SOA

ELI LILLY & CO

Volume 12

CIVIL

Begun: 3-05-08
end: 3-10-08

IN THE

TRIAL COURTS

OF THE

STATE OF ALASKA

PLAINTIFF'S ATTORNEY

DEFENDANT'S ATTORNEY

TYPE OF PROCEEDING

MASTER ASSIGNED	DATE ASSIGNED	DATE DISQUALIFIED	BY WHOM DISQUALIFIED

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

15764

FILING FEE
RECEIPT# _____

INDEXED _____

OTHER _____

CV-E-A

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

FILED IN OPEN COURT
Date: 3-10-08
Clerk:

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

Case no. 3AN-06-5630CIV

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

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for **Denice Torres**.

Start (Page:Line)	End (Page:Line)
175:9	175:13
175:16	175:17
188:11	188:15
188:18	189:3
201:1	201:8
358:19	359:13
400:16	403:4
418:11	418:23
424:9	424:16
477:21	478:10

Start (Page:Line)	End (Page:Line)
545:7	545:13
552:2	552:15

Lilly objects to Plaintiff's exhibits for use during the testimony of Denise Torres:

Plaintiff's Exhibit	Objection(s)
Zyprexa MDL Plaintiff's Exhibit 08564	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing planning document Subject to Motion in Limine regarding Profits and Price Foundation (Alaska R. Evid. 901)
Zyprexa Plaintiff's Exhibit 10036	Subject to Motion in Limine regarding Profits and Price Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
Zyprexa MDL Plaintiffs' Exhibit No 09624	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing and planning document Subject to Motion in Limine regarding Profits and Price Hearsay (Alaska R. Evid. 801, 802)
Zyprexa MDL Plaintiff's Exhibit No. 09054	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document concerning planning Subject to Motion in Limine. regarding Profits and Price Subject to Motion in Limine regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802)
Zyprexa MDL Plaintiff's Exhibit No. 00946	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing plan Hearsay (Alaska R. Evid. 801, 802) Foundation (Alaska R. Evid. 901)
Zyprexa MDL Plaintiffs' Exhibit No 06360	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document
Zyprexa Plaintiff's Exhibit 10035	Subject to Motion in Limine regarding Profits and Price Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal communication related to potential line extensions for Zyprexa Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

	Objection(s)
[illegible]'s Exhibit [illegible]	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document describing sales representatives' interactions with physicians Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)

Lilly reserves the right to object to these exhibits, and any others that may be introduced by Plaintiff, under the Alaska Rules of Evidence or any other applicable rule of law, based on this Court's rulings or the purposes for which Plaintiff seeks to use the exhibits at trial.

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Andrea E. Girolamo-Welp,
ASBA No. 0211044

Dated: March 8, 2008

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

FILED IN OPEN COURT
Date: 3-10-08
Clerk: Tacy

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

Case no. 3AN-06-5630CIV

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

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for Robin Pitts Wojcieszek.

Start (Page:Line)	End (Page:Line)
17:2	17:22
23:9	23:15
23:21	24:1
27:25	28:12
83:14	83:19
95:2	95:17
98:9	98:18

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial Deposition Designations for Robin Pitts Wojcieszek:

Start (Page:Line)	End (Page:Line)	Objection
20:18 20:24	20:22 21:2	Mischaracterization of document (Plaintiff's Ex. 10094 – March 28, 2007 letter from FDA to Lilly) (Alaska R. Evid. 403).
29:17	29:22	Relevance; probative value is outweighed by the danger of unfair prejudice; (Alaska R. Evid. 401; 403); motion in limine: other litigation
29:23	30:1	Relevance; probative value is outweighed by the danger of unfair prejudice (Alaska R. Evid. 401; 403)
48:1 48:15	48:13 48:22	Improper hypothetical; assumes facts not in evidence; vagueness; argumentative; foundation. (Alaska R. Evid. 401, 611)
55:24 56:11 56:16 56:23	56:8 56:12 56:21 57:17	Foundation; lack of personal knowledge; (Alaska R. Evid. 401; 602).
79:13	79:18	Speculation. (Alaska R. Evid. 401, 403)
81:9 81:21	81:19 81:22	Speculation as to FDA's understanding of the meaning of "induce"; lack of personal knowledge (Alaska R. Evid. 401, 403, 602).
94:10	94:19	Hearsay (Alaska R. Evid. 801).

Lilly also objects to Plaintiff's exhibits for use during the testimony of Robin Pitts Wojcieszek:

Plaintiff's Exhibit	Objection(s)
Zyprexa Plaintiff's Exhibit No 10104	Relevance; probative value is outweighed by prejudice, delay and confusion, subsequent remedial measures, (Alaska R. Evid. 401, 402, 403, 407). Subject to Motion in Limine re: recent regulatory events.

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

FILED IN OPEN COURT
Date 3-10-08
Clerk

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

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

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for Jack Jordan:

Start (Page:Line)	End (Page:Line)
238:7	238:19
238:22	239:2
244:9	244:11
244:14	244:20
248:8	248:20
332:8	332:17
342:16	343:1
343:9	343:24
344:5	344:10
344:13	344:15

Start (Page:Line)	End (Page:Line)
369:12	369:24
375:8	375:21
376:2	376:13
393:15	395:1
421:14	422:11
422:14	422:15
462:11	462:14
462:23	463:7

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial Deposition Designations for Jack Jordan.

