - - - - - - - X

STATE OF ALASKA, :

Plaintiff, : Case No.:

: 3AN-06-5630CIV

vs. :

ELI LILLY AND COMPANY, :

Defendant. :

- - - - - - - - - - - - - - - - X

Confidential Videotaped Deposition of

NATHANIEL RAY MILES

Washington, D.C.

Wednesday, November 14, 2007

9:06 a.m.

Pages: 1 - 296

Reported by: Dana C. Ryan, RPR, CRR

PHDAE --

A Yeah.

Q -- public health division --

A Division --

Q -- account --

A -- account --

Q -- executive --

A -- executive. You can --

Q -- he communicated with?

A The department . . .

Q Officials?

A Uh-huh, the department officials and . . .

Q Okay. Ally specialists communicated with?

A With the coalitions, the -- the advocacy groups, the coalitions, et cetera.

Q Okay. Sales force communicated with?

A Docs -- doctors and --

Q Okay. Who among these groups would communicate with -- if, for

example, in Alaska -- well, in Alaska I believe there was a drug utilization review board?

A Uh-huh. Usually in a case like that it -- we -- they'd bring in the OL, the outcomes liaison, to --

Q Okay.

A -- do the -- to do the presentation.

Q Okay.

MR. ROGOFF: Are we talking, Mr. Markum, about a presentation to a DUR board?

MR. MARCUM: I'm just talking in general about who communicates with members of the DUR board.

MR. ROGOFF: Oh.

THE WITNESS: Oh, yeah. With members -- to do the presentation, it's usually the outcomes liaison. The sales reps talk to some of the DUR members, but most of the time

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

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630

VIDEOTAPED 30(b)(6) DEPOSITION OF
STATE OF ALASKA
DESIGNEE: DAVID CAMPANA

Wednesday, September 19, 2007
9:30 a.m.
Volume II

Taken by Counsel for Defendant
at
Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

hormone and Clozapine.

Q. If I'm understanding you correctly, during Dr. Porter's tenure, he worked with you on some medication issues, and, after his departure, you didn't have a counterpart to work on medication issues?

A. Correct.

Q. Another way that you described that the state could address safety issues with the medication is to review the medication for the PDL, correct?

A. Correct.

Q. And the outcome of a review for that reason could be that the medication is put on -- is treated as non-preferred, correct?

A. Correct.

Q. And -- or the outcome could be that all the atypicals are preferred?

A. Sure.

Q. And, again, as you said before lunch, becoming non-preferred wouldn't stop any prescriber from prescribing the medication, it would just mean that the prescriber has to explain the medical necessity?

A. Correct.

Q. And as we have discussed, you have not reviewed Zyprexa or any of the other anti-psychotics for the PDL, correct?

A. The typical or atypical anti-psychotics have not been reviewed for the preferred drug list.

Q. Why didn't you review Zyprexa after you learned the information you have described about Zyprexa's relationship to diabetes?

A. We did review it as far as under the drug utilization review program.

Q. Why didn't you review it for the PDL?

A. We didn't take over that class or didn't review that therapeutic class in the preferred drug list.

Q. And that was the decision of you and your First Health counterpart?

A. Correct. And as reasons I had previously stated, and also the mental health community is under terrific pressure here due to low funding and due to over-abundance of patients and small infrastructure to take care of those patients, so why do we want to add one more hoop to that whole overrun entity?

Q. So was that resource issue the reason? I want to be very precise about my question here. There came a point in time when you had gathered information about Zyprexa's relationship to diabetes, correct?

A. Correct.

Q. And you interpreted that information to be communicating that Zyprexa actually caused diabetes?

Q. I mean what I'm trying to ascertain is whether there were people like Bob Labbe or Dwayne Peeples or the commissioners that also met with Lilly.

A. As far as whether Bob Labbe or the commissioner have met with Eli Lilly, I don't know. There is no way I could know that.

Q. Is it a fairly regular part of your work as pharmacy program manager to meet with representatives of drug companies?

A. Yes. I keep my door open for anyone who wants to come and see me, whether it be a pharmaceutical representative, a provider, or a recipient.

Q. Who from Eli Lilly have you met with? I want to cover this whole time period as best you can.

A. From 1996?

Q. It's your lawsuit.

A. I have -- I remember that I met with a person from the diabetic drug section. I don't remember what her name was. And then I have met with Kevin Walters.

And I have met with Kevin Walters quite a bit because he works with us on the CNS contract.

Q. Is Kevin Walters the only Lilly employee who you have met with, who you have discussed Zyprexa with?

A. To my knowledge, he is the only one that I have discussed that with. I have met with another

representative out of Salt Lake, and our discussions were on the CNS product rather than the Zyprexa.

Q. When was the first -- I mean estimate for me sort of the time period in which you have been interacting with Kevin Walters by years.

A. I believe 2003 is the first time I had met with Kevin Walters.

Q. Prior to 2003, you had not met with any Lilly representative about Zyprexa?

A. I don't recall.

Q. Did you have any other communications with Lilly regarding Zyprexa? I mean, telephone conversations, letters, any promotional material sent to you, anything of that nature?

A. I'm sure I got promotional material, and I don't really remember anything, you know, in particular.

Q. If I was trying to find out everything that you have communicated with Lilly about Zyprexa, other than your interactions with Kevin Walters, how would I go about finding that out?

A. I don't know.

Q. There is no documentation that would assist me?

A. There is no documentation that would assist you in that.

Q. You have no memory that we could test in this

run that showed diabetic medication use among anti-psychotic users?

A. That's my understanding of what we did here.

Q. And what precipitated the committee reviewing this issue and running these reports at this time in late 2004?

A. I don't remember exactly, although we do get a list of items that we can run in our drug utilization review, and it may have been an item that came up in the criteria set that we could run.

Q. You always could run it, but you don't always run it, do you?

A. Well, we run based on what comes up in the criteria set. As far as what I remember, we did determine that it would be a good idea to go ahead and run the mental health drugs and look for diabetic use or the diabetic issues coming up for mental health drugs.

Q. You don't know where that good idea came from?

A. I don't remember exactly where that came from.

Q. After this time, after this late fall 2004 period, has that report been run again by the state?

A. I don't remember us running that exact type of report again.

Q. Why not?

A. I don't remember.

STATE OF ALASKA

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH CARE SERVICES

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November 2, 2004

Alaska Medical Assistance Drug Utilization Review (DUR) Committee

SUBJECT: Agenda for meeting

Dear Committee Members:

The next DUR Committee meeting will take place on, November 19, 2004 at 1:30 pm.. Please note, the meeting will be held at 4501 Business Park Blvd. Suite #24 (Building 'L'). Please make arrangements to attend this meeting in person. The minutes for the September 17th meeting are attached.

Meeting Agenda:

(1) Approve the minutes from the October 22, meeting.

(2) DUR Meeting schedule

(3) Continuing discussion on what should be done with Long Acting opioids that were on PA and are now under the PDL?

(5) Profile review to continue with the profiles sent numbers 0409000...., specifically the set numbered 89 to 176. Please note that some profiles appear to be missing, that is due to the fact that some profiles were pulled from the package.

(6) Distribute next set of profiles.

Sincerely,

Dave Campens

Dave Campens, R.Ph., DUR Coordinator

Attachment

**The future meeting dates are currently scheduled as follows: November 19, 2004, December 17*

ZYP-AK-03348

EXHIBIT 16 9/11/07 CMH&A

002028

EXHIBIT E
PAGE 7 OF 16

Attachment 1.

DUR Committee Meeting Minutes
For meeting on 10/23/04

PRESENT: Dave Campana, R.Ph., DMA Pharmacy Program Manager; Charlene Hampton, RPh.; Arthur Hansen, D.D.S.; Alex von Hafften, M.D.

EXCUSED: Greg Polston and Heidi Brainerd

1. The meeting called to order at 1:20 p.m. by Dave.

2. Profile review was begun on profiles from the September run, it was noted that not all profiles were present since Terry Babb removed that were insignificant to keep the number close to 100.

3. There was discussion on max units for opioid analgesics that were reviewed by the P&T in September. The Committee gave several parameters to Dave to research prior to the next P&T meeting.

4. Dr. vonHaffen did a presentation on the mental health disease process and the effect on metabolic disorders that were prevalent in this month's profiles. He also presented a schematic of metabolic diseases with and without mental illness. He discussed the necessity of obtaining metabolic laboratory tests while treating those with mental illness. We should pay attention to those taking atypicals who are not taking anti-hypertensives or anti-lipidemic drugs. He further recommended the best alternative for an intervention letter would be to have the mental health professionals get more frequent laboratory tests for the mentally ill. Dr. vonHaffen presented an assessment tool he has started using to obtain weight and other parameters on his patients. There was a consensus that this month's intervention include a request to complete metabolic function tests and other items discovered in the profiles and other notable items such as multiple prescriber.

5. Profile review will continue on the October set since the Committee did not complete review of the set.

6. With the removal of Vioxx from the market, does it make sense to send last month's intervention profiles. The consensus of the Committee was to send the profiles and letters to high risk patients.

7. Profiles noted below require a special note as indicated under discussion in addition to the request to have lab tests done while on atypical anti-psychotics.

Hypodysmenorrheic agents			
Count	Profile ID	Action	Discussion
8	040800002009	P	LIC03 + Lisinopril Drug Interaction
17	040800000017	P	Trazodone + Provigil - is this appropriate
18	040900000018	P	Lithium 450 Larvicial used with a quick escalation in dose
36	040900000036	P	Multiple prescriber letter

27	84096000697	P	Multiple prescriber letter
28	84096000659	P	Multiple prescriber letter
27	84096000677	P	Multiple prescriber letter
181	84096000188	P	Drug-Interaction Oxycodn (Anticholinergic)+ Aricept (Cholinesterase Inhibitor)

EXHIBIT E
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002031

EXHIBIT E
PAGE 10 OF 16

K L M N F G H I J

Baseline Metabolic Assessment Tool

Patents with [illegible] — particularly those being treated with antipsychotic drugs — are at increased risk for obesity, hyperlipidemia, and [illegible]. This assessment [illegible] developed [illegible] in an initial assessment [illegible] complications.

Date: ____________

Name: ____________

Height (in)	____	Fasting blood glucose (mg/dL)	____	Date checked: ____
Weight (lb)	____	Fasting lipid panel (mg/dL)	____	Date checked: ____
BMI (kg/m²)	____	Total cholesterol	____	
Waist circumference	____	LDL	____	
[illegible] (cm)	____	HDL	____	
Blood pressure (mm Hg)	____	Triglycerides	____	

Fasting refers to no food or [illegible] for at least 12 hours prior to testing

Current medications: ____________

Metabolic Syndrome Criteria (ICD-9 code 259.8)

[illegible] of the following risk factors

Risk Factor	Defining Level
☐ Abdominal obesity	
Men	>40 in (>102 cm)
Women	>35 in (>88 cm)
☐ Triglycerides	≥150 mg/dL
☐ HDL cholesterol	
Men	<40 mg/dL
Women	<50 mg/dL
☐ Blood pressure	≥130/≥85 mm Hg
☐ Fasting glucose	≥100 mg/dL

Type 2 Diabetes Criteria (ICD-9 code 250.00)

Diabetes	FPG ≥126 mg/dL (preferred) OR Casual plasma glucose ≥200 mg/dL with symptoms of diabetes
Prediabetes	FPG 100-125 mg/dL [illegible]
Normal	FPG <100 mg/dL

FPG = fasting plasma glucose.

Total, LDL, and HDL Cholesterol Classification

Total (mg/dL)	
<200	Desirable
200-239	Borderline high
≥240	High
LDL (mg/dL)	
<100	Optimal
100-129	Near/above optimal
130-159	Borderline high
160-189	High
≥190	Very high
HDL (mg/dL)	
<40	Low
≥60	High

[illegible]

Determining Body Mass Index (BMI) From Height and Weight

	Body Mass Index (kg/m²)						Overweight					Obese		
Height (in)	19	20	21	22	23	24	25	26	27	28	29	30	35	40
	Body Weight (lb)													
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	124	[illegible]	[illegible]	[illegible]	143	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	128	[illegible]	138	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	133	[illegible]	[illegible]	148	[illegible]	[illegible]	204
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	137	[illegible]	[illegible]	153	[illegible]	[illegible]	211
[illegible]	100	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	158	[illegible]	191	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	163	[illegible]	[illegible]	225
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	204	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	172	[illegible]	[illegible]	191	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	177	[illegible]	[illegible]	197	230	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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71	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
72	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
73	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
74	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
75	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
76	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Recommendations/actions: ____________

ZYP-AK-03352

002032

EXHIBIT E

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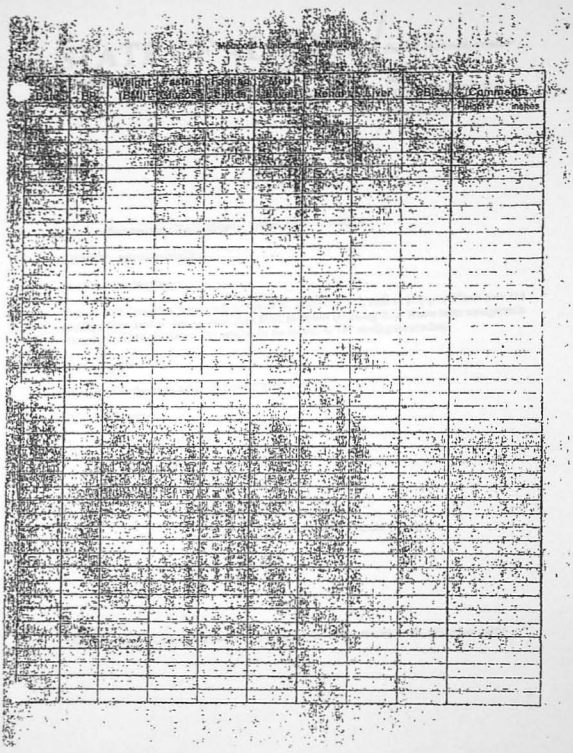

ZYP-AK-03353

002033

EXHIBIT E
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K L M N F G H I J

STATE OF ALASKA

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH CARE SERVICES

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December 3rd, 2004

Alaska Medical Assistance Drug Utilization Review (DUR) Committee

SUBJECT: Agenda for meeting.

Dear Committee Members:

The next DUR Committee meeting will take place on, December 17th, 2004 at 1:30 pm. Please note, the meeting will be held at 4501 Business Park Blvd. Suite #24 (Building 'L'). Please make arrangements to attend this meeting in person. The minutes for the November 19th meeting are attached.

Meeting Agenda:

(1) Approve the minutes from the November 19th meeting.

(2) Profile review.

(3) Distribute next set of profiles.

Sincerely,

Dave Campana

Dave Campana, R.Ph., DUR Coordinator

Attachment

**The future meeting dates are currently scheduled as follows: 12/17/04, 1/28/05, 2/18/05, 3/18/05, 4/15/05, and 5/20/05*

EXHIBIT 12-9-04 Campana

ZYP-AK-03344

002034

EXHIBIT E
PAGE 13 OF 16

K L M N F G H I J

Attachment 1.