Start (Page:Line)	End (Page:Line)	Objection
Start (Page:Line)	**End (Page:Line)**	**Objection**
137:24	138:6	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 602, 701)
164:15	164:19	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in limine – profit/net worth/price (Alaska R. Evid. 401, 402, 403)
166:21	166:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
167:1	167:2	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)

Start (Page:Line)	End (Page:Line)	Objection
167:10	167:20	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
168:14	168:17	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
174:24	175:10	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
175:24	176:14	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
189:17	189:19	Compound; Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 611)
189:20	190:2	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
209:15	209:20	Ambiguous; Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 611)
223:13	223:17	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
223:22	223:24	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
236:4	236:7	Foundation; Misstates the evidence; Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
237:24	238:6	Foundation; Misstates the evidence; Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
243:24	244:8	Relevance; Probative value outweighed by danger of unfair prejudice; Summary Judgment – Off-label marketing (Alaska R.

Start (Page:Line)	End (Page:Line)	Objection
		Evid. 401, 402, 403)
246:9	246:18	Foundation; Misstates the evidence; Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
246:19	247:4	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
296:17	296:24	Foundation; Misstates the Evidence; Ambiguous; Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
297:18	297:20	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
301:20	302:2	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
306:1	306:7	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
308:18	309:4	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
309:5	309:10	Foundation; Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 601, 702)
309:11	309:21	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
318:15	318:23	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 611)

...ge:Line)	End (Page:Line)	Objection
339:6	339:11	Relevance; Probative value outweighed by danger of unfair prejudice; Argumentative; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 611)
342:8	342:9	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
342:11	342:15	Relevance; Probative value outweighed by danger of unfair prejudice; Argumentative; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 611)
343:2	343:8	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
344:16	345:9	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
347:12	348:4	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Other Lilly Drugs; Motion in limine – profit/net worth/prices (Alaska R. Evid. 401, 402, 403)
355:20	356:2	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label (Alaska R. Evid. 401, 402, 403)
362:20	363:3	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
363:16	364:18	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
366:19	366:23	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label; Motion in limine – profit/net worth/prices (Alaska R. Evid. 401, 402, 403)
368:5	368:14	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)

ıge:Line)	End (Page:Line)	Objection
369:2	369:11	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
373:22	375:7	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
388:7	388:23	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
389:6	389:20	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
396:7	397:8	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
413:6	413:8	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
421:05	421:13	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
422:16	423:6	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
436:14	436:22	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
437:20	438:7	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)
456:13	458:1	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in limine – profit/net worth/price; Motion in limine – Other Lilly drugs (Alaska R. Evid. 401, 402, 403)

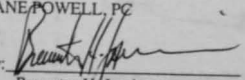
Lilly also objects to Plaintiff's exhibits for use during the testimony of Jack Jordan

Plaintiff's Exhibit	Objection(s)
Zyprexa MDL Plaintiffs' Exhibit No. 3872 (Jordan Dep. Exh. 8)	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document that discusses market positioning and strategy MIL regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
Zyprexa MDL Plaintiffs' Exhibit No. 8632 (Jordan Dep. Exh. 13)	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing sales representative interaction with physicians
Zyprexa MDL Plaintiffs' Exhibit No. 1301 (Jordan Dep. Exh. 23)	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing plan Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) M.I.L. regarding Profits and Price

Lilly reserves the right to object to these exhibits, and any others that may be introduced by Plaintiff, under the Alaska Rules of Evidence or any other applicable rule of law, based on this Court's rulings or the purposes for which Plaintiff seeks to use the exhibits at trial.

Respectfully submitted,

LANE POWELL, PC

By: 

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Dated: March 8, 2008

...D IN OPEN COURT
Date: 3-10-08
Clerk:

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

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

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

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for **John Lechleiter**.

Start (Page:Line)	End (Page:Line)
71:1	71:10
120:14	121:7
122:6	122:18
149:3	149:12
267:11	268:11
277:12	277:17
292:24	293:10
300:11	300:21
310:11	310:20
365:24	366:6
367:12	368:12

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Dated: March 8, 2008

Start (Page:Line)	End (Page:Line)
267:12	268:11
300:11	300:21

3. Jack Jordan

Start (Page:Line)	End (Page:Line)
342:16	343:1
369:12	369:24
375:8	375:21
376:2	376:13
421:14	422:11
422:14	422:15

4. Mike Bandick

Start (Page:Line)	End (Page:Line)
403:21	403:24
404:24	405:7
419:23	420:9
420:14	420:21
448:21	449:4
449:16	449:24
450:1	450:7
504:13	504:15
504:18	504:21

Robin Wojcieszek

Start (Page:Line)	End (Page:Line)
17:2	17:22
23:9	23:15
23:21	24:1
27:25	28:12
83:14	83:19
95:2	95:17
97:23	98:18

6. Charles Beasley, M.D.

Start (Page:Line)	End (Page:Line)
83:2	83:8
142:24	143:7
143:21	143:23
144:1	144:12
148:5	148:18
149:20	149:24
150:18	151:10
157:11	158:7
184:23	185:15
202:17	203:9
208:20	209:10
210:2	210:11

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Dated: March 8, 2008

FILED IN OPEN COURT
Date: 3-10-08
Clerk:

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

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

CHARLES BEASLEY

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for Charles Beasley (July 26, 2006):