DUR Committee Meeting Minutes
For meeting on 11/19/04

PRESENT: Terry Babb, PharmD.; Heidi Brainerd, R.Ph.; Dave Campana, R.Ph., DMA Pharmacy Program Manager; Charlene Hampton, RPh.; Arthur Hansen, D.D.S.; Greg Polston, M.D.; Alex von Hafften, M.D.

EXCUSED: N/A

1. The meeting called to order at 1:22 p.m. by Dave.

2. Remaining profiles from the previous run were reviewed.

3. The next DUR meeting will be on December 17th (No P&T meeting)

4. Profiles for December 17th meeting will be distributed by mail.

5. Dr. von Hafften provided his presentation on antipsychotics with the associated risk of metabolic disorder to those who were not present at the last meeting

   - anti-psychotic drugs, 60% risk of metabolic syndrome

   - Clozapine/Zyprexa cause weight gain

6. Dr. Polston – LA opioid decision would have been better to use max units

7. With the decision to add morphine and hydromorphone to PA it makes sense to add short acting hydromorphone and methadone.

8. The intervention letter for profiles reviewed in October & November is to contain references to performing appropriate laboratory tests while on the antipsychotics due to the risk of metabolic disorders. The intervention should also include any profile or drug interaction noted in the minutes.

Criteria: Atypical antipsychotics with Oral Hypoglycemic agents

Count	Profile ID	Action	Discussion
1	04090000001	P	
2	04090000002	P	concern labs not shown
9	04090000009	P	Lithium & Lisinopril
38	04090000036	P	Multiple Prescribers
37	04090000037	P	Multiple Prescribers

K L M N F G H I J

39	04090000039	P	Multiple Prescribers
89	04090000089	P	Multiple Prescribers Letters
90	04090000090	P	Rosiglitazone CHF DI
93	04090000093		Labs done, difficult to manage patient, Zyprexa 50mg
102	04090000102	P	61 year old male; fluid metformin & simvastatin; Geodon/Zyprexa
103	04090000103		47 year old male; topiramate; paxil seroquel no labs 14 prescribers
104	04090000104		5 prescribers no labs ability & cogentin 3 mg
107	04090000107	P	Effexor & HTN may CK
108	04090000108	P	CHF on Rosiglitizone & metformin
111	04090000111		77 year old female
116	04090000116		67 year old male CHF & metformin; 8 prescribers
121	04090000121	P	24 multi-prescribers: clozaril & cogentin; depo-provera; ER violence; lockin.
124	04090000124		27 year old female multi-prescribers: diabetic
127	04090000127		14 year old male 11 prescribers; thyroid prob; $LiCO_3$
129	04090000129	P	41 year old female; Effexor + HTN
135	04090000135		35 year old male; 5 prescribers; Zyprexa + Topimate
138	04090000138	P	70 year old; 8 prescribers, Rosiglit + Metformin
139	04090000139		labs done; psychiatric moving right dir.
150	04090000150		60 year old female; 6 RPh renal failure; effexor DI verapamil; hospital admit for drug & poisoning opiate & benzo; eff benzo & opiate by end
154	04090000154		Haldol & Seroquel; Haldol Dz blockers inc seroquel same goal with only seroquel
155	04090000155		50 year old male diabetic not on ACE dr ARB
158	04090000158		7 prescribers 3 pharm, back to back Tequin - Levaquin,Carbidopa more sensitive to atypical
159	04090000159	P	58 year old female; $31,000; 18 multi-prescribers
159	04090000159		47 year old male 14 prescribers $LiCO_3$; BiPolar back off antidepressants; HTN Effexor
160	04090000160	P	48 year old female 2 prescribers; PVD, sertraline dose 150-250; max 200; 4-19 150; 5-18 250
161	04090000161		62 year old female go off zyprexa
164	04090000164		37 year old female diabetic, anemic hyperlipedemic, seroquel, antabuse, leave alone

172	04090000172	P	18 prescribers D-D
173	04090000173	P	
174	04090000174	P	68 year old female D-D cimetidine
183	04090000183	P	4 Atypical antipsychotic metaformin
185	04090000185	P	Diabetic not on ADE, no statin
188	04090000188	P	Detrol XL & Aricept
192	04090000192		Lorazepam 6 mg
194	04090000194	P	Multi-prescribers; furosemide + geodon, arrhythmia risk
218	04090000218	P	Multi-prescribers
225	04090000225	P	Multi-prescribers
233	04090000233	P	Effexor + HTN; High dose Seroquel

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

PLAINTIFF'S FIRST AMENDED RESPONSES TO DEFENDANT'S FIRST SET OF INTERROGATORIES

Pursuant to Rules 26(e)(2) and 33 of the Alaska Rules of Civil Procedure, Plaintiff hereby amends it's Responses to Defendant's First Set of Interrogatories as follows. Plaintiff specifically reserves the right to further supplement and or amend these responses as discovery continues and as provided for by the applicable rules of procedure.

INTERROGATORIES

INTERROGATORY NO. 1: Identify each Medicaid State Plan in effect for the State of Alaska since 1996, and for each plan:

a. state whether pharmacy benefits are offered as part of the coverage;

b. state whether pharmacy benefits are offered for Zyprexa prescriptions; and

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500 L STREET
FOURTH FLOOR
ANCHORAGE, AK
99501
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FAX: 907.274.0819

ANSWER: See response to Request for Production No. 3. The State has had a formulary since approximately 1995. The State has had a PDL since approximately 2004. The PDL does not include any atypical antipsychotic medications.

a. Zyprexa is on the formulary but it is not on the PDL.

b. There are no rules, regulations and/or restrictions on the prescription of Zyprexa except the general requirement that the prescription be "medically necessary."

c. Other atypical antipsychotic medications are on the formulary but there are no atypical antipsychotics on the PDL.

INTERROGATORY NO. 3: Did you ever modify the formulary and/or PDL for any antipsychotic drug? If so, explain why.

ANSWER: Neither the PDL nor the formulary has ever been modified for any antipsychotic drug.

INTERROGATORY NO. 4: Identify the Alaska employees or representatives who communicated with Lilly about Zyprexa since 1996.

ANSWER: David Campana and Tom Porter, M.D.

INTERROGATORY NO. 5: Identify each employee of Alaska that had supervisory or management responsibility for any of the pharmacy benefits offered to Medicaid recipients, or any role in selecting drugs for the formulary and/or PDL, since 1996. For all employees identified in response to this interrogatory, identify all documents they considered regarding Zyprexa.

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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

VIDEOTAPED DEPOSITION OF THOMAS J. PORTER, M.D.

December 5, 2007
10:12 a.m.

Taken at:
The Offices of Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

Reported by: Leslie J. Knisley
Shorthand Reporter

beginning of this tape, I said that the time was 11:12; the time was actually 10:12 a.m.

Q (BY MR. ROTHSCHILD) Dr. Porter, while we were off the record, I clarified my request to you made on the record and asked you just to read through the first 27 paragraphs of the Complaint, which contain the factual allegations.

Have you done that?

A I have, sir.

Q Okay. And have you read carefully through each of the paragraphs?

A Yes, sir.

Q Okay. What paragraphs do you believe you -- what events alleged in those paragraphs do you believe you have knowledge about?

A I have none.

Q Tell me what you did in your position as chief medical officer for the federal clinic in the late 1960s.

A I was the medical officer and also saw patients in a general practice outpatient clinic, making referrals to Seattle, my home hospital, when necessary for additional or specialist training. I did this for two years, sir.

Q And what was -- what did you do as the

A I think we met because we were friends.
Q Are these people you knew before you took your position as medical --
A Quite a few of them, yes, sir.
Q Did you ever meet with anybody from Eli Lilly?
A I don't recall.
Q Okay. Was it ever the case that representatives from pharmaceutical companies would actually come to your place of work while you were medical officer at the State of Alaska?
A No, sir.
Q Did the State reimburse the antipsychotic drug Zyprexa during the time that you were medical officer?
A We had an open pharmacy. I would assume that Zyprexa was probably used and prescribed by the psychiatrists or mental health people.
Q But you're answering that question based on sort of an assumption as opposed to any recollection of whether it did or didn't?
A That is correct, sir. I do not recall specific prescriptions of Zyprexa.
Q Do you know when Zyprexa launched?
A No, sir, I don't.

Q Did you do anything to educate yourself about Zyprexa when it was launched?
A No, sir, I did not.
Q Did you do anything to educate yourself about Zyprexa at any time during your employment for the State of Alaska?
A I don't recall, sir.
Q Have you done anything to keep yourself current about literature regarding Zyprexa since you retired from the State of Alaska?
A Zyprexa is not normally a pediatric drug, so I generally leave those sorts of informations to the old-people doctors. "Old" being over 18.
Q So the answer is no?
A The answer is no. Yes, sir. Excuse my frivolity.
Q That's all right. Do you know what class of drugs Zyprexa belongs to?
A I believe it's an antipsychotic.
Q And do you have any familiarity with what other antipsychotic medications were available during your tenure for the State of Alaska?
A I'm familiar with some. Thorazine, the

MR. BIGGS: Objection; asked and answered.

A I was told about the side effects this morning at the predeposition hearing being hyperglycemia and development of diabetes mellitus.

Q (BY MR. ROTHSCHILD) And you don't know that to be true independent of what you were told this morning?

A I do not recall that I know that to be true.

Q Fair enough. We asked the State of Alaska a written question early in the litigation, which was asking them to identify the Alaska employees or representatives who communicated with Lilly about Zyprexa since 1996. And the answer we received was, David Campana and Tom Porter.

From everything I've heard today, we may be going down a blind passage, but is it the case that in your capacity as an employee for the State of Alaska you ever communicated with Lilly about Zyprexa?

A Sir, I do not remember. That was six years ago and spread over 13 years.

Q From what you've described to me, your contacts with pharmaceutical companies, other than to receive the package inserts, was as a general matter very limited, correct?

A That is correct, yes, sir.

Q So -- and sitting here today, you have no recollection of any specific communications with anybody at Eli Lilly about Zyprexa?

A I do not remember, sir.

Q Okay. You don't have -- am I correct in understanding you don't have any specific recollections about any communications with anybody from Eli Lilly about anything?

A I've gotten literature about Cialis.

Q I'm not going to follow up on that.

A Thank you, sir.

Q Other --

A Your question, no.

Q Okay. So -- and I just -- you know, I want to make sure I cover everything here.

You can't remember any in-person or verbal communications with anybody at Eli Lilly about anything?

A That is correct.

Q You, as a general matter, received

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

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

VIDEOTAPED DEPOSITION OF JOEL GILBERTSON

December 6, 2007
9:03 a.m.

Taken at:
The Offices of Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

Reported by: Leslie J. Knisley
Shorthand Reporter

Q When did that happen?
A I can only give you years. 2003, 2004 and probably 2005, but I -- I know for certain 2003 and 2004.
Q Do you remember the names of the individuals that you interacted with?
A I remember two, but I may get one name wrong. But I don't remember others that there may have been.
Q Okay.
A The two that I do remember are Sam Kito, who was an Alaska-based lobbyist for Eli Lilly, who I don't remember any personal offices in my -- meetings in my office, but I do know he was lobbying and I would encounter him in the legislature. And then Nate Miles, I believe was his name, who was a regional lobbyist for Ely Lilly.
Q What did they lobby you about?
A They lobbied me in 2003 to not implement a preferred drug list, and then during -- when I say "me," I mean the State, not me personally. And then they lobbied the State in 2003 and 2004 to have their drugs -- or mental health drugs carved out from the States's preferred drug list.

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RE: State of Alaska v. Eli Lilly & Co., 3AN-06-05630 CI

DISCOVERY MASTER ORDER
State's First Motion to Compel
Lilly's Motion to Compel
Lilly's Motion for Commission for Subpoena

Introduction

The State of Alaska seeks damages from Eli Lilly & Co. for harm allegedly caused by Lilly's marketing and sale of the drug Zyprexa. The State asserts claims in strict product liability for failure to warn and design defect, for violation of the State's Unfair Trade Practices and Consumer Protection Act, and for negligence, negligent misrepresentation and fraud.

The State has not filed a class action and is not seeking damages for individual patients. Instead, the state seeks to recover for excess expenditures allegedly incurred by

K L M N J

information from its database is unduly burdensome. Lilly asserts that it must search approximately 40,000 entries in the call note database, a task that may take 1300 hours. The State disputes this assertion.

I do not have enough information to determine how burdensome the search for Alaska related Zyprexa call notes will be. But Lilly's proposed solution to the issue appears reasonable. Lilly proposes to produce a random sample of Zyprexa related call notes and suggests that any pattern relevant to these proceedings should reveal itself through that sample.

Lilly shall produce a random sample of 4,000 Alaska call notes referencing Zyprexa.

Int. #7, RFP # 10. Lilly withdrew its objection at oral argument.

Int. #12. GRANTED in part. The State seeks financial information regarding Lilly's worldwide revenue from Zyprexa sales, cost of products sold, gross margin, operating expenses, other expenses and income before taxes. Lilly agrees to produce publicly available information regarding sales and revenue, but objects to engaging in forensic accounting to calculate cost of products sold, gross margin, operating expenses and pre-tax income. While the more detailed financial information may help the State prove a motive for misrepresentation or corroborate the State's claim that Lilly's marketing tactics resulted in increased sales, the publicly available information offered by Lilly is relevant to the same issue. In light of the State's interest in efficient discovery to maintain the March 2008 trial date, Lilly's objections to produce other than publicly available information are sustained. Lilly must produce publicly available worldwide Zyprexa sales revenue responsive to this request.

Int. #13. Granted in part. The State seeks information regarding Lilly's Alaska Zyprexa sales revenue, and its gross margin and income before taxes. For the reasons stated regarding Int. # 12, Lilly must produce publicly available Alaska Zyprexa sales revenue responsive to this request.

Int. # 19 and 20. Lilly's 9//21/2007 letter is responsive to this request.

RFP # 4, 5 and 6. GRANTED. The State seeks documents regarding communications about Zyprexa from Lilly to Alaska physicians other than those made by Lilly sales representatives. Those include communications made by "thought leaders" – physicians or other consultants retained by Lilly to communicate about Zyprexa on Lilly's behalf. At oral argument Lilly counsel conceded that these documents may be discoverable and indicated that counsel had not made a search for them. Counsel also indicated that he would check but was not certain whether he had the capability of locating that information in Lilly's file database.

Lilly shall make a diligent search for documents responsive to these requests and produce those documents within 15 days. If unable to locate documents Lilly must explain efforts made in that regard.

Int. # 5, 15, 16, 17 and 18; RRFP # 8, 15, 17, and 18. GRANTED in part. Lilly did not object to the discoverability of the information sought by these requests but referred the State to the MDL collection to obtain that information. The State asks that Lilly at least designate the Bates ranges for that information to ease the burden of locating the documents.

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

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

ELI LILLY AND COMPANY'S OBJECTIONS AND RESPONSES TO PLAINTIFF'S FIRST REQUESTS FOR PRODUCTION TO DEFENDANT

Defendant Eli Lilly and Company ("Lilly) hereby serves the following Objections and Responses to Plaintiff's First Requests for Production to Defendant.

PRELIMINARY STATEMENT

Lilly notes that there is a multi-district litigation captioned *In re Zyprexa Products Liability Litigation*, MDL 1596, pending in the Eastern District of New York before the Honorable Jack Weinstein (the "MDL"). Lilly has produced approximately twelve million pages of materials, with indices or objective coding, pursuant to the terms of Case Management Order (CMO) No. 2.[1] Consistent with the Court's direction and the parties' intent in the MDL to conduct discovery as efficiently and expeditiously as possible, Lilly's responses to the MDL document requests, together with documents

[1] The MDL Plaintiffs' Steering Committee has acknowledged the comprehensiveness of Lilly's document production in the MDL. *See* The Plaintiffs' Steering Committee Memorandum Summarizing the Status and Location of Information Obtained by the Committee in These MDL 1596 Proceedings, a copy of which is attached as Exhibit A. In addition, Judge Weinstein has entered an Order stating , in pertinent part, "In order to reduce transactional costs and the burdens on state courts, I have ruled that these materials shall be made available free of charge to litigants in state cases." *See* Memorandum on Cooperation Between Federal and State Judges, MDL 1596 (JBW), dated January 18, 2007, attached as Exhibit B.

admissible evidence. The fact that Lilly has answered all or part of any discovery request is not intended as, and shall not be construed to be, a waiver of any objection to any request.

GENERAL OBJECTIONS

Lilly makes the following General Objections which are in addition to, and incorporated within, each of the Specific Responses set forth below:

1. Lilly objects to these discovery requests to the extent they seek information and/or documents which are neither relevant to the claims or defenses of any party nor calculated to lead to the discovery of admissible evidence, including but not limited to information about adverse events not at issue; concern any Lilly product other than Zyprexa; seek documents and information about events that took place after prescribing physicians issued the Zyprexa prescriptions to Alaska's Medicaid recipients that Plaintiff claims were the cause of the damages that Plaintiff seeks in this matter or, in any event, after September 1, 2004; are not limited to contacts with physicians that prescribed the Zyprexa prescriptions for Alaska's Medicaid recipients that Plaintiff claims were the cause of the damages that it seeks in this matter; or seek information concerning doses, formulations or products containing Zyprexa not used by Plaintiff's Medicaid recipients.

2. Lilly objects to these discovery requests, both individually and as a whole, on the ground that they are overly broad, burdensome and oppressive. Responding to these discovery requests as currently drafted would be unreasonably difficult and expensive.

3. Lilly objects to these discovery requests on the ground that no distinction is made between privileged and non-privileged information, documents,

costs associated with the use of Zyprexa" as vague and undefined. Lilly further objects to these requests as overbroad, unduly burdensome, and premature, as Plaintiff has not produced information sufficient to identify physicians who issued the prescriptions giving rise to Plaintiff's claims in this lawsuit.

REQUEST FOR PRODUCTION NO. 7: Produce an electronic, searchable database copy of all call notes generated by any sales representative in Alaska between October 1996 to the present which relate or refer to Zyprexa.

RESPONSE: Lilly incorporates General Objection Nos. 1, 2, 4, 5, 7, 12, 13 and 16 as if set forth fully herein. Lilly also objects to the phrase "generated by sales representatives in Alaska" as vague and undefined. Lilly further objects to these requests as overbroad, unduly burdensome, and premature, as Plaintiff has not produced information sufficient to identify physicians who issued the prescriptions giving rise to Plaintiff's claims in this lawsuit.

REQUEST FOR PRODUCTION NO. 8: Produce color copy samples of any and all advertisements for Zyprexa which appeared in medical journals published in the United States between October 1996 to the present.

RESPONSE: Lilly incorporates General Objection Nos. 1, 2, 7, 12, 13 and 16 as if set forth fully herein. Lilly also objects to the term "samples" as vague and undefined. Subject to and without waiving these objections, Lilly states that promotional materials submitted to the FDA are contained in the MDL collection, which Plaintiff may access subject to the entry of an appropriate protective order.

REQUEST FOR PRODUCTION NO. 9: Produce any and all documents relating to, referring to or embodying any communications between Lilly or any employee or representative of Lilly and any employee or representative of Alaska's executive or legislative branch of government regarding the efficacy, benefits, risks or costs associated with the use of Zyprexa from October 1996 to the present.

RESPONSE: Lilly incorporates General Objection Nos. 1, 2, 3, 4, 5, 6, 7, 12, 13 and 16 as if set forth fully herein. Lilly also objects to this request on relevance

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

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

MOTION ARGUMENTS BEFORE THE DISCOVERY MASTER

Pages 1 - 168
Tuesday, September 11, 2007
11:00 A.M.

at
LANE POWELL
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

which a small number of them were Alaska-based call notes, a couple of hundred. In addition, to the extent that there were prescribers that prescribed Zyprexa and the claim is that diabetes was caused as a result of that prescription, call notes involving certain of those prescribers were also produced as part of the litigation.

DISCOVERY MASTER: In the MDL.

MR. BOISE: In the MDL or state court actions as well. What you have here, then, is if there was -- there is a mechanism that was set up to do some form of sampling of the total database. Now, what we've done in response to the plaintiff's motion, the State's motion, is say, "Okay. How many of those call notes can we isolate to Alaska?" And we've approximated that number to be about 40,000 of these entries. And what we have proposed is a similar system as to what we have utilized in other fora which is sampling method to extract a certain percentage of those, or to the extent that there are doctors that they believe have been deceived, we can identify those physicians and produce call notes for those doctors so we can get at what is really going on in that note.

A call note is not a verbatim record. It

is a jotting used by sales representatives to jog their memory in the short term. So it hardly reflects the full nature of any communication, and to get the full measure, certainly we would have to get some information around that communication above and beyond perhaps the call note.

What I heard today for the first time, which I think is interesting, is the emphasis really on Donna. And certainly the database is searchable, and we could, for example, search and produce the Alaska call notes that reference Donna or mushy middle or things of that nature --

MR. SUGGS: It's not just Donna.

MR. BOISE: -- and produce those terms. But if there is certain allegations that they're making they want us to look for, extract and produce, we are all for some reasoned approach.

Just so you get a fuller picture of mood, thought and behavior -- and this really ties to the database argument a little bit.

DISCOVERY MASTER: May I ask you a question before you continue?

MR. BOISE: Absolutely.

DISCOVERY MASTER: Do you object to producing the call notes other than overbroad and

burdensome? If you object to produce a random sample? Or tell me why you're not willing to produce them all.

MR. BOISE: The full data set? Yeah, the burden is in our history. And we have a long history of producing call notes in the litigation. It's about -- the review-and-produce time is about two minutes per call note of review time. So you can do the math for --

DISCOVERY MASTER: And you say there are 40,000 Alaskan?

MR. BOISE: Alaska call notes.

DISCOVERY MASTER: On Zyprexa?

MR. BOISE: Well, that could involve Zyprexa. We have to look at them to see whether they involve Zyprexa.

DISCOVERY MASTER: You have to look at them individually?

MR. BOISE: Yes.

MR. SUGGS: Your Honor.

DISCOVERY MASTER: I don't want to interrupt his argument. I'll let you respond when he finishes.

MR. BOISE: Yeah, and, you know, there is a lot of long discussion about, you know, how much

discovery of physicians is going to take place ultimately in this case. And certainly the extent that Lilly would pursue any physician's deposition, we would do what we have always done in the underlying litigation, is produce the call notes that associate with that physician. So those interactions are part of the discovery record, that we take it on a physician-by-physician basis. If there is more reasoned way to get at this to meet the State's needs short of 40,000, whether it's, you know, searching certain terms or not, we're willing to discuss that. We just have not had the opportunity to discuss whether anything short of this is even of interest.

Just so the allegation doesn't go unsaid. I know we're not trying the case before you today. Bipolar disorder for which Zyprexa is indicated is a mood disorder. So when the plaintiffs claim that if a doctor writes "mood" down in a record or "mood" somehow gets to a database, that that means it's nonindicated, we would say that's exactly why we need to look at medical record which would show the elements of bipolar disorder.

You know, it's a new disorder, and that's exactly what the Donna profile, to use the example, is going to. There is certainly a profile consistent

with bipolar disorder.

So we're willing to, on call notes, produce a subset, a reasonable subset, come up with some accommodation with the State to meet their needs.

As far as identifying the actual reps, we would be willing to extract from the call note database the reps that worked in Alaska and get that list of individuals to the State to take that off the table, as well.

As far as -- now, going forward in trying to collect all the files of all the people that ever worked in Alaska, we would suggest that that is unnecessary for a number of reasons.

The primary reason is -- again referring to a database production that Lilly has made in the underlying litigation that the State has access to. Mr. Suggs is pulling documents to show Your Honor today in many scores, which is highlighting the fact they've had discovery on many of these issues.

One issue where there has been extensive discovery, are there resources that are available to sales representatives. There is a database, which Mr. Suggs knows well, called Knowledge Management, or KM, which is the resource guide for which sales reps

can pull information to utilize in the field.

They have that centralized database and data source, and to go out and then to try to collect the pieces for a rep where they have the source from which they pull the information is duplicative and, you know, has largely been rejected in litigation as such.

So if there is a rep of interest, again, what we've done in the litigation is say, "Here's a rep we're really interested in. Let's talk about it. Let's see if their file is pertinent to the allegations that are made." And we in certain circumstances certainly produced those files. But to do whole-cloth "go and collect from the field information that's already been produced from the source" we think is inappropriate, and we think there are better ways to get at the call note database than what has been suggested.

MR. SUGGS: As part of our unfair trade practices claim, we're entitled to try and establish the communications that they had with all physicians in the state, not just particular physicians.

This call note database, they can sort this by state. So they can pull out all the Alaska with the click of a button, just like I did right there.

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.	)	

MEMORANDUM IN SUPPORT OF PLAINTIFF'S MOTION TO COMPEL DISCOVERY

I. INTRODUCTION

This case involves Lilly's conduct related to the prescription drug Zyprexa. The State has brought various claims for relief against Lilly in connection with the use of Zyprexa in Alaska's Medicaid program, the most pertinent of which for the purposes of this motion include Lilly's failure to warn physicians and payors like the State of the inherent risks of Zyprexa and Lilly's fraud, misrepresentation and deception in the marketing of Zyprexa. On February 8, 2007, the State served its first sets of Interrogatories and Requests for Production on Lilly which, for the most part, focused on Lilly's marketing of Zyprexa for use by Medicaid programs generally; Lilly's marketing and communications regarding the use of Zyprexa within Alaska; its communications with national organizations in positions to influence the use of Zyprexa in Alaska; and

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at trial and relevancy for purposes of discovery are two different matters," and relevancy for purposes of discovery is "to be construed liberally."[5]

Under these guideposts, the State's requests seek information that is clearly relevant to the subject matter of the action and to its claims and Lilly's defenses in this action. The State has asserted common law and statutory claims which require it to demonstrate, among other things, Lilly's knowledge of Zyprexa's risks, that Lilly did not communicate those risks adequately to others, and that Lilly's communications regarding Zyprexa were misleading or false in other respects.

B. Interrogatory No. 4 and corresponding Request for Production No. 7.

The State has requested the identities of Lilly's sales representatives in Alaska from October 1996 to the present and a database of "call notes" generated by those sales representatives. The electronic database of call notes consist of brief reports generated by sales representatives shortly after they make sales presentations to physicians and thus contain contemporaneous evidence of what Lilly's sales force told prescribing physicians about Zyprexa.[6] That evidence is clearly relevant to the State's failure to warn, fraud and unfair trade practice claims. Lilly has responded by incorporating essentially the same general objections as those indicated previously, and further responded by stating the

[5] *Doe v. Alaska Superior Court, Third Judicial Dist.*, 721 P.2d 617, 620-21 (Alaska 1986).

[6] The process of making sales presentations to physicians is often referred to in the pharmaceutical industry as "detailing" and sales representatives are often referred to as "detailmen."

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request is premature because the State has not identified the specific physicians who prescribed Zyprexa which resulted in injury for which the State is claiming damages.

However, the State's request cannot be conditioned upon or limited by its identification of specific prescribing physicians in Alaska. The State's Unfair Trade Practice and Consumer Protection (UTPA) claims are not limited to prescriptions which resulted in injury to anyone and include misleading conduct by Lilly which violated the Act without regard to any subsequent injury. Misleading and improper detailing of any Alaska physician falls within the ambit of such a violation, even if the physician did not ultimately write a Zyprexa prescription. Thus, limiting the State's discovery to actual prescribing physicians does not afford the State full discovery of relevant and admissible evidence of Lilly's communications and conduct regarding Zyprexa. Moreover, Lilly clearly has information regarding which physicians it detailed in Alaska regarding Zyprexa, and should be compelled to produce all such information. In addition, the electronic call notes database contains a "field" of data indicating the state in which the physician lives and thus Lilly can easily retrieve all of the call notes relating specifically to communications with Alaska physicians regarding Zyprexa. This information is relevant and admissible evidence of Lilly's knowledge, communications and conduct related to Zyprexa.

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C. **Interrogatory No. 7 and corresponding Request for Production No. 10.**

The State has requested the identities of those responsible for developing and implementing marketing programs to support access to Medicaid recipients and any documents regarding the same. Lilly's specific objection is again based on its improper assertion that the State is only entitled to discovery of Lilly's conduct directed specifically to physicians, thereby rendering any other activities or communications irrelevant. As stated above, this is simply incorrect. Lilly's activities and communications aimed at access by or promotion for the State's Medicaid population are central to the State's claims. The crux of the State's common law and statutory claims are that Lilly's misconduct resulted in increased Medicaid expenditures and these requests seek information and documents related to marketing programs that may have directly resulted in those increased expenditures. Such information is clearly relevant to the State's claims.

D. **Interrogatory Nos. 12 and 13.**

The State has requested specific financial information on an annual basis related to sales of Zyprexa both globally and in Alaska. Again, Lilly has incorporated a number of its general objections (12 of them) and only specifically objected that the information sought is unduly burdensome, overly broad and irrelevant to any claims for relief in the litigation. However, Lilly has failed to define its burden in relation to producing this information.

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A party resisting discovery on grounds the discovery is overly broad or burdensome must set forth facts "demonstrating that the time and expense involved in responding to discovery is *unduly* burdensome," thus imposing an obligation on the party "to provide sufficient detail in terms of time, money and procedure required to produce the requested documents."[7] This showing requires more than the mere assertion of the party or its attorney.[8]

Lilly is a publicly traded company, and is therefore required to maintain and periodically report similar information to that requested by the State. Thus, any claim that the request is unduly burdensome is specious. Moreover, the information is relevant to the subject matter of this action. Evidence of Lilly's sales and profits for Zyprexa is relevant to establish Lilly's state of mind and motive to engage in fraud, misrepresentation and unfair trade practices. The State believes that Lilly's conduct in this case was motivated by financial gain and the information requested is clear evidence of this motivation. Further, to the extent the requested information shows increasing financial gains after certain promotional conduct complained of by the State was

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[7] *Superior Film of America, Inc. v. UCB Films, Inc.*, 219 F.R.D. 649, 651 (D. Kan. 2004).