Start	End
58:22	59:1
81:16	81:18
81:20	81:24
82:1	82:10
83:2	83:8
111:14	111:24
112:8	114:24
142:24	143:7

Start	End
143:21	143:23
144:1	144:12
148:5	148:18
149:20	149:24
150:18	151:10
157:11	158:7
184:23	185:15
186:24	187:4
187:6	187:10
202:17	203:9
208:20	209:10
210:2	210:11
210:16	211:13
218:9	218:11
243:24	243:24
248:5	248:10
253:8	253:13
253:15	253:16
256:17	257:5
260:20	263:13
272:18	272:22
272:24	273:8
296:11	297:8

Start	End
298:8	298:20
301:23	302:4
391:3	391:7
391:10	391:18

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial Deposition Designations for Charles Beasley (July 26, 2006):

Start	End	Objection
78:17	79:6	Hearsay (Alaska R. Evid. 802)
80:22	81:12	Foundation; (Alaska R. Evid. 602, 701)
84:9	85:1	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
95:23	96:12	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
111:2	111:13	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
135:15	136:2	Foundation; Ambiguous (Alaska R. Evid. 403, 602, 611, 701)
142:3	142:15	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
147:19	148:4	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
149:12	149:19	Foundation; Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 602, 701)
150:7	150:17	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)

Start	End	Objection
285:12	285:24	Hearsay (Alaska R. Evid. 802)
286:15	287:1	Foundation (Alaska R. Evid. 602, 701)
287:10	288:1	Hearsay; Foundation (Alaska R. Evid. 602, 701, 802)
288:6	288:13	Hearsay; Foundation (Alaska R. Evid. 602, 701, 802)
288:14	288:21	Hearsay; Foundation (Alaska R. Evid. 602, 701, 802))
293:6	294:8	Hearsay (Alaska R. Evid. 802)
295:10	295:22	Foundation (Alaska R. Evid. 602, 701)
296:3	296:10	Foundation (Alaska R. Evid. 602, 701)
297:14	297:20	Hearsay; Foundation (Alaska R. Evid. 602, 701, 802)
297:21	298:7	Foundation (Alaska R. Evid. 602, 701)
304:21	305:8	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)
305:9	305:11	Hearsay; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 403, 602, 701, 802)
305:12	306:1	Hearsay; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 403, 602, 701, 802)
306:19	307:3	Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403)
307:4	307:21	Probative value outweighed by danger of unfair prejudice; Argumentative (Alaska R. Evid. 403, 611)
310:1	310:15	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)
310:16	310:19	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)
310:20	311:5	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)

Start	End	Objection
311:6	311:19	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
317:20	318:9	Hearsay (Alaska R. Evid. 802)
345:22	346:8	Compound; Misstates the evidence (Alaska R. Evid. 611)
346:18	347:5	Compound (Alaska R. Evid. 611)
347:6	347:14	Compound (Alaska R. Evid. 611)
347:15	347:18	Compound; Ambiguous; Comment by counsel (Alaska R. Evid. 403, 611)
347:19	347:23	Compound; Ambiguous (Alaska R. Evid. 403, 611)
347:24	348:13	Compound; Ambiguous; Comment by counsel (Alaska R. Evid. 403, 611)
386:4	386:16	Hearsay (Alaska R. Evid. 802)
386:17	386:22	Hearsay; Argumentative (Alaska R. Evid. 611, 802)
390:9	390:20	Hearsay; Compound; Misstates the evidence; Asked and answered (Alaska R. Evid. 611, 802)
390:21	391:2	Hearsay; Compound; Misstates the evidence; Asked and answered (Alaska R. Evid. 611, 802)
391:19	392:1	Hearsay; Asked and answered (Alaska R. Evid. 611, 802)
393:17	393:19	Hearsay; Asked and answered (Alaska R. Evid. 611, 802)
393:20	394:1	Hearsay; Asked and answered (Alaska R. Evid. 611, 802)
394:2	394:8	Foundation (Alaska R. Evid. 602, 701)
394:12	394:17	Hearsay; Asked and answered (Alaska R. Evid. 611, 802)
394:18	395:10	Compound; Misstates the evidence (Alaska R. Evid. 611)
395:11	395:18	Asked and answered (Alaska R. Evid. 611)

Defendant Eli Lilly and Company ("Lilly") hereby objects to Plaintiff's exhibits for use during the designated deposition testimony of Charles Beasley (July 26, 2006):

Plaintiff's Exhibit	**Objection(s)**
Zyprexa MDL Plaintiffs' Exhibit N. 988	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 1345	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 6890	Not relevant to labeling claims (Alaska R. Evid. 401, 402). Prejudicial, confusing, waste of time (Alaska R. Evid 403). Lay witness opinion (Alaska R. Evid. 701).
Zyprexa MDL Plaintiffs' Exhibit No. 8042	No foundation as to page 3 (Alaska R. Evid. 901).
Zyprexa MDL Plaintiffs' Exhibit No. 4858	Subject to motion in limine regarding adverse events (hearsay – notice).
Zyprexa MDL Plaintiffs' Exhibit No. 195	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 6998	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 1449	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 1453	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 6128	Admitted except for portion discussing OUS marketing efforts. Object as not relevant to labeling claims (Alaska R. Evid. 401, 402).
Zyprexa Plaintiff's Exhibit No. 10004; Beasley Dep. Exh. 1.	Not relevant to Phase I (Alaska R. Evid. 401), Hearsay, Foundation, Unfairly prejudicial.