[8] *See Chubb Integrated Serv. Sys. Ltd. v. Nat'l Bank of Washington*, 103 F.R.D. 52, 60-61 (D.D.C. 1984) ("An objection must show specifically how an interrogatory is overly broad, burdensome, or oppressive, by submitting affidavits or offering evidence which reveals the nature of the burden.").

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implemented, it is clear evidence of the result of the conduct. Lilly should be required to produce the requested information.

E. Interrogatory Nos. 19 and 20 and corresponding Request for Production Nos. 19 and 20.

The State has requested the identification of any civil or criminal investigations or actions involving Lilly and Zyprexa and the identities of involved Lilly employees or representatives and any corresponding witness statements, testimony or other documents related thereto. Lilly resists disclosure by invoking 14 of its general objections. Lilly also asserts claims of attorney-client privilege and work product protection, yet fails to demonstrate how either concept applies to the particular information sought. Rule 26(b)(5), Alaska R. Civ. P., requires a party withholding information it claims is privileged or subject to protection as work product to "make the claim expressly" and "describe the nature of the documents, communications, or things not produced or disclosed in a manner that, without revealing the information itself privileged or protected, will enable other parties to assess the applicability of the privilege or protection." It is Lilly's burden to establish its entitlement to either form of protection from disclosure.[9] Lilly has supplied no information in its responses fulfilling the burden imposed on it by Rule 26(b)(5) or demonstrating the applicability of the attorney-client privilege or work product doctrine to the documents withheld in discovery.

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[9] *See Plate v. State*, 925 P.2d 1057, 1066 ("The party asserting the privilege bears the burden of proving that the contested communication is protected by the privilege.").

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RE: State of Alaska v. Eli Lilly & Co., 3AN-06-05630 CI

DISCOVERY MASTER ORDER
STATE'S SECOND MOTION TO COMPEL

For the reasons stated below, the State's Second Motion to Compel is GRANTED.

The State's second motion to compel seeks discovery of information related to a March 28, 2007 letter from the FDA to Lilly regarding a drug called Symbyax, a combination of Zyprexa and Prozac. The letter refers to a study or research submitted by Lilly and expresses concern that information known to Lilly about weight gain, hyperglycemia, and hyperlipidemia associated with the drug was not included in Lilly's proposed warnings. The state seeks information regarding the studies and communications between Lilly and the FDA regarding the March 28 letter.

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Lilly claims that information sought by the State is irrelevant because it was developed in 2006 or later and the State's claims are based on conduct preceding 2006. Lilly also argues that even if the information is relevant, the court should impose a discovery cutoff date similar to that imposed by the MDL (2004) because with a medicine on the market, new information is developed daily. Finally, Lilly claims that it should not be required to disclose information regarding Prozac, the other drug in Symbyax.

I find that the discovery seeks information that may lead to the relevant evidence. The FDA letter expresses the same concerns raised by the State in this litigation – whether Zyprexa (alone or in combination) creates an increased risk of diabetes symptoms. Although Lilly presented the studies to the FDA in 2006, it is possible that the studies were based on information available earlier. Finally, because the request focuses on a discrete issue, allowing this discovery will not automatically open Lilly up to ongoing discovery of information generated at later times.

Lilly shall answer the State's Interrogatories 1-9 within 10 days. Lilly shall produce the documents requested by the State's RFP Nos. 1-6 within 15 days.

To the extent that information responsive to these discovery requests is contained in the MDL discovery collection, Lilly's counsel shall identify a specific means of locating the information, or if unable to locate it, explain why counsel believes it is there and what efforts were made to locate it.

Lilly is not required to produce information regarding Prozac, if it is possible to segregate that information from the discovery.

Dan A. Hensley
Discovery Master

002069

EXHIBIT M
PAGE 3 OF 3

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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 OBJECTIONS AND RESPONSES TO PLAINTIFF'S FIRST INTERROGATORIES TO DEFENDANT**

Defendant Eli Lilly and Company ("Lilly" or "Defendant") hereby answers and objects to Plaintiff's First Interrogatories to Defendant ("Request" or "Interrogatories") as follows:

PRELIMINARY STATEMENT

Lilly notes that there is a multi-district litigation captioned *In Re Zyprexa Products Liability Litigation*, MDL 1596, pending in the Eastern District of New York before the Honorable Jack Weinstein (the "MDL"). Lilly has produced approximately fifteen million pages of materials, with indices or objective coding, pursuant to the terms of MDL Case Management Order (CMO) No. 2.[1] Consistent with the Court's direction and the parties'

[1] The MDL Plaintiffs' Steering Committee has acknowledged the comprehensiveness of Lilly's document production in the MDL. *See* Declaration of Melvyn I. Weiss in Opposition to Motion to Dissolve Multidistrict Litigation and/or Motion to Dissolve the Plaintiff Liaison Committee, Motion to Stay Settlement of Any MDL Cases Pending Hearing of These Motions and in Support of the Motion to Lift the Stay on Discovery, a copy of which is attached as Exhibit A. Further elaboration is provided by The Plaintiffs' Steering Committee Memorandum Summarizing the Status and Location of Information Obtained by the Committee in These MDL 1596 Proceedings, to which Plaintiff may have access upon entry of an appropriate protective order. In addition, Judge Weinstein has entered an Order stating, in pertinent part: "In order to reduce transactional costs and the burdens on state courts, I have ruled that these materials shall be made available free of charge to litigants in state cases." *See* Memorandum on Cooperation Between Federal and State Judges, MDL 1596 (JBW), dated January 18, 2007, attached as Exhibit B.

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GENERAL OBJECTIONS

Lilly makes the following General Objections which are in addition to, and incorporated within, each of the Specific Responses set forth below:

1. Lilly objects to these discovery requests to the extent they seek information and/or documents which are neither relevant to the claims or defenses of any party nor calculated to lead to the discovery of admissible evidence, including but not limited to information about adverse events not at issue; concern any Lilly product other than Zyprexa; seek information or documents that were prepared after the date(s) of the Zyprexa prescriptions to Alaska's Medicaid recipients that Plaintiff claims were the cause of the damages it is seeking in this matter and/or, in any event, after September 1, 2004; are not limited to contacts with physician(s) who issued the prescriptions to Plaintiff's Medicaid recipients that Plaintiff claims caused the damages it is seeking in this matter; or seek information concerning doses, formulations or products containing Zyprexa not used by Plaintiff's Medicaid recipients.

2. Lilly objects to these discovery requests, both individually and as a whole, on the ground that they are overly broad, burdensome and oppressive. Responding to these discovery requests as currently drafted would be unreasonably difficult and expensive.

3. Lilly objects to these discovery requests on the ground that no distinction is made between privileged and non-privileged information, documents, and/or trial preparation materials and, therefore, these requests call for information and material which is beyond the scope of permissible discovery and which is protected from disclosure by the attorney-client privilege and the attorney work product doctrine. In setting forth its responses, Lilly does not waive the attorney-client privilege, work product doctrine, or other privilege or immunity

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INTERROGATORY NO. 11. Identify any and all Lilly employees responsible for communicating with Comprehensive NeuroScience (CNS) from October 1996 to the present regarding the development of Expert Consensus Guideline Series (ECGS) which relate or refer to the use of Zyprexa and describe the "chain of command" or order of authority of reporting relationships from the level of such employees to the Chief Executive Officer of Lilly.

ANSWER: Lilly incorporates General Objection Nos. 1, 2, 3, 4, 5, 6, 7, 9, 12, 13 and 16 as if set forth fully herein. Lilly also objects to this interrogatory on relevance grounds. In its Memorandum Describing Claims and Proofs, setting forth the claims it seeks to prove in this lawsuit and the means by which it seeks to prove them, Plaintiff explicitly set forth that the only alleged misrepresentations about which it would submit evidence in support of its claims for damages are representations to prescribing physicians. Accordingly, interrogatories relating to communications between Lilly and any person or entity other than physicians that prescribed the Zyprexa prescriptions to Alaska's Medicaid recipients which Plaintiff claims were the cause of the damages it is seeking in this matter are not relevant to any of the claims in this lawsuit, nor reasonably calculated to the discovery of admissible evidence. Lilly further objects to this interrogatory on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to the discovery of admissible evidence, as there is no allegation in the complaint referring or relating to CNS and/or the development of ECGS relating or referring to the use of Zyprexa. Lilly also objects to the phrase "from the level of such employees to the Chief Executive Officer of Lilly" as overbroad and unduly burdensome

INTERROGATORY NO. 12. With respect to sales of Zyprexa worldwide from October 1996 to the present, for each year state the:

a. Revenue from such sales;
b. Cost of product sold;
c. Gross margin;

d. Operating Expenses;
e. Other Expenses; and
f. Income before taxes.

ANSWER: Lilly incorporates General Objection Nos. 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 13 and 16 as if set forth fully herein. Lilly objects to the terms in subparts a-f in their entirety as vague and undefined. Lilly also objects to this interrogatory, including all of its subparts, on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, and seeks information that is not relevant to any of the claims set forth or relief sought in this lawsuit

INTERROGATORY NO. 13. State the annual revenue from sales of Zyprexa in Alaska from October 1996 to the present and the gross margin and income before taxes from such sales.

ANSWER: Lilly incorporates General Objection Nos. 1, 2, 3, 4, 5, 6, 7, 8, 9, 12, 13 and 16 as if set forth fully herein. Lilly objects to the terms "annual revenue," "gross margin," "income before taxes," and "in Alaska" as vague and undefined. Lilly also objects to this interrogatory on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, and sees information that is not relevant to any of the claims set forth or relief sought in this lawsuit.

INTERROGATORY NO. 14. Identify the individuals who created and/or maintained the documents that were produced in the Zyprexa MDL with the following beginning Bates Numbers:

ANSWER: Lilly incorporates General Objection Nos. 1, 2, 3, 4, 5, 6, 7, 9, 12, 13, 14, and 16 as if set forth fully herein. Lilly objects to the terms "created and/or maintained" as vague and undefined. Subject to and without waiving these objections, Lilly will provide, where available, the identity of the custodian or document database from whom/which each document was obtained. Further subject to and without waiving these

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

NOTICE OF FILING PLEADING AND EXHIBITS UNDER SEAL

On this date the State of Alaska is filing a pleading titled "Plaintiff's Response to Defendant's Motion to Compel Discovery." Because one or more exhibits filed with these pleadings 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.

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& SANDERS
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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 & COMPANY'S MOTION TO COMPEL DISCOVERY AND MEMORANDUM IN SUPPORT**

COMES NOW, Defendant Eli Lilly and Company ("Lilly"), through counsel of record, and pursuant to Civil Rule 37(a), hereby moves to compel meaningful responses to the discovery demands it has served upon the State of Alaska (the "State") seeking the factual bases of the State's Alaska Unfair Trade Practices and Consumer Protection Act claim.[1] The State's boilerplate responses to Lilly's discovery offer no more than the fact-devoid allegations of the Complaint, and fail to supply even one single fact demonstrating the who, what, when, where, or how of Lilly's alleged misconduct.

With the trial's first phase less than three months away and summary judgment briefing already before the Court, the State's refusal to provide Lilly with critical information about its claim is unjustified and prejudices Lilly's ability to defend this case. Lilly requests that the Court order the State to produce this information immediately.

[1] This motion is being filed with the Court, rather than with the discovery master because Judge Hensley has advised that he would be unavailable the month of December. Additionally, Lilly moves only on discrete discovery items in the instant motion, but reserves its rights to seek court intervention on the State's other discovery deficiencies at a later time.

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I. DEFICIENCIES IN THE STATE'S DISCOVERY RESPONSES

A. Information Regarding the State's UTPCPA Claim.

Count 5 of the Complaint is for violation of the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471, *et seq.* (the "UTPCPA"), which the State vaguely alleges Lilly violated in its marketing and advertising of Zyprexa.[2] The State has proposed that the liability elements of the UTPCPA claim be tried in the first phase of the bifurcated trial, scheduled to start in March 2008.

On October 29, Lilly served a set of interrogatories and requests for production of documents upon the State, specifically tailored to the State's UTPCPA claim, and designed to elicit the facts that the State will rely upon to establish its claim.[3] The interrogatories obligate the State to enumerate each instance in which it alleges that Lilly violated the UTPCPA, and to state the specific factual bases for each such instance, and the resulting ascertainable loss.[4] But the State has refused to supply this information.

In its responses, the State instead merely repleads the same vague allegations set forth in the Complaint:

[2] *See* Complaint at ¶¶ 52-55.

[3] *See* Exhibit A, Lilly's Fourth Set of Interrogatories; Exhibit B, Lilly's Fourth Set of Requests for Production.

[4] *See* Exhibit A.

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> Lilly "minimize[ed] the magnitude and hazard of olanzapine-induced weight gain";
>
> Lilly "den[ied] a causal relationship between olanzapine and hyperglycemia and/or diabetes;
>
> Lilly "claim[ed] that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications; and
>
> Lilly "misrepresented that Zyprexa was an appropriate treatment for 'complicated mood disorder' and other off-label uses."[5]

These superficial answers are mimicked verbatim in each of the State's responses.[6] At no place has the State identified any specific act, communication, document or event by which Lilly made these alleged communications to the State of Alaska or any Alaska prescriber, or whether and how the State suffered an ascertainable loss from these actions. In addition, the State's pharmacy director Dave Campana and former medical director Thomas Porter, designated as the only witnesses from the State with knowledge about the State's communications with Lilly and the events described in the Complaint, were unable to specify any misrepresentations by any representative of Lilly. Indeed Dr. Porter denied having knowledge of any events in the Complaint, and had no recollection of any communications from anybody at Lilly about anything.

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[5] Exhibit C, Plaintiff's Responses to Defendant's Fourth Set of Interrogatories.

[6] *Id.*

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The State purports to justify its failure to provide specific facts on the grounds that discovery is ongoing.[7] Pursuant to Civil Rule 37(a)(2)(B), Lilly has in good faith conferred with the State in an effort to secure the discovery without court action to no avail. *See*, Exhibit F, Letter from Eric Rothschild to Christiaan Marcum, dated November 30, 2007, and Exhibit D.

II. ARGUMENT

Lilly's discovery seeks the information needed to defend against the State's UTPCPA claim. It requires the State to provide the specific facts (namely the who, what, when, where, and how) of Lilly's alleged violation(s) of the UTPCPA. Yet all that the State has provided are boilerplate responses that are no more informative that the allegations of the Complaint. This case is far beyond the pleadings stage, and it is not enough for the State merely to rest on the allegations of the Complaint.[8] It must provide specific facts demonstrating that there is a genuine issue for trial.[9]

Plainly, to prevail on its UTPCPA claim, the State must present evidence of specific misconduct occurring in Alaska. In *Lee v. State*, for example, the Alaska Supreme Court upheld a finding that the defendant violated the UTPCPA because the State was able to point

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[7] *See id*; Exhibit D, Letter from Christiaan Marcum to Eric Rothschild, dated December 3, 2007.

[8] *See generally Meyer v. State, Dep't of Revenue, Child Support Enforcement Div. ex rel. N.G.T.*, 994 P.2d 365 (Alaska 1999).

[9] *Id.* at 367.

to specific advertisements the defendant placed in the Anchorage Daily News, specific misrepresentations on the defendant's website, and specific statements contained in specific handouts at a specific presentation.[10] Case law regarding other states' unfair trade practices act makes clear that a party alleging violation of the act can only proceed upon a showing of specific facts of misconduct.[11]

In stark contrast to the proof offered in *Lee*, the State has yet to present to Lilly anything more than a vague impression of what its UTPCPA claim is about. The State's discovery responses are without substance, and the witnesses put up by the State as most knowledgeable about the communications with Lilly and allegations in the Complaint (Dave Campana and Thomas Porter) were unable to identify the actions that constitute violations of the UTPCPA. The State has not identified the equivalent of the advertisements, websites or brochures, that the Supreme Court found sufficient to sustain the UTPCPA violation in *Lee*. In light of the facts that the first phase of the trial is scheduled to commence in fewer than

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[10] *Lee v. State*, 141 P.3d 342, 345-46, 351 (Alaska 2006).

[11] *See e.g., Frederico v. Home Depot*, __ F.3d __, 2007 WL 3310553 (3rd Cir. (N.J.) Nov. 9, 2007) (affirming dismissal of claim under New Jersey Consumer Fraud Act where plaintiff made only generic allegations and failed to spell out specific misrepresentations alleged); *USAlliance Fed. Credit Union v. Cumis Ins. Soc'y., Inc.*, 346 F.Supp.2d 468, 472 (S.D.N.Y. 2004) (dismissing claim brought under New York Consumer Protection Act for failure to include specific allegations as to acts that formed basis of claim); *Bob Timberlake Collection, Inc. v. Edwards*, 626 S.E.2d 315, 323 (N.C. 2006) (affirming dismissal of claim brought under North Carolina Unfair and Deceptive Trade Practices Act upon plaintiff's failure to allege specific conduct by defendant causing injury to plaintiff); *Marshall v. Priceline.com, Inc.*, 2006 WL 3175318 (Del.Super. Oct. 31, 2006) (dismissing consumers' claim under Delaware Consumer Fraud Act in absence of specific allegation that a fraud was committed in Delaware).

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three months and that summary judgment briefing is already before the Court, the Court should order the State to supply this information immediately.

The State's position that it has no obligation to provide meaningful discovery responses because discovery is ongoing is not sufficient. At a minimum, the State must articulate to Lilly the facts concerning Lilly's alleged unlawful acts in Alaska that it was aware of when it first chose to assert its UTPCPA claim, and when it represented to the Court that it was ready to go to trial in March. In fact, the State's counsel represented at the deposition of Dave Campana that he could "point to lots" of false statements made by Lilly to the State of Alaska,[12] but has never "pointed to" a single one of them. To the extent that ongoing discovery does have some bearing on the State's ability to respond fully, the State should be required to explain what discovery is needed, provide Lilly with the facts of which it is presently aware, and supplement its responses once discovery is complete.

III. CONCLUSION

For the foregoing reasons, Lilly respectfully requests that the Court enter an order in the form attached requiring the State to provide immediately complete responses to Interrogatories Nos. 66-72 and produce documents in response to Document Request No. 60. Alternatively, Lilly requests that the Court order the State to supplement its responses and production immediately after the State's completion of discovery, and permit Lilly to supplement its summary judgment motion at that time.

[12] Exhibit E, Campana Tr. at p. 300.

DATED this 13th day of December, 2007.

Attorneys for Defendant

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Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
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By _____
Brewster H. Jamieson, ASBA No. 8411122
Andrea E. Girolamo-Welp, ASBA No. 0211044

I certify that on December 13, 2007, a copy of the foregoing was served by e-mail and hand-delivery on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-2911

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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 FOURTH SET OF INTERROGATORIES TO PLAINTIFF STATE OF ALASKA

Pursuant to Rule 33 of the Alaska Rules of Civil Procedure, defendant Eli Lilly and Company ("Lilly") requests that plaintiff State of Alaska, in accordance with the definitions and instructions set forth below, answer each interrogatory separately and under oath, within thirty days of service hereof.

INSTRUCTIONS

1. Each interrogatory shall be answered separately and fully in writing under oath, unless it is objected to, in which event the reasons for objection shall be stated in lieu of an answer. The answers are to be signed by the person making them, and the objection signed by the attorney making them. An interrogatory otherwise proper is not necessarily objectionable merely because an answer to the interrogatory involves an opinion or contention that relates to fact or the application of law to fact.

2. Unless otherwise indicated, plaintiff should respond to these interrogatories by listing all documents referred to in formulating its responses, wherever located, along with the date prepared, sent and/or received. Where only a portion of a document relates or refers to the subject indicated, the entire document, along with all attachments, appendices and/or exhibits, must nevertheless be noted in your response.

3. If any interrogatory is answered by a reference to documents, compilations, abstracts and/or other records, please attach same as exhibits to plaintiff's responses to these interrogatories.

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EXHIBIT A
PAGE 1 OF 11

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4. For any document that you claim is being withheld under claim of privilege, work product, or for any other reason, please set forth the following information:

a. the general subject matter of the document and a description of the file or other location where it was found;

b. the title, heading or other location where it was found;

c. the date appearing on the document (if no date appears thereon, then the approximate date on which the document was prepared);

d. the general nature or description of the document (i.e., whether it is a letter, memorandum, invoice, etc.) and the number of pages of which it consists;

e. the identity of each person who prepared, authored or signed the document;

f. the identity of each person to whom the document (or copy thereof) was addressed and/or sent;

g. the identity of each person who has custody of the document (or a copy thereof); and

h. the specific basis or ground upon which the document is being withheld.

5. If you do not have all the documents responsive to any paragraph, please so state and identify each person who you know or believe may have such documents.

6. Each of the following interrogatories is intended to be a continuing interrogatory, and Lilly hereby demands that if at any later date, plaintiff obtains any additional facts, or forms any conclusions, opinions, or contentions different from those set forth in the answers to these interrogatories, plaintiff shall supplement and/or amend the answers to these interrogatories promptly, and sufficiently in advance of trial, to fully set forth such differences.

7. Unless otherwise indicated, the relevant time period is 1996 to the present.

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DEFINITIONS

1. The definitions set forth in Alaska Rule of Civil Procedure 33 are adopted herein.

2. The term "you" or "your" or "plaintiff" or "Alaska" means plaintiff State of Alaska.

3. The term "Lilly" means defendant Eli Lilly and Company.

4. The term "Medicaid recipient" means a resident of the State of Alaska that received Medicaid assistance from 1996 to the present.

5. The term "PBM" means any person or entity that has managed, administered, or has otherwise been responsible for providing pharmacy benefits to Alaska Medicaid recipients.

6. The term "employees" means the individuals employed by Alaska during the relevant time period, regardless of whether they are currently employed by Alaska.

7. The term "Complaint" means the Complaint filed by Alaska on March 1, 2006.

8. "Document" shall have the meaning set forth in Rule 34 of the Alaska Rules of Civil Procedure, and includes all forms of writings as defined in Rule 1001(1) of the Alaska Rules of Evidence, and includes any reduction to tangible form, whether written, recorded, taped, filmed, videotaped or in computer, digital or magnetic memory or storage, of communication, information, or data, including any graphic matter of any kind or nature, however produced or reproduced, and also includes originals, drafts, and non-identical copies, wherever located. "Document" shall include, but not be limited to, books, contracts, agreements, correspondence, electronic mail (email), computer tapes, discs, magnetic memory, printouts and keypunch cards, memoranda, diaries, notes reports, bulletins, printed forms, telegraphic communications, pleadings and other legal papers, notes. telexes, telegrams, telecopies, facsimile reproductions, or "faxes," factual compilations, data

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compilations, statistical compilations, plans, diagrams, journals, change orders, studies, surveys, sketches, art work, graphics, checks, ledgers, catalogues, brochures, pamphlets, press releases, advertisements, invoices, minutes, photographs, microfilms, microfiche, films, personnel files, quotes, stenographic notes, computer disks, telephone records, schedules, bids, voice recordings, and transcriptions. This definition shall apply to all Documents in the possession, custody or control of the Defendant herein, or that of their attorneys, agents, employees, officers, directors, or representatives, irrespective of who generated, prepared or signed the Documents.

9. The term "communication" means any exchange or transfer of information in the form of facts, ideas, inquiries, or otherwise, whether written, oral, or in any other form.

10. The terms "concerning" or "concern" mean regarding, relating to, referring to, describing, evidencing or constituting.

11. When referring to a person, "to identify" means to give, to the extent known, the person's full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment. Once a person has been identified in accordance with this subparagraph, only the name of that person need be listed in response to subsequent discovery requesting the identification of that person.

12. When referring to documents, "to identify" means to give, to the extent known, the (i) type of document; (ii) general subject matter; (iii) date of the document; and (iv) author(s), addressee(s) and recipient(s).

13. The terms "all" and "each" when used separately shall be construed as "all and each." The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope. The use of the singular form of any word includes the plural and vice versa.

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14. "State the basis" shall mean (i) identify each and every communication, document, and thing (and, where pertinent, the section, article, or subparagraph thereof), which forms any part of the source of a part of your information concerning the alleged facts or legal conclusions referred to by the interrogatory; (ii) state separately the acts or omissions to act on the part of any person (identifying the acts or omissions to act by stating their nature, time and place and identifying the persons involved) which form any part of your information concerning the alleged facts or legal conclusions referred to in the interrogatory; and (iii) state separately any other fact which forms the basis of your information concerning the alleged facts or legal conclusions referred to in the interrogatory.

15. A request that you "describe in detail" means, in the case of an act, transaction, event, relationship, thing or occurrence:

a full description of such act, transaction, event, relationship, thing or occurrence, including complete references to date(s), place(s), person(s) involved and the manner or means of such involvement;

a. identification of the source of the information concerning such act, transaction, event, relationship, thing or occurrence including the date on which such information was received;

b. identification of each document that evidences, refers or relates to such act, transaction, event, relationship, thing or occurrence; and

c. identification of each person having knowledge of such act, transaction, event, relationship, thing or occurrence.

INTERROGATORIES

Interrogatory No. 66: State the number of times that you contend Lilly violated the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471, et seq., as alleged in the Fifth Claim for Relief in the Complaint by:

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(a) "represent[ing] Zyprexa had characteristics, uses, benefits and/or qualities that it did not have;"

(b) "represent[ing] that Zyprexa was of a particular standard, quality and grade suitable for consumption when in fact it was not;"

(c) "advertis[ing] Zyprexa with an intent not to sell it as advertised;"

(d) "engag[ing] in conduct creating a likelihood of confusion or a misunderstanding and which misled or damaged buyers of Zyprexa, including the State of Alaska;"

(e) "us[ing] misrepresentations or omissions o material facts with the intent that others rely on the misrepresentations or omissions in connection with the sale of Zyprexa;" and/or

(f) "violat[ing] the labeling and advertising provisions of AS 17.20."

Answer:

Interrogatory No. 67: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's representing that "Zyprexa had characteristics, uses, benefits and/or qualities that it did not have, in violation of AS 45.50.471(b)(4)," as alleged in paragraph 53(a) of Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false, including but not limited to identifying what characteristics, uses, benefits and/or qualities Lilly represented Zyprexa to have, which it did not have.

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Answer:

Interrogatory No. 67: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's representing that "Zyprexa was of a particular standard, quality and grade suitable for consumption when in fact it was not, in violation of AS 45.50.471(b)(6)," as alleged in paragraph 53(b) of Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false, including but not limited to identifying what characteristics, standard, quality and grade Lilly represented Zyprexa to have, which it did not have.

Answer:

Interrogatory No. 68: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "advertis[ing] Zyprexa with an intent not to sell it as advertised, in violation of AS 45.50.471(b)(8)," as alleged in paragraph 53(c) of the Complaint. Your response should identify each and every representation you contend constitutes an advertisement, the content of the advertisement, where the advertisement was published, transmitted, or otherwise communicated, the date of the advertisement, who

received the advertisement, and the basis for your contention that Lilly's intent contradicted the content of the advertisement.

Answer:

Interrogatory No. 69: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "engag[ing] in conduct creating a likelihood of confusion or a misunderstanding and which misled or damaged buyers of Zyprexa, including the State of Alaska, in violation of AS 45.50.471(b)(11)," as alleged in paragraph 53(d) of the Complaint. Your response should describe in detail each incidence of alleged conduct, identify who engaged in the conduct and describe their involvement, identify when the conduct occurred, identify where the conduct occurred, and identify what was confusing or misleading about the conduct, and identify what buyers were misled and/or damaged by the conduct.

Answer:

Interrogatory No. 70: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "us[ing] misrepresentations or omission of material facts with the intent that others rely on the misrepresentations or omissions in

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connection with the sale of Zyprexa, in violation of AS 45.50.471(b)(12)," as alleged in paragraph 53(e) of the Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false. For each omission, your response should identify the information that was omitted, the date that the information should have been communicated, and the person(s) to whom the information should have been communicated.

Answer:

Interrogatory No. 71: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "violat[ing] the labeling advertising provisions of AS 17.20, in violation of AS 45.50.471(b)(48)," as alleged in paragraph 53(f) of the Complaint. Your response should identify each provision of AS 17.20 that you contend was violated, describe in detail each incidence of alleged conduct resulting in that violation of AS 17.20, identify who engaged in the conduct and describe their involvement, identify when the conduct occurred, and identify where the conduct occurred.

Answer:

Interrogatory No. 72: For each individual violation enumerated in response to Interrogatory No. 66, identify the "ascertainable loss of money or property" that you contend resulted from that specific violation.

Answer:

DATED this 29th day of October, 2007.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square, Suite 3000
Philadelphia, Pennsylvania 19103-2711
(215) 981-4000

LANE POWELL LLC

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

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

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

009867.0038/162007.1

VERIFICATION CERTIFICATE

STATE OF ALASKA)
) ss.
THIRD JUDICIAL DISTRICT)

I, _____, being first duly sworn upon oath, depose and state that I am the _____ for the State of Alaska. I have reviewed the answers to the foregoing interrogatories and to the best of my knowledge and belief, the answers are true and complete.

STATE OF ALASKA

By_____
Its: _____

SUBSCRIBED AND SWORN TO THIS _____ day of _____, 2007, at _____, Alaska.

_____
Notary in and for the State of Alaska
My commission expires:_____

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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 FOURTH SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS TO PLAINTIFF STATE OF ALASKA**

Defendant Eli Lilly and Company ("Lilly"), pursuant to Alaska Rule of Civil Procedure 34, requests that plaintiff State of Alaska produce for inspection and copying the following documents, materials, and things within its possession, custody, or control within thirty days of service of this discovery request at the offices of Lane Powell LLC, 301 W. Northern Lights Blvd., Suite 301, Anchorage, Alaska 99503. In responding to these requests for production, please furnish all information available to you, including any information possessed by any agent, employee or attorney representing you.