Lilly reserves the right to object to these exhibits, and any others that may be introduced by Plaintiff, under the Alaska Rules of Evidence or any other applicable rule of law, based on this Court's rulings or the purposes for which Plaintiff seeks to use the exhibits at trial.

Dated: March 8, 2008

Respectfully submitted,

LANE POWELL, PC

By: _____

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Attorneys for Defendant
Eli Lilly and Company

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

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

Judges Rulings
3/14/08
Mark Rindner

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

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for **Gary Tollefson, M.D.** The highlighted excerpts are those that must be presented together with the State's affirmative designations to ensure proper context.

Start (Page:Line)	End (Page:Line)	
82:6	82:15	include
96:23	97:13	✓
97:16	97:23	✓
98:2	98:13	✓
109:4	109:18	include last objection to question was sustained
124:12	124:18	include
126:10	127:11	✓
142:15	143:9	
203:13	203:15	✓
203:18	204:3	✓

Start (Page:Line)	End (Page:Line)	Objection
209:19	209:22	Vague, misstates evidence; question re-phrased (Alaska R. Evid. 403, 602; 611)

Lilly also objects to Plaintiff's exhibits for use during the testimony of Gary Tollefson, M.D.:

Plaintiff's Exhibit	Objection(s)
Zyprexa MDL Plaintiff's Exhibit No. 6100	Relevance; probative value is outweighed by prejudice, delay and confusion; foundation (Alaska R. Evid. 401, 402, 403, 901). Subject to Motion in Limine: profits and price.

Lilly reserves the right to object to these exhibits, and any others that may be introduced by Plaintiff, under the Alaska Rules of Evidence or any other applicable rule of law, based on this Court's rulings or the purposes for which Plaintiff seeks to use the exhibits at trial.

Respectfully submitted,

Dated: March 9, 2008

LANE POWELL, PC

By:_____

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Attorneys for Defendant
Eli Lilly and Company

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

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

JUDGES' RULINGS 3/16/09 MarkPhi

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

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for **Bruce Kinon, M.D**. The highlighted excerpts are those that must be presented together with the State's affirmative designations to ensure proper context.

Start (Page:Line)	End (Page:Line)	
52:9	52:16	include -
65:20	66:7	✓
72:16	72:17	✓
73:17	73:18	include
80:7	80:15	
82:4	82:18	✓
92:10	92:15	✓
93:7	93:17	✓
140:15	141:7	
236:8	236:20	include
237:17	237:24	✓

Start (Page:Line)	End (Page:Line)	
241:2	241:21	
247:10	247:12	include
263:18	263:22	
264:1	264:11	include although it may not be needed given my ruling as to question
412:14	412:23	

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial

Deposition Designations for Bruce Kinon:

Start (Page:Line)	End (Page:Line)	Objection	
51:11	52:8	Foundation; lack of personal knowledge; authentication. (Alaska R. Evid. 401; 602, 901).	sustained
53:3	53:24	Foundation; lack of personal knowledge; authentication. (Alaska R. Evid. 401; 602, 901).	sustained
84:9	84:18	Foundation; lack of personal knowledge; authentication. (Alaska R. Evid. 401; 602, 901).	overruled
139:4	139:23	Lay opinion as to what was "generally accepted" in the field. (Alaska R. Evid. 701).	overruled
235:13	235:24	Vague; foundation (Alaska R. Evid. 401; 602; 901).	overruled
244:16	244:22	Probative value is outweighed by the danger of unfair prejudice; calls for a legal conclusion as to "liability"; probative value is outweighed by the danger of unfair prejudice; lay opinion testimony, calls for expert opinion (Alaska R. Evid. 403; 701).	overruled
245:6	251:8	Foundation; lack of personal knowledge; authentication. (Alaska R. Evid. 401; 602, 901).	overruled
261:12	261:18	Foundation; probative value is outweighed by the danger of unfair prejudice (Alaska R. Evid. 401; 403).	sustained

Start (Page:Line)	End (Page:Line)	Objection
262:14	266:6	Foundation; probative value is outweighed by the danger of unfair prejudice (Alaska R. Evid. 401; 403).
265:9	265:10	Argumentative.

sustained

sustained

Lilly also objects to Plaintiff's exhibits for use during the testimony of Bruce Kinon:

Plaintiff's Exhibit	Objection(s)
Zyprexa MDL Plaintiffs' Exhibit No. 1213	Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802)
Zyprexa MDL Plaintiffs' Exhibit No. 4517	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
Zyprexa MDL Plaintiffs' Exhibit No. 8905	Not Relevant (Alaska R. Evid. 401, 402).
Zyprexa MDL Plaintiffs' Exhibit No. 4532	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: draft, incomplete marketing planning document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
Zyprexa MDL Plaintiffs' Exhibit No. 7668	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407)
Zyprexa MDL Plaintiffs' Exhibit No. 5522	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: market research/marketing planning document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)

overruled

overruled

overruled

sustained as to authenticity Mike interview with this witness

overruled

~~overruled~~ (need to discuss)

These objections are overruled but is this witness able to authenticate — objection to question well sustained

Lilly reserves the right to object to these exhibits, and any others that may be introduced by Plaintiff, under the Alaska Rules of Evidence or any other applicable rule of law, based on this Court's rulings or the purposes for which Plaintiff seeks to use the exhibits at trial.