INSTRUCTIONS

1. Any request for production propounded in the disjunctive shall also be read as if it is propounded in the conjunctive and *vice-versa*. Any request for production propounded in the masculine shall be read as if propounded in the feminine and *vice-versa*. Any request for production propounded in the singular shall be read as if propounded in the plural and *vice-versa*.

2. If you know of any documents or things responsive to these requests which are not in your possession, custody or control, identify such documents and state the name and business address of the person who has possession, custody and control thereof. "Identify" in this context means to provide, to the extent known, the (i) type of document(s); (ii) general subject matter of the document(s); (iii) date of the document(s); and (iv) full

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EXHIBIT B
PAGE 1 OF 4

C D E F

names, present or last known addresses and present or last known places of employment of the authors(s), addressee(s) and recipient(s) thereof.

3. For any document which you claim is being withheld under claim of privilege, work product, or for any other reason, please set forth the following information:

a. the general subject matter of the document and a description of the file or other location where it was found;

b. the title, heading or other location where it was found;

c. the date appearing on the document (if no date appears thereon, then the approximate date on which the documents was prepared);

d. the general nature or description of the document (i.e., whether it is a letter, memorandum, invoice, etc.) and the number of pages of which it consists;

e. the identity of each person who prepared, authored or signed the document;

f. the identity of each person to whom the document (or copy thereof) was addressed and/or sent;

g. the identity of each person who has custody of the document (or a copy thereof); and

h. the specific basis or ground upon which the document is being withheld.

4. If there are no documents or things that are responsive to a request, affirmatively state so for each such request.

5. Unless otherwise indicated, the relevant time period is 1996 to the present.

DEFINITIONS

1. The definitions set forth in Alaska Rule of Civil Procedure 34(a) are adopted herein.

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2. "Document" shall have the meaning set forth in Rule 34 of the Alaska Rules of Civil Procedure, and includes all forms of writings as defined in Rule 1001(1) of the Alaska Rules of Evidence, and includes any reduction to tangible form, whether written, recorded, taped, filmed, videotaped or in computer, digital or magnetic memory or storage, of communication, information, or data, including any graphic matter of any kind or nature, however produced or reproduced, and also includes originals, drafts, and non-identical copies, wherever located. "Document" shall include, but not be limited to, books, contracts, agreements, correspondence, electronic mail (email), computer tapes, discs, magnetic memory, printouts and keypunch cards, memoranda, diaries, notes reports, bulletins, printed forms, telegraphic communications, pleadings and other legal papers, notes. telexes, telegrams, telecopies, facsimile reproductions, or "faxes," factual compilations, data compilations, statistical compilations, plans, diagrams, journals, change orders, studies, surveys, sketches, art work, graphics, checks, ledgers, catalogues, brochures, pamphlets, press releases, advertisements, invoices, minutes, photographs, microfilms, microfiche, films, personnel files, quotes, stenographic notes, computer disks, telephone records, schedules, bids, voice recordings, and transcriptions. This definition shall apply to all Documents in the possession, custody or control of the Defendant herein, or that of their attorneys, agents, employees, officers, directors, or representatives, irrespective of who generated, prepared or signed the Documents.

3. The term "you" or "your" or "plaintiff" or "Alaska" means plaintiff State of Alaska.

4. The term "Lilly" means defendant Eli Lilly and Company.

5. The term "Medicaid recipient" means a resident of the State of Alaska that received Medicaid assistance from 1996 to the present.

6. The term "PBM" means any person or entity that has managed, administered, or has otherwise been responsible for providing pharmacy benefits to Alaska's Medicaid recipients.

7. The term "employees" means the individuals employed by Alaska during the relevant time period, regardless of whether they are currently employed by Alaska.

8. The term "Complaint" means the Complaint filed March 1, 2006.

9. The term "communication" means any exchange or transfer of information in the form of facts, ideas, inquiries, or otherwise, whether written, oral, or in any other form.

10. The terms "concerning" or "concern" mean regarding, relating to, referring to, describing, evidencing or constituting.

REQUESTS FOR PRODUCTION

Request for Production No. 60: All documents referenced or identified in response to Lilly's Fourth Set of Interrogatories.

Response:

DATED this 29th day of October, 2007.

Attorneys for Defendant

PEPPER HAMILTON LLP
Andrew R. Rogoff, admitted *pro hac vice*
Eric J. Rothschild, admitted *pro hac vice*
3000 Two Logan Square, Suite 3000
Philadelphia, Pennsylvania 19103-2711
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LANE POWELL LLC

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

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

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

106666.0983/162016.1

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 RESPONSES TO DEFENDANT'S FOURTH SET OF INTERROGATORIES

Pursuant to Rule 33 of the Alaska Rules of Civil Procedure, Plaintiff, the State of Alaska, provides the following Answers to Defendant's Fourth Set of Interrogatories. The State specifically reserves the right to supplement and amend these responses as provided by the applicable rules of procedure.

INTERROGATORIES

INTERROGATORY NO. 66: State the number of times that you contend Lilly violated the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471, et seq., as alleged in the Fifth Claim for Relief in the Complaint by:

(a) "represent[ing] Zyprexa had characteristics, uses, benefits and/or qualities that it did not have;"

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(b) "represent[ing] that Zyprexa was of a particular standard, quality and grade suitable for consumption when in fact it was not;"

(c) "advertis[ing] Zyprexa with an intent not to sell it as advertised;"

(d) "engag[ing] in conduct creating a likelihood of confusion or a misunderstanding and which misled or damaged buyers of Zyprexa, including the State of Alaska;"

(e) "us[ing] misrepresentations or omissions of material facts with the intent that others rely on the misrepresentations or omissions in connection with the sale of Zyprexa;" and/or

(f) "violat[ing] the labeling and advertising provisions of AS 17.20."

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label

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uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 67: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's representing that "Zyprexa had characteristics, uses, benefits and/or qualities that it did not have, in violation of AS 45.50.471(b)(4)," as alleged in paragraph 53(a) of Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false, including but not limited to identifying what characteristics, uses, benefits and/or qualities Lilly represented Zyprexa to have, which it did not have.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates

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comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 67: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's representing that "Zyprexa was of a particular standard, quality and grade suitable for consumption when in fact it was not, in violation of AS 45.50.471(b)(6)," as alleged in paragraph 53(b) of Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false, including but not limited to identifying what characteristics, standard, quality and grade Lilly represented Zyprexa to have, which it did not have.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal

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relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 68: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "advertis[ing] Zyprexa with an intent not to sell it as advertised, in violation of AS 45.50.471(b)(8)," as alleged in paragraph 53(c) of the Complaint. Your response should identify each and every representation you contend constitutes an advertisement, the content of the advertisement, where the advertisement was published, transmitted, or otherwise communicated, the date of the advertisement, who received the advertisement, and the basis for your contention that Lilly's intent contradicted the content of the advertisement.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by

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minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 69: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "engag[ing] in conduct creating a likelihood of confusion or a misunderstanding and which misled or damaged buyers of Zyprexa, including the State of Alaska, in violation of AS 45.50.471(b)(11)," as alleged in paragraph 53(d) of the Complaint. Your response should describe in detail each incidence of alleged conduct, identify who engaged in the conduct and describe their involvement, identify when the conduct occurred, identify where the conduct occurred, and identify what was confusing or misleading about the conduct, and identify what buyers were misled and/or damaged by the conduct.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to

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the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 70: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "us[ing] misrepresentations or omission of material facts with the intent that others rely on the misrepresentations or omissions in connection with the sale of Zyprexa, in violation of AS 45.50.471(b)(12)," as alleged in paragraph 53(e) of the Complaint. For each representation, your response should identify who made the representation, the recipient(s) of the representation, the method of communication, the date of the representation, the content of the representation, and the basis for your contention that the representation was false. For each omission, your response should identify the information that was omitted, the date that the information should have

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been communicated, and the person(s) to whom the information should have been communicated.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 71: Identify every alleged violation enumerated in response to Interrogatory No. 66 which was the result of Lilly's "violat[ing] the labeling advertising provisions of AS 17.20, in violation of AS 45.50.471(b)(48)," as alleged in paragraph 53(f) of the Complaint. Your response should identify each provision of AS 17.20 that you contend was violated, describe in detail each incidence of alleged conduct resulting

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in that violation of AS 17.20, identify who engaged in the conduct and describe their involvement, identify when the conduct occurred, and identify where the conduct occurred.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

INTERROGATORY NO. 72: For each individual violation enumerated in response to Interrogatory No. 66, identify the "ascertainable loss of money or property" that you contend resulted from that specific violation.

ANSWER: The State objects to the foregoing interrogatory in that discovery is ongoing in this case. The State has only recently received document discovery from Lilly

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and is still in the process of taking depositions of Lilly witnesses with information relevant to the State's claims. Subject to and without waiving this objection, it is clear that Lilly engaged in conduct violating the above-referenced provisions of the Alaska statutory law by minimizing the magnitude and hazards of olanzapine-induced weight gain, denying a causal relationship between olanzapine and hyperglycemia and/or diabetes, and by claiming that hyperglycemia and/or diabetes occurring during treatment with olanzapine occurred at rates comparable to other antipsychotic medications. Moreover, Lilly misrepresented that Zyprexa was an appropriate treatment for "complicated mood disorders" and other off-label uses. This list is intended to be illustrative and not exhaustive. It is clear Lilly engaged in this conduct nationwide, and the State anticipates proving at trial that such conduct occurred in Alaska.

Respectfully SUBMITTED and DATED this 28 day of November, 2007

FELDMAN, ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
Eric T. Sanders
Alaska Bar No. 7510085

GARRETSON & STEELE
Matthew L. Garretson
Joseph W. Steele
5664 South Green Street
Salt Lake City, UT 84123
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Counsel for Plaintiff

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RICHARDSON, PATRICK, WESTBROOK
& BRICKMAN, LLC
H. Blair Hahn
Christiaan A. Marcum
P.O. Box 1007
Mt. Pleasant, SC 29465
(843) 727-6500
Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Plaintiff's Responses to Defendant's Fourth Set of Interrogatories** 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 J Crowe
Date 11/28/07

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RICHARDSON PATRICK WESTBROOK & BRICKMAN, LLC

Christiaan Marcum
843.727.6522 Direct Dial No.
843.216.6509 Direct Fax No.
cmarcum@rpwb.com

December 3, 2007

VIA US MAIL AND EMAIL
Eric Rothschild, Esquire
Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799

Re: State of Alaska v. Eli Lilly and Company
Case No.: 3AN-06-5630CIV

Dear Eric:

I am in receipt of your letter dated November 30th regarding the State's Responses to Lilly's Fourth Sets of Interrogatories and Requests for Production.

We have provided you with the basis for our allegations in previous discovery responses and briefing in this case, including a recitation of facts and citation of documents developed in the MDL discovery. However, Lilly has delayed the production of every piece of Alaska-specific discovery the State has requested and which would allow the State to provide more detailed responses to your Fourth Interrogatories. As stated in our responses, we have only recently received this discovery and have just begun the depositions of Alaska-specific witnesses. Moreover, we have agreed to delay some of these depositions at *your* request. Thus, it is not appropriate for the State to answer these interrogatories at this time, and it will not do so until the discovery on these issues is fully developed.

With kindest regards, I remain,

Sincerely yours,

Christiaan Marcum

cc: Matthew L. Garretson, Esq.
Joseph W. Steele, Esq.
Eric T. Sanders, Esq.
David Suggs, Esq.
Brewster Jamieson, Esq.

IN THE SUPERIOR COURT OF THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630

VIDEOTAPED 30(b)(6) DEPOSITION OF
STATE OF ALASKA
DESIGNEE: DAVID CAMPANA

Wednesday, September 19, 2007
9:30 a.m.
Volume II

Taken by Counsel for Defendant
at
Lane Powell, LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

letter came out?
A. Yes.
Q. As of March 2006, did you have anything that you would base your contention that the package insert was a misrepresentation of -- misrepresentation to the State of Alaska that Zyprexa was safe and effective?
A. No.
Q. You were not aware of anything that would support the contention that that was a misrepresentation?
A. Correct.
Q. Do you know whether it is accurate that Eli Lilly knowingly misrepresented to the State of Alaska that Zyprexa was safe and effective?
A. I don't know.
Q. Okay. Again, when we're talking about misrepresentations to the State of Alaska, you can point to the package insert, but you can't point to any misrepresentations that one person from Lilly said to anybody at Alaska, correct?
A. Correct.
Q. The next sentence --
MR. HAHN: His lawyers would be able to point to lots though. Don't worry.
MR. ROTHSCHILD: I can't wait to meet them.
MR. HAHN: You have met them.

Pepper Hamilton LLP
Attorneys at Law

3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799
215.981.4000
Fax 215.981.4750

Eric Rothschild
direct dial: 215 981 813
direct fax: 215 981 4750
rothsche@pepperlaw.com

November 30, 2007

VIA EMAIL

Christiaan Marcum, Esq.
Richardson Patrick Westbrook & Brickman, LLC
1037 Chuck Dawley Boulevard
Building A
Mt. Pleasant, SC 29464

Re: **State of Alaska v. Eli Lilly and Company**
Case No.: 3AN-06-5630CIV

Dear Christiaan:

We are in receipt of plaintiff State of Alaska's (the "State") Responses to defendant Eli Lilly and Company's ("Lilly") Fourth Sets of Interrogatories and Requests for Production of Documents.

These discovery demands obligate the State not only to enumerate each instance in which it alleges Lilly violated the Alaska Unfair Trade Practices and Consumer Protection Act, but also to state the specific factual bases for each such instance. The State's responses do neither. Indeed, the responses fail to specify even one single communication, document, or event that could form the factual basis of the State's claim, much less how the Act was violated.

Given that it is the State's position that evidence developed in the Zyprexa MDL provides the basis for proving the aspects of the case it proposes to include in the first phase of the trial, there is no basis to withhold information about the purported violations of the Unfair Trade Practices Act claim already in the State's possession, even if it is the case that ongoing discovery may relate to the Unfair Trade Practices Act claim. At this stage of the litigation, with summary judgment motions due on December 10, the State has no grounds to avoid furnishing

Lilly with a description of the communications, marketing pieces, or other documents that it contends constitute violations of the Unfair Trade Practices Act.

If you contend that there is some specific discovery or testimony that you require in order to fully respond to this set of discovery demands, please describe. Should we not hear back from you by Tuesday, December 4, we plan to file a motion to compel with the Court.

Very truly yours,

Eric Rothschild

cc: Eric T. Sanders, Esq.
David Suggs, Esq.
Joseph W. Steele V, Esq.
Brewster H. Jamieson, Esq.

In the Supreme Court of the State of Alaska

Eli Lilly and Company,

Petitioner,

v.

State of Alaska,

Respondent.

Supreme Court No. **S-12936**

Order
Petition for Review

Date of Order: **1/14/08**

Trial Court Case # **3AN-06-05630CI**

Before: Fabe, Chief Justice, and Eastaugh and Carpeneti, Justices. [Matthews and Winfree, Justices, not participating.]

On consideration of the Petition for Review filed on **12/7/07**, and the response filed on **12/17/07**,

IT IS ORDERED:

The Petition for Review is **DENIED**.

Entered by direction of the court.

Clerk of the Appellate Courts

Marilyn May
Marilyn May

cc: Supreme Court Justices
Judge Rindner
~~Trial Court Clerk/Anchorage~~

Distribution:

Brewster H Jamieson
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Anchorage AK 995032648

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Feldman Orlansky & Sanders
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Anchorage AK 99501

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.	)	
	)	

MEMORANDUM IN SUPPORT OF PLAINTIFF'S RENEWED MOTION TO COMPEL AND MOTION FOR SANCTIONS

I. INTRODUCTION

On February 8, 2007, the State served its first sets of Interrogatories and Requests for Production, which were followed on May 31, 2007, by the State's Second Interrogatories and Requests for Production. After Lilly stone-walled any meaningful response to most of the State's discovery requests, the State filed motions to compel on both sets of discovery. After extensive briefing and a day long hearing in front of the Discovery Master, Lilly withdrew some objections to certain requests and was ordered by the Discovery Master to respond to others. While Lilly has responded to some of those requests, it has failed to meaningfully respond to others and has effectively evaded the Orders of the Discovery Master.

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This memorandum is submitted in support of Plaintiff's Renewed Motion to Compel and Motion for Sanctions. The issues requiring legal discussion are addressed below along with the specific discovery issues which remain outstanding.

II. SPECIFIC RESPONSE DEFICIENCIES

A. Interrogatory Nos. 1 and 3 and Corresponding Request for Production Nos. 1 and 3.

The State's interrogatories and requests for production sought information regarding Lilly's marketing of Zyprexa for use in Alaska's Medicaid program and communications by Lilly employees regarding the efficacy, benefits, risks or costs associated Zyprexa use. Specifically, the State requested the identities of individuals responsible for communicating on such topics with representatives of Alaska's Medicaid program (Interrogatory No. 1, Request for Production No. 1) and members of any organization, committee or authority responsible for determining which prescription drugs will be on any Alaska formulary, pharmaceutical and therapeutics list or preferred drug list (Interrogatory No. 3, Request for Production No. 3). Lilly withdrew its objection to these requests at the hearing in front of the Discovery Master, as noted in the Discovery Master's September 24, 2007 Order.[1] Further, on the record at that hearing Lilly committed to producing witness names and documents related to those topics.[2] To

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[1] Discovery Master Order, September 24, 2007, pp. 9, 10 (Exhibit 1).

[2] September 11, 2007 Hearing Transcript, pp. 64-66 (Exhibit 2).

this date, Lilly has only identified and produced documents for two such witnesses. The State has taken the depositions of those witnesses, and it is abundantly clear that Lilly has failed to meaningfully respond to the State's discovery requests.

The first witness identified was Nathaniel Miles, a manager of Public Affairs. At his deposition, Miles made it clear that he did not communicate with members of the Alaska Medicaid department or any DUR or P&T committees regarding any of the issues of inquiry in the State's discovery requests.[3] His communications were primarily with legislators, and communications with persons falling within the categories of individuals covered by the State's requests would have been handled by others, including sales representatives and outcomes liaisons.[4]

The second identified witness was Kevin Walters, a Public Health Division account executive. Walters denied ever discussing any Lilly product with Alaska Medicaid representatives, and indicated that communications regarding the issues raised in the State's requests would have been by sales representatives and Lilly employees referred to as "outcomes liaisons."[5]

Lilly has identified its Alaska sales representatives, and the State has issued deposition notices for some of them. However, Lilly never identified any Alaska

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3 Deposition of Nathaniel Miles, pp. 216-218 (Exhibit 3).

4 *Id.* (Exhibit 3).

5 Deposition of Kevin Walters, pp. 86-93 (Exhibit 4).

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outcomes liaisons as witnesses, nor produced any documents from those individuals' custodial files. The witnesses above both identified Trina Clark as an Alaska outcomes liaison for the relevant time period,[6] and Walters further identified Jeff Hill as an Alaska outcomes liaison for the relevant time period.[7] Lilly should be required to immediately produce the custodial files, including but not limited to all relevant documents and emails, for these witnesses and to produce them both for deposition as soon thereafter as possible.

B. Request for Production No. 7.

The State requested the database of "call notes" generated by Lilly sales representatives. The Discovery Master ordered the production of a random sampling of 4,000 such call notes as urged by Lilly during the hearing. However, counsel for Lilly also represented during the hearing that Lilly would produce call notes for any physician whose deposition Lilly sought to take in this case, as was the practice in the MDL proceedings.[8] Lilly has now noticed the depositions of seven physicians: Dr. Carolyn Rader; Dr. Lucy Curtiss; Dr. Alexander Von Hafften; Dr. Jeffrey Magee; Dr. Ramzi

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[6] Deposition of Nathaniel Miles, p. 51 (Exhibit 5); Deposition of Kevin Walters, p. 87 (Exhibit 6).

[7] Deposition of Kevin Walters, p. 87 (Exhibit 6).

[8] September 11, 2007 Hearing Transcript, pp. 88-89 (Exhibit 7).

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Nassar; Dr. Robert Schults; and Dr. Verner Stillner. Lilly should immediately produce any and all call notes detailing sales visits to those physicians.

In addition, the sampling of only 4,000 call notes produced to the State does not include any call notes which occurred after August 5, 2004. The State asserts that Lilly is liable for negligence, strict liability and statutory causes of action up to the present day and Lilly should therefore be required to provide call notes reflecting its conduct with Alaska physicians through the present day.

C. Interrogatory Nos. 12 and 13.

The State requested specific financial information on an annual basis related to sales of Zyprexa both globally and in Alaska. The Discovery Master ordered Lilly to produce publicly available data responsive to both requests. While Lilly provided such data through the year 2004, it has refused to do so for 2005 to the present arguing that its objection to providing information after September 2004 was not overruled by the Discovery Master. However, in reviewing the transcript, the issue of the date scope of production on financial issues was not argued, and the Discovery Master certainly did not sustain any objection to scope related to date or limit Lilly's production obligation in that manner.[9] Lilly should be required to produce the responsive financial information for 2005 to the present.

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[9] *Id.* pp. 95-97 (Exhibit 8).

III. Conclusion

For the reasons stated above and in its Renewed Motion to Compel and Motion for Sanctions, the State requests that the Court grant its motion in all respects and set a deadline by which Lilly must supplement its discovery responses with all information and documents responsive thereto, and by which it must produce witnesses for deposition. Further, the State requests the Court grant it fees and costs related to the depositions of Nathaniel Miles and Kevin Walters, as well as those associated with bringing this motion.

Dated this 11 day of December, 2007.

FELDMAN, ORLANSKY & SANDERS
Counsel for Plaintiff

BY /s/ Joseph W. Steele
Eric T. Sanders
Alaska Bar No. 7510085

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Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of **Memorandum in Support of Plaintiff's Renewed Motion to Compel and for Sanctions** 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 Crowl
Date 12/12/07

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Dan A. Hensley
Attorney
Practice Limited to Mediation and Arbitration
1036 W. 22d Ave.
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September 24, 2007

Brewster Jamieson, Esq.
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Anchorage, AK 99503

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

RE: State of Alaska v. Eli Lilly & Co., 3AN-06-05630 CI

DISCOVERY MASTER ORDER
State's First Motion to Compel
Lilly's Motion to Compel
Lilly's Motion for Commission for Subpoena

Introduction

The State of Alaska seeks damages from Eli Lilly & Co. for harm allegedly caused by Lilly's marketing and sale of the drug Zyprexa. The State asserts claims in strict product liability for failure to warn and design defect, for violation of the State's Unfair Trade Practices and Consumer Protection Act, and for negligence, negligent misrepresentation and fraud.

The State has not filed a class action and is not seeking damages for individual patients. Instead, the state seeks to recover for excess expenditures allegedly incurred by

have that access because the production from the State has been so shoddy that Lilly cannot be assured of the accuracy of the edited database information.

For the reasons stated above, Lilly is not entitled to access to patient identifying information. Because the State has committed to making additional database discovery, Lilly's claim of risk of inaccurate production is not persuasive.

Rulings on Individual Discovery Requests

Lilly's Motion to Compel (August 6, 2007)

DENIED. See discussion of Access to Patient Medical Records above.

Lilly's Motion for Application For Commission to Issue Subpoena

DENIED. See discussion of Access to patient Medical records and Discovery Regarding State's Medicaid Data Base above.

State's First Motion to Compel (July 10, 2007)

DENIED in part and GRANTED in part.

Int. # 1, RFP # 1. Lilly withdrew its objection at oral argument.

Int. # 2, RFP # 2. DENIED. The State seeks information regarding communications about Zyprexa from Lilly to public payors of medical bills in Alaska other than Medicaid. Lilly argues that the information sought will not lead to admissible evidence because the State's claims are limited to misrepresentations to Medicaid. The State argues that this information is relevant because other public payor organizations could influence the State and prescribing physicians regarding the use of Zyprexa.

The State has access to the MDL collection that likely contains a representative sample of communications about Zyprexa made by Lilly to numerous organizations. It is also likely that the communications made to other payors in Alaska are similar to

communications made to the State and evidence of communications available in the MDL collection.

The evidence sought by the State is technically discoverable – but it appears that the ability of other payors to influence the State is tenuous and the information sought is also likely redundant to information already available to the State. Given the State's interest in limiting unnecessary discovery so as to preserve the March 2008 trial date, Lilly's objection to the discovery as overbroad is sustained.

Int. # 3, RFP #3. Lilly withdrew is objection at oral argument.

Int. #6, RFP #9. DENIED. The State seeks information regarding communications about Zyprexa from Lilly to representatives of Alaska's executive or legislative branch. Lilly asserts the same objections noted above regarding Int. #2. The State does not have any evidence that other members of the Alaska executive branch or the Alaska Legislature influenced Alaska Medicaid regarding the use of Zyprexa. Lilly's objection is sustained.

Int. # 8, RFP #11; Int. #9, RFP # 12; Int. #10, RFP # 13; Int. # 11, RFP # 14. DENIED. The State seeks information regarding communications about Zyprexa from Lilly to patient advocacy groups, the American Psychiatric Association, the Texas Medication Algorithm Project, and Comprehensive NueroScience. Lilly's objections are sustained for the reasons stated above in Int. #2.

Int. #4, RFP #7. GRANTED in part. The State seeks information regarding call note references to Zyprexa generated by Lilly sales representatives in Alaska. Call notes are brief entries made by sales representatives documenting meetings with physicians. Lilly recognizes that the information may be discoverable but claims that retrieving the

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

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

Case No. 3AN-06-05630 CI

MOTION ARGUMENTS BEFORE THE DISCOVERY MASTER

Pages 1 - 168
Tuesday, September 11, 2007
11:00 A.M.

at
LANE POWELL
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

MR. BOISE: I think so, yeah.

MR. SUGGS: Okay. Let's hear it.

MR. BOISE: I think so. I mean, the -- I guess I'm first addressing Plaintiff's First Motion to Compel, and the first category, and I'm on page, you know, 2 of that motion where there is a number of interrogatories and requests for production that have been grouped together where the State asks for the names of individuals that communicated with the Alaska Medicaid program, representatives of other public payers and representatives of any formulary interactions, as well as representatives of the Executive or Legislative branch.

And the areas -- and then it goes on for categories of information about interactions with patient advocacy, the APA, TMAP and CNS, and I think where we can narrow the dispute is Lilly has identified two names and will identify other names of representatives that dealt with the Alaska Medicaid program and produce their files. There is one more name in particular that we understand and are ready for production.

We still dispute the representatives of, quote, other public payers. This has been about Medicaid information.

DISCOVERY MASTER: Don't make your argument. Just tell me what's off the table.

MR. BOISE: Fair enough. Off the table. So public payer still on table. Interactions with Alaska formulary we would treat as off the table, that we would give you the identity of the individuals that dealt with the Alaska formulary decisionmakers. Employees of the Executive and Legislative branch to the extent not included in that would still be on the table and would be still subject to the motion to compel.

On the patient advocacy groups, the APA and CNS, Alaska-based individuals that dealt with those organizations we would take off the table. To the extent that it's seeking information beyond that or seeking information regarding TMAP, we would say it's still on the table.

MR. SUGGS: I'm not sure I understand. So of the four bullet points on page 4 of our motion, you're willing to give us the discovery request on the first two but not the last two, or did I misunderstand?

MR. BOISE: For the first, second and fourth bullet point, we're prepared to give you the information from the Alaska-based folks, the people

who deal with Alaska on these issues. Since we think there are none for the third bullet point, the TMAP reference, that would be not. Would be still on the table.

MR. SUGGS: Well, okay. Then I -- so you're -- the important caveat here with respect to those items on the page 4 is that you're only prepared to give us the names of Alaska-based folks who deal with those areas?

MR. BOISE: We'll give you the names of Alaska-based folks that deal with those areas and produce documents, whether from those or others, that reference, refer to interactions with Alaska.

DISCOVERY MASTER: Okay. Anything else, Mr. Boise?

MR. BOISE: Yeah. On page 7, there is interrogatories that deal with call notes.

MR. SUGGS: Excuse me. Can I interrupt here? What I would suggest is that we deal with these chunks first, and this first chunking, he's already addressed that. And he's now getting into part B of our motion, and I would suggest that we can probably keep things more under control if we deal with these in chunks. Would that be acceptable?

DISCOVERY MASTER: You want to argue them

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

- - - - - - - - - - - - - - - - - X

STATE OF ALASKA, :

Plaintiff, : Case No.:

vs. : 3AN-06-5630CIV

ELI LILLY AND COMPANY, :

Defendant. :

- - - - - - - - - - - - - - - - - X

Confidential Videotaped Deposition of

NATHANIEL RAY MILES

Washington, D.C.

Wednesday, November 14, 2007

9:06 a.m.

Pages: 1 - 296

Reported by: Dana C. Ryan, RPR, CRR

state action team that that was the -- the number one issue, because I've never heard them go in and just push a certain drug at a certain time. I -- I really always hear them go in and -- and I try to get them to fight for the open access message, and we do a pretty good job of it.

Q Okay. Just so I'm clear, you, as a member of the Alaska State Action Team, communicated only with legislators; is that your testimony?

A For -- primarily. I mean, if -- if -- if -- like a -- you see on my reports, I was always backup for somebody if somebody needed me to do something. That very rarely ever happened. That wasn't -- you know, I just said I would back anybody up or -- or whatever in -- in going in. So, I mean, I might have gone to a department meeting or something every now and then to -- to sit in for somebody or whatever, but that was -- I was legislation.

Q Okay. Kevin Walters, the

PHDAE --

A Yeah.