Respectfully submitted,

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By:_____

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Attorneys for Defendant
Eli Lilly and Company

Dated: March 9, 2008

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.	)	

DEFENDANT ELI LILLY AND COMPANY'S MOTION FOR RECONSIDERATION OF RULINGS ON OBJECTIONS TO AFFIRMATIVE DEPOSITION DESIGNATIONS OF GARY TOLLEFSON, M.D.

Defendant Eli Lilly and Company ("Lilly") respectfully requests that the Court reconsider its rulings regarding the admissibility of the following excerpt from the deposition of Gary Tollefson, M.D. This designation by the State reflect its allegations that Lilly engaged in off-label promotion—allegations which the Court has deemed irrelevant to, and beyond the scope of, any claim that State asserts. Consistent with the Court's rulings regarding other similar designated testimony in other depositions, Lilly's objections set forth below should be sustained. Relevant pages of the transcripts are attached.

Start (Page:Line)	End (Page:Line)	Objection
124:5 124:21	124:9 125:21	Relevance, vague; foundation; personal knowledge; (Alaska R. Evid. 401, 402, 403, 602, 611). Subject to ruling on Motion for Summary Judgment: off label.

Sustained

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LANE POWELL LLC

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ASBA No. 8411122
Andrea E. Girolamo-Welp,
ASBA No. 0211044

Attorneys for defendant Eli Lilly and Company

Dated: March 10, 2008

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document has been served via email upon counsel listed below, and by hand delivery and email upon Mary Beth Rivers, Room 532, Tower Two, Captain Cook Hotel.

Adam B. Michaels

Counsel List

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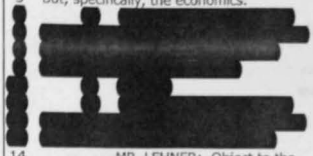
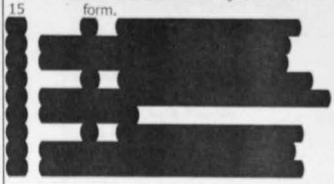
Mount Pleasant, SC 29464-4190

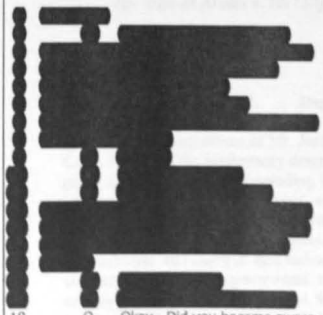
Date: March 10, 2008

was spent on the drug; is that correct?
MR. LEHNER: Object to the form.
A. Probably reflecting both. But, specifically, the economics.



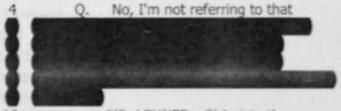
MR. LEHNER: Object to the form.



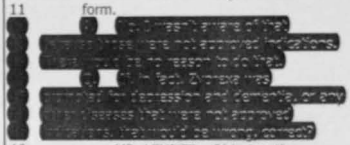


Q. Okay. Did you become aware of efforts to promote Zyprexa to physicians for dementia and depression?
MR. LEHNER: Object to the form.
A. If you're referring to the disease state prioritization table here --

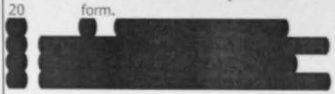
Q. No, I'm not.
A. -- these are clinical candidates.
Q. No, I'm not referring to that

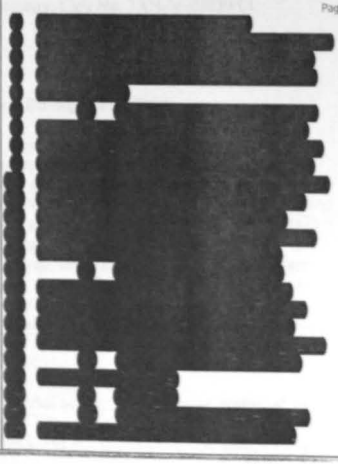


MR. LEHNER: Object to the form.



MR. LEHNER: Object to the form.





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March 9, 2008

Honorable Mark Rindner
Alaska Court System
825 West Fourth Avenue
Room 432
Anchorage, AK 99501-2004

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

Dear Judge Rindner:

I. Depositions – Rulings – Play Back

On the depositions of Mr. Jordan, Mr. Bandick and Ms. Torres it appears that the Court has made the preliminary determination that the fact that these witnesses met with many attorneys for Lilly (including Lilly's trial counsel) prior to their testimony is not admissible evidence. With respect, we ask the Court to reconsider. It is highly relevant that these ex-Lilly employees met with the Lilly attorneys on numerous occasions before they gave their sworn testimony. Bias/prejudice is a fundamental element of impeachment and one that this author has taught at National Institute of Trial Advocacy courses and other lawyer/student training for years. These individuals are all ex-employees of Lilly. The fact that the witnesses have met with and are presented by counsel for Eli Lilly goes directly to bias or prejudice of the witness. The fact that a non-party witness met with Lilly counsel demonstrates a potential for bias; in fact, it is the essence of bias/prejudice. e.g. Alaska R. Evid. 613.

Further, despite this Court's initial pre-trial ruling that witnesses presented by deposition would be presented just like all other witnesses (because they are in fact just like other witnesses) Lilly has now engaged this Court in a dual process by again arguing

that for some reason they should get two bites at the same apple. Thus, they have proposed a cumbersome process whereby they want to play some testimony in our presentation (like interrupting a witness on the stand) and then also play a cross-examination. We again object to this process and ask the Court to stand by its own ruling. To the extent, however, that the Court allows Lilly to engage in this logistical morass we ask the Court to:

(1) Not allow Lilly to play answers to questions which we properly and timely objected to at the deposition as "nonresponsive." To do so would allow a witness and a party, Lilly, to benefit when its witnesses gave self-serving and nonresponsive answers and a proper objection was timely made at the deposition.

(2) Not allow Lilly to play "answers" only without the question.

Both of the above have been part of Lilly's proposed "contemporaneous" offers.

Finally, as a matter of logistics, the State informs the Court that it cannot insert Lilly's "contemporaneous" offers Lilly into our video presentation. Thus, Lilly needs its own "cuts" ready to the extent the Court permits any "contemporaneous" offers. We are prepared to play depositions all day Tuesday and parts of each day during our case thereafter. In order to remain on this schedule and have our presentation ready, we must proceed with our video deposition preparation.

II. Zyprexa's Other Uses

Additionally, in follow-up to our letter of Friday, February 7, 2008, the State vehemently asserts that to disallow evidence of (not a claim for) other uses of Zyprexa beyond schizophrenia and bipolar mania is manifestly unjust in light of the factual evidence that such uses were widely known within Lilly (40% of Zyprexa's use was not for schizophrenia/bipolar mania) and was the subject of intense focus within Lilly's PCP marketing for Zyprexa. These uses included dementia/Alzheimer's and children, as well as mood, thought and behavior disorders. As reflected in the attached exhibits #8329 and Torres #26/Lechleiter #4 dated November 2000 and November 2001 respectively:

"Zyprexa questions from the field"

Question: Since the diagnosis of our 3 patients in Zyprexa core message piece are: Martha – dementia…We know that we are to describe the symptoms and stay away from diagnoses, but for our own background can you elaborate on dementia…

Answer: Dementia is a broad classification…Alzheimer's disease is the most prevalent form of dementia." (Ex. AK8329)

"Based on the outcome described by Alan Breier below, the Zyprexa team is recommending that we abandon our effort to seek regulatory approval for use of Zyrpexa to treat Alzheimer's psychoses…

We recommend not pursuing a formal indication for Alzheimer's psychosis because of the mixed clinical results…the high FDA threshold, concerning safety risks…The recommended approach is to support this segment with a publication strategy." (Torres Ex. #26/Lechleiter Ex. # 4).

Thus, Lilly was not only promoting Zyprexa use in the elderly, with no indication, but did so when they knew they had no FDA approvable studies to support such use. These were not patients who needed to be "saved" from prisons, suicide, frontal lobotomies and electric shock. Surely, when doctors were performing their "risk/benefit analysis" (trumpeted by Lilly's counsel on opening) in regard to elderly/Alzheimer's/dementia patients they needed to be "warned" of diabetes/hyperglycemia? The State has been forced to remain silent when we have direct evidence contradicting Lilly's opening remarks. Such a process is fundamentally unfair and denies the State due process in rebutting Lilly's false defense.

Further, Lilly's support of the other uses of Zyprexa went to the highest levels of the company. As reflected in Torres Exhibit #29, John Lechleiter, the current Lilly CEO, made a bolded recommendation in an e-mail of March 2003 to "…expand our work with Zyprexa in this same child-adolescent population." Are these the patients to whom the "risk/benefit equation" was so tilted in favor of Zyprexa that they were saved from prisons, suicide and frontal lobotomies? Of course not. This evidence cannot be excluded. To do so will deny the State its due process rights.

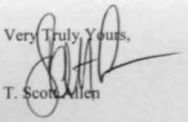
Finally, Lilly's counsel stated on multiple occasions in opening that Zyprexa was indicated for "bipolar disorder." Zyprexa is not indicated for bipolar disorder. As but one example, please see the attached sworn testimony of Mr. Jack Jordan:

Q. Just so the record is clear, Zyprexa was never indicated for bipolar disorder, was it, sir?

A. No, it wasn't. No. (Page 236, Lines 4-7)

Lilly's counsel misrepresented both Zyprexa's indications and uses in its opening statement. To permit Lilly to paint this false picture and require the State to be silent when there is evidence to the contrary is unjust and violates due process. We ask the court for relief. There is a difference between a cause of action and the offer of evidence to rebut a defense.

Very Truly Yours,



T. Scott Allen

cc: George Lehner, Esq.

EXHIBIT 8329

Darren L Dobbs
11/16/00 10:49 AM

To: J Dean Barron/AM/LLY@LILLY, S Suzanne Huxen/AM/LLY@Lilly, Sherry M Korczynski/AM/LLY@Lilly, John N Law/AM/LLY@LILLY, Nicholas G Love/AM/LLY@LILLY, Martis F Morrison/AM/LLY@LILLY, Russell D Patyk/AM/LLY@LILLY, Donald V Stewart/AM/LLY@LILLY, Julie M Tweedie/AM/LLY@LILLY
cc: Michael E Bandick/AM/LLY@Lilly, Karen Behar/AM/LLY@LILLY, Mark J Bernauer/AM/LLY@Lilly, Ajay K Bhardwaj/AM/LLY@Lilly, James Delisle/AM/LLY@Lilly, Donald P Hay/AM/LLY@Lilly, Christine M Pierce/AM/LLY@Lilly, Arthur S Snow Jr/AM/LLY@LILLY, James M Sweeney/AM/LLY@LILLY, Jo A Taylor/AM/LLY@LILLY
Subject: Zyprexa questions from the field

Area Zyprexa Champions:
Below is a response from Zyprexa medical to recent questions from the field. Please disseminate to your respective areas. Also, for future questions, please send them to Art Snow in training and development. I have enjoyed working with all of you and will miss our interactions in my new assignment. Thanks!
Darren

Question:

- We know that Zyprexa has a low potential for drug-drug interactions, but we need to feel a little more confident about a "cocktail" question that has come up for several of the reps: Can doctors use Zyprexa with Aricept or Excelon? It is thought that Aricept/Excelon works on the Alzheimer's and Zyprexa can pick up the unmet need of agitation that goes with it. Is it common to add Zyprexa; what doses of Zyprexa are added; anything to warn the doc about? Also, if Zyprexa is going after the Alzheimers indication, wouldn't it make sense to forget the Aricept/Excelon (we know that we can't discuss future indications, but is there good data/ medical letter to support Alzheimers efficacy).

Answer:

- Zyprexa has multiple metabolic pathways and though it has not been studied with Aricept or Excelon, we would not expect any significant interaction between Zyprexa and these medications. During other interaction studies, it was found that other medications metabolized through similar pathways as Zyprexa (1A2 and 2D6) may influence the plasma levels of Zyprexa (the other drug's plasma levels are not effected). With Zyprexa's broad range of dosing and blood levels, changes in the blood levels for Zyprexa does not create a concern unless there are more factors involved (i.e. elderly, smoking). Additionally, the notion that Zyprexa has significant anticholinergic effects (thus negating the increase in acetylcholine by Aricept and Exelon) has not been a factor during our studies in the elderly. In fact, we have seen a trend toward cognitive improvement with Zyprexa. Secondly, at the current time, we are not pursuing an indication for treatment of Alzheimers. We had submitted for an indication for the behavioral disturbances associated with Alzheimers; however, it was withdrawn due to vagueness on the FDA's part regarding a definition of efficacy that they would utilize to determine a medications approval for this use.

Question:

- Since the diagnosis of our 3 patients in the Zyprexa core message piece are: Martha - dementia, David - bipolar, Christine - schizo; can you enlighten us a little more about dementia. We know that we are to describe the symptoms and stay away from diagnoses, but for our own background, can you elaborate on dementia and how it is different from other things like Alzheimers, etc. We are getting a little grief from some of our docs about promoting Zyprexa for dementia, but according to the slides in the audioconference set, there is no FDA approved drug for dementia.

Answer:

- Dementia is a broad classification that basically indicates a disease which produces a decline in cognitive functioning. As we know, there are many other symptoms associated with this as well

ZY 5032 1127

(behavioral disturbances, psychosis). Alzheimers disease is the most prevalent form of dementia, estimated at over 80% of dementia cases. Other forms may include vascular dementia, leweybody dementia, dementia NOS.

Question:

- Dosing of 2.5 mg vs 5 mg - we are finding that 2.5 mg is the dose most often used in nursing homes. We want to stay consistent with our 5 mg message for ambulatory outpatients. For our own benefit, what are the real differences between 2.5 and 5 mg in efficacy and safety for the "Martha" type patient. If the patient is on multiple meds, when and how are patients started on Zyprexa in both settings - the nurse home and outpatients.

Answer:

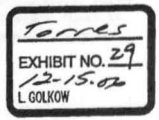
- Regarding 2.5mg efficacy, we currently do not have any firm evidence of the efficacy at this dose. While some of the patients in our Alzheimer studies were taking a 2.5mg dose, the dose most efficacious was 5mg and 10mg. Support for the 2.5mg dosing at this point is anecdotal in nature. The only evidence we have to date of efficacy at 2.5mg is that 20% of patients in an open label, flexible dosing dementia study by Kinon et. al. were on a mean dose of >0 -2.5mg (mean dose of the study was 5mg). As you know, our package insert states efficacy at 5 to 20mg, not 2.5 to 20mg. More studies are needed with regard to dosing in elderly populations to clearly identify if 2.5mg is both safe and efficacious.

Thanks to Marlis Morrison for forwarding these questions.

ZY 5032 1128

TORRES EXHIBIT 29

To: CN=Scott A Allgyer/OU=AM/O=LLY@Lilly; CN=Alan Breier/OU=AM/O=LLY@Lilly; CN=Denice M Torres/OU=AM/O=LLY@Lilly
Date: 03/18/2003 11:18:56 AM
From: CN=John C Lechleiter/OU=AM/O=LLY
Subject: Re: Notes from Day in Field with Neuroscience Reps



FYI -- John
----- Forwarded by John C Lechleiter/AM/LLY on 03/18/2003 11:18 AM -----

Michael F Ackermann
03/18/2003 09:42 AM
To: John C Lechleiter/AM/LLY
cc:
Subject: Re: Notes from Day in Field with Neuroscience Reps

John:

Thanks for the message and the "boldness". Here is a quick update.
80,100mg strengths are on the list and are being developed. Actually, another important formulation is the liquid preparation as many 6-7 year olds do not swallow a capsule.
Strattera and co-morbid bipolar is currently not on the list, however, we think we need to do co-administration studies with Zyprexa, redacted to have safety and efficacy data around co-administration since Bipolar and depression are frequentlycomorbid disorders with ADHD.
Co-morbid anxiety and Depression studies are on-going.
I agree that Risperdal is way ahead of Zyprexa regarding safety and efficacy data in children/adolescents. I will f/u with Jack Jordan.

John, again, this is terrific feedback.

Regards,

Mike

John C Lechleiter
To: Michael F Ackermann/AM/LLY@Lilly, Alan Breier/AM/LLY@Lilly, H Christian Fibiger/AM/LLY@Lilly, John R

03/17/2003 05:36 PM

Hayes/AM/LLY@Lilly, Susan Mahony/AM/LLY@Lilly, Gerhard Mayr/AM/LLY@Lilly, Michael MD McDonald/AM/LLY@Lilly, David Michelson/AM/LLY@Lilly, Anne Nobles/AM/LLY@Lilly, Bill Robinson/AM/LLY@Lilly, Gino Santini/AM/LLY@Lilly, Christopher John Shaw/AM/LLY@Lilly, Sidney Taurel/AM/LLY@Lilly, Mauricio F Tohen/AM/LLY@Lilly, Gary D Tollefson/AM/LLY@Lilly, Denice M Torres/AM/LLY@Lilly, Albertus vandenBergh/AM/LLY@Lilly, August M Watanabe/AM/LLY@Lilly

cc: Scott A Allgyer/AM/LLY@Lilly, John C Lechleiter/AM/LLY@Lilly

Subject: Notes from Day in Field with Neuroscience Reps

Attached are my notes form a recent visit to Cincinnati in late February, where I met with a group of our Neuroscience sales representatives and spent part of the next day in the field calling on psychiatrists. **I have highlighted in bold the inputs that I consider to be most significant or that came up most often, and would appreciate if the global and U.S. teams would follow up as appropriate.**

redacted

redacted

Zyprexa/redact

Physician comments:

* Having data available upon request concerning the use of Zyprexa in bipolar depression would be helpful
* Small doses of Risperdal are being used to replace Xanax and benzos....This individual would like to be able to try small doses of Zyprexa

Comment made that we are losing scripts to Risperdal for treatment of disruptive kids because J&J has the data, and we don't....

* **"With child psychs, Zyprexa is a distant third across a range of disorders...."**

*** Editorial note: it appears to me that the fact we are now talking to child psychs and peds and others about Strattera means that we must seize the opportunity to expand our work with Zyprexa in this same child-adolescent population.**

* Weight gain was the issue I heard about most consistently. One comment, "It is a very good drug, but the majority of my patients gain weight." Comment made that this seems to be worse in females...."Men gain, but then stop."

From conversation with Lilly reps:

redacted

redacted psychiatrists will need "specific" symptoms we are looking to treat with OFC versus Zyprexa so as not to confuse the customer and potentially take a clear Zyprexa Monotherapy patient

* Most of the negative noise in the market is around weight gain, not diabetes, but Pfizer, in particular, is trying to put together a story suggesting that Zyprexa has a particular problem with respect to weight, triglycerides, and hyperglycemia, or that it causes insulin resistance
* Would like to have data on Zyprexa effect on anxiety
* Need direct comparisons vs. Seroquel and Risperdal in core symptoms of mania
* Availability of ZYDIS formulation could not come soon enough, redacted

redacted

* Zyprexa is getting traction with some neurologists for treatment of pain
* **Need to consider the case for lower dose strengths of Zyprexa**
* Not enough samples available -- don't have samples for two weeks of the month

redacted

TORRES EXHIBIT 26

John C Lechleiter
11/20/2001 06:18 AM

To: Charles E Golden/AM/LLY, Pedro P Granadillo/AM/LLY, Rebecca O Kendall/AM/LLY, Gerhard Mayr/AM/LLY, Sidney Taurel/AM/LLY, August M Watanabe/AM/LLY
cc: Alan Breier/AM/LLY@Lilly, Simon Harford/AM/LLY@Lilly, Gwen Krivi/AM/LLY@Lilly, Gino Santini/AM/LLY@Lilly, Jennifer L Stotka/AM/LLY@Lilly, Gary D Tollefson/AM/LLY@Lilly, Albertus VanDenBergh/AM/LLY@Lilly
Subject: update on Zyprexa Dementia Program

Based on the outcomes described by Alan Breier below, the Zyprexa team is recommending that we abandon our effort to secure regulatory approval for use of Zyprexa to treat Alzheimers psychosis. I accept their recommendation at this point. We have one ongoing study which could result in a further publication, but will not alone suffice for registration.

If you'd like to discuss this further, let me know. Gus, is this something you would like to see reviewed and minuted at PMC?

--John
---- Forwarded by John C Lechleiter/AM/LLY on 11/20/2001 06:21 AM ----

Alan Breier
11/19/2001 10:13 AM

To: John C Lechleiter/AM/LLY@Lilly
cc: Alan Breier/AM/LLY@Lilly, Patrizia Cavazzoni/AM/LLY@Lilly, Deborah Lehman Kadam/AM/LLY@Lilly, John A Krueger/AM/LLY@Lilly, Alvin H Rampey Jr/AM/LLY