Q -- public health division --

A Division --

Q -- account --

A -- account --

Q -- executive --

A -- executive. You can --

Q -- he communicated with?

A The department . . .

Q Officials?

A Uh-huh, the department officials and . . .

Q Okay. Ally specialists communicated with?

A With the coalitions, the -- the advocacy groups, the coalitions, et cetera.

Q Okay. Sales force communicated with?

A Docs -- doctors and --

Q Okay. Who among these groups would communicate with -- if, for

example, in Alaska -- well, in Alaska I believe there was a drug utilization review board?

A Uh-huh. Usually in a case like that it -- we -- they'd bring in the OL, the outcomes liaison, to --

Q Okay.

A -- do the -- to do the presentation.

Q Okay.

MR. ROGOFF: Are we talking, Mr. Markum, about a presentation to a DUR board?

MR. MARCUM: I'm just talking in general about who communicates with members of the DUR board.

MR. ROGOFF: Oh.

THE WITNESS: Oh, yeah. With members -- to do the presentation, it's usually the outcomes liaison. The sales reps talk to some of the DUR members, but most of the time

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

STATE OF ALASKA, :
Plaintiff, :
:
vs. :No. 3AN-06-05630
:
ELI LILLY AND COMPANY, :
Defendant. :

December 5, 2007

Videotaped Deposition of KEVIN R. WALTERS held in the law offices of Pepper Hamilton, LLP, One Logan Square, Philadelphia, Pennsylvania 19103, beginning at approximately 9:11 a.m., before Ann V. Kaufmann, a Registered Professional Reporter, Certified Realtime Reporter, Approved Reporter of the U.S. District Court, and a Notary Public.

GOLKOW TECHNOLOGIES, INC.
One Liberty Place, 51st Floor
Philadelphia, Pennsylvania 19103
877.370.3377

MR. BRENNER: Objection, lacks foundation.

Q. Your customers were concerned about cost, weren't they?

A. Costs?

Q. Of Zyprexa. We'll get specific.

A. I never talked product with my customers.

Q. Never discussed Zyprexa with any of your customers?

A. No.

Q. Okay. Who discussed Zyprexa with your customers?

A. That responsibility would fall to others within our company.

Q. What others in your company would have responsibility for discussing Zyprexa with customers in Alaska?

A. Sales.

Q. Okay. Anyone else?

A. Not to my knowledge.

Q. Okay.

A. Outcome liaisons.

Q. Okay. Who was the outcomes liaison for Alaska?

A. During that time period?

Q. Uh-huh.

A. Of 2002?

Q. Let's start there --

A. Okay.

Q. -- 2002.

A. Trina Clark.

Q. Okay. And was Trina Clark still the outcomes liaison for Alaska in 2003?

A. I'm not sure.

Q. Okay. Was Trina Clark the outcomes liaison in 2004?

A. A new outcomes liaison took over as Trina moved to North Carolina.

Q. Okay. Who was that outcomes liaison?

A. Jeff Hill.

Q. Jeff --

A. Hill.

Q. -- Hill. Okay.

Is Trina still employed by

Eli Lilly?

A. Yes, she is.

Q. Okay. I just asked because you indicated she had moved to North Carolina.

A. Uh-huh.

Q. Just a new territory for her?

A. Yes.

Q. Is she still an outcomes liaison, do you know?

A. Yes, she is.

Q. Okay. So Jeff Hill became the outcomes liaison for Alaska in approximately 2003?

A. It would be a guess on my part.

Q. Okay. Is Jeff Hill still the outcomes liaison for Alaska?

A. He is not.

Q. Okay. When did -- well, who is?

A. Currently there's no one.

Q. Okay. When did there cease

to be an outcomes liaison for Alaska?

A. I need to amend that.

Q. Okay.

A. There was an individual just hired for that open position as the outcomes liaison. He is not fully integrated yet.

Q. Well, what is this individual's name and when was he hired?

A. I don't know the specifics of when he was hired. It would have been within the last two to three months.

Q. Okay. Do you know the specifics of his name?

A. Yes, I do. It escapes me at this moment.

Q. Okay.

A. Steven Cheng. There we go.

Q. Steven Cheng?

A. C-H-E-N-G.

Q. Okay. Prior to Steven Cheng, was Jeff Hill the last outcomes liaison for Alaska?

A. Yes.
Q. Okay. And when did -- is Jeff Hill still with the company?
A. He is not.
Q. Okay. When did he leave Eli Lilly?
A. 2007.
Q. Okay. Was he outcomes liaison for Alaska until 2007 when he left?
A. Yes --
Q. Okay.
A. -- among other responsibilities.
Q. Okay. So you never discussed any Lilly product with your customers?
A. I did not discuss product with my customers.
Q. Okay. Did you do presentations to Alaska's P&T Committee?
A. No.
Q. You did not, okay. Never did any formulary presentations on a

Lilly product?

A. No.

Q. And would that have been the responsibility of an outcomes liaison?

A. It could have been.

Q. Okay. Who else could it have been the responsibility of?

A. Are you referring to a P&T Committee meeting, public meeting? I'm not sure what --

Q. We could start there, yeah, Pharmacy & Therapeutics.

A. It would be the primary role of an outcomes liaison to present at a P&T public meeting, yes.

Q. Okay. Excuse me for one second.

A. Uh-huh.

MR. MARCUM: Let's go off the record for a second.

THE VIDEOGRAPHER: We're going off the record. The time is 10:48 a.m.

(Recess.)

THE VIDEOGRAPHER: We're back on the record. The time is 11:08 a.m.

BY MR. MARCUM:

Q. Mr. Walters, you testified a minute ago that you never communicated with your customers about any Lilly product; correct?

A. I don't discuss product with my customers, correct.

Q. Okay. So it's fair to say you would have never communicated with any employee or representative of Alaska Medicaid or any of your other customers in Alaska regarding the efficacy, benefits, risks, or costs associated with the use of Zyprexa?

A. Correct.

Q. Okay. You would have never communicated with them regarding any evidence Lilly had that Zyprexa use increased the risk of hyperglycemia?

A. Correct.

Q. Okay. You would have never communicated with them regarding the magnitude of olanzapine weight gain?

A. That would be the responsibility of other individuals within our company, correct.

Q. You would have never communicated with them regarding cardiovascular effects of Zyprexa side effects?

A. Correct, that would be other individuals.

Q. Okay. And your testimony was that those other individuals to which you are referring were outcome liaisons and the sales force; correct?

A. Correct.

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

MR. BRENNER: No questions.

THE VIDEOGRAPHER: We're going off the record. The time is 11:09 a.m. This is the end of Tape 2 of the deposition of Kevin Walters.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

- - - - - - - - - - - - - - - - - X

STATE OF ALASKA, :

Plaintiff, : Case No.:

: 3AN-06-5630CIV

vs. :

ELI LILLY AND COMPANY, :

Defendant. :

- - - - - - - - - - - - - - - - - X

Confidential Videotaped Deposition of

NATHANIEL RAY MILES

Washington, D.C.

Wednesday, November 14, 2007

9:06 a.m.

Pages: 1 - 296

Reported by: Dana C. Ryan, RPR, CRR

A Other than, you know, talking to my boss if there was an issue or something.

Q Okay. You mentioned earlier that the state action team might have an outcomes liaison. Is that Trina Clark -- that's who's reflected here -- in 2003?

MR. ROGOFF: Excuse me. Could we just -- don't mark on that -- write on the exhibit. Thanks.

THE WITNESS: Say that one more time. I'm sorry.

BY MR. MARCUM:

Q Okay. Trina Clark is listed here. Do you know who Trina Clark is?

A Yes.

Q Okay. And was she the outcomes liaison for the Alaska State Action Team?

A In '03, I'd say yes.

Q Okay. Outcomes liaisons,

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

STATE OF ALASKA, Plaintiff,	:	
vs.	:	No. 3AN-06-05630
ELI LILLY AND COMPANY, Defendant.	:	

December 5, 2007

Videotaped Deposition of KEVIN R. WALTERS held in the law offices of Pepper Hamilton, LLP, One Logan Square, Philadelphia, Pennsylvania 19103, beginning at approximately 9:11 a.m., before Ann V. Kaufmann, a Registered Professional Reporter, Certified Realtime Reporter, Approved Reporter of the U.S. District Court, and a Notary Public.

GOLKOW TECHNOLOGIES, INC.
One Liberty Place, 51st Floor
Philadelphia, Pennsylvania 19103
877.370.3377

Q. Okay. Who was the outcomes liaison for Alaska?

A. During that time period?

Q. Uh-huh.

A. Of 2002?

Q. Let's start there --

A. Okay.

Q. -- 2002.

A. Trina Clark.

Q. Okay. And was Trina Clark still the outcomes liaison for Alaska in 2003?

A. I'm not sure.

Q. Okay. Was Trina Clark the outcomes liaison in 2004?

A. A new outcomes liaison took over as Trina moved to North Carolina.

Q. Okay. Who was that outcomes liaison?

A. Jeff Hill.

Q. Jeff --

A. Hill.

Q. -- Hill. Okay.

Is Trina still employed by

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

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

MOTION ARGUMENTS BEFORE THE DISCOVERY MASTER

Pages 1 - 168
Tuesday, September 11, 2007
11:00 A.M.

at
LANE POWELL
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

burdensome? If you object to produce a random sample? Or tell me why you're not willing to produce them all.

MR. BOISE: The full data set? Yeah, the burden is in our history. And we have a long history of producing call notes in the litigation. It's about -- the review-and-produce time is about two minutes per call note of review time. So you can do the math for --

DISCOVERY MASTER: And you say there are 40,000 Alaskan?

MR. BOISE: Alaska call notes.

DISCOVERY MASTER: On Zyprexa?

MR. BOISE: Well, that could involve Zyprexa. We have to look at them to see whether they involve Zyprexa.

DISCOVERY MASTER: You have to look at them individually?

MR. BOISE: Yes.

MR. SUGGS: Your Honor.

DISCOVERY MASTER: I don't want to interrupt his argument. I'll let you respond when he finishes.

MR. BOISE: Yeah, and, you know, there is a lot of long discussion about, you know, how much

discovery of physicians is going to take place ultimately in this case. And certainly the extent that Lilly would pursue any physician's deposition, we would do what we have always done in the underlying litigation, is produce the call notes that associate with that physician. So those interactions are part of the discovery record, that we take it on a physician-by-physician basis. If there is more reasoned way to get at this to meet the State's needs short of 40,000, whether it's, you know, searching certain terms or not, we're willing to discuss that. We just have not had the opportunity to discuss whether anything short of this is even of interest.

Just so the allegation doesn't go unsaid. I know we're not trying the case before you today. Bipolar disorder for which Zyprexa is indicated is a mood disorder. So when the plaintiffs claim that if a doctor writes "mood" down in a record or "mood" somehow gets to a database, that that means it's nonindicated, we would say that's exactly why we need to look at medical record which would show the elements of bipolar disorder.

You know, it's a new disorder, and that's exactly what the Donna profile, to use the example, is going to. There is certainly a profile consistent

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

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

MOTION ARGUMENTS BEFORE THE DISCOVERY MASTER

Pages 1 - 168
Tuesday, September 11, 2007
11:00 A.M.

at
LANE POWELL
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska

MR. SUGGS: Sounds like they've agreed to give it to us.

DISCOVERY MASTER: That's all you want on 7 --

MR. SUGGS: Yup.

DISCOVERY MASTER: -- and 10, Interrogatory No. 7, RFP No. 10?

MR. SUGGS: Yeah. The next chunk, Your Honor, was Interrogatory Nos. 12 and 13 where we requested specific financial information on an annual basis related to the sales of Zyprexa both globally and in Alaska. They objected by saying that this was unduly burdensome and overbroad, but they failed to define their burden in relation to producing that information. And frankly, since Lilly is a publicly traded corporation, it's therefore required to maintain and periodically report similar information to that requested by the State. So we think their claim of undue burden is unfounded.

More importantly, Your Honor, the information is clearly relevant to the subject matter of this action. It's relevant to show state of mind and motive to engage in fraud, misrepresentation and unfair trade practices. And moreover, evidence of increasing financial gains after certain promotional

conduct complained of by the State was implemented.

For example, the off-label promotion to primary care physicians is clear evidence of the result of that conduct.

DISCOVERY MASTER: Mr. Boise.

MR. BOISE: Lilly is a publicly traded company, and it does report publicly some of the types of information that plaintiffs seek and would be at least responsive to the allegation or the need to show some sort of motive. That is, there are net sales figures that are available on publicly available documents, and if Mr. Suggs can't locate them, I can certainly help him, where net sales would be shown for Zyprexa and other data that is sought.

What we've simply objected to was trying to -- you know, the actual request includes: What is the income before taxes, or what is the cost of products sold? I mean to engage in some form of accounting exercise to get at the very general issue that Lilly is a publicly traded company, that it's a for-profit company, and it publicly reports the types of information that is sought but not the specific information that is sought.

If the allegation is increase in sales yields, increase in revenue and there was increase in

sales over periods of time, Lilly doesn't object to producing the publicly available information where that information can be derived, or alternatively, suggest the State can pull it up today and see the net sales figures for the product.

MR. SUGGS: Well, we're not just asking for net sales figures. As you know, we're also asking for measures of profitability, and we're not just asking for the corporation-wide figures but also for the sales and profitability in Alaska.

MR. BOISE: To address the Alaska point, certainly the Medicaid sales is certainly something that we can produce or something that you already have access to. I don't know of a way beyond measuring Medicaid sales how to get out the issue of all sales in Alaska. The information is not kept in that way, it's not maintained in that way. But we certainly could give you a proxy, which would be Medicaid sales over time, and have no objection to doing so.

MR. SUGGS: Well, Your Honor, we think we're entitled to the profitability information, not just sales.

DISCOVERY MASTER: All right.

MR. SUGGS: Your Honor, our next chunk was

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 RENEWED MOTION TO COMPEL AND MOTION FOR SANCTIONS

The State of Alaska, through its undersigned attorneys, hereby moves for an order compelling Lilly to answer certain of the State's First Interrogatories and Requests for Production or, in the alternative, granting such other relief as the Court may deem just and proper.

The grounds for the motion are that Lilly has failed to adequately respond to the State's interrogatories and requests, as required by the Alaska Rules of Civil Procedure and previous orders of the Discovery Master. Specific insufficiencies are set forth in the State's Memorandum in Support of Plaintiff's Renewed Motion to Compel and Motion for Sanctions. Plaintiff also requests costs and attorney's fees in bringing this motion, and further costs and fees specified in the accompanying memorandum.

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The undersigned hereby certifies and affirms in accordance with Rule 37(a)(2)(A), Alaska R. Civ. P., that further consultation with opposing counsel in an effort to resolve the matters contained in said motion would serve no useful purpose.

Dated this 11 day of December, 2007.

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Certificate of Service

I hereby certify that a true and correct copy of **Plaintiff's Renewed Motion to Compel and Motion for Sanctions ~~and (proposed) Order~~** was served by mail / ~~messenger~~ / facsimile on:

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

By Peggy S Crowe
Date 12/12/07

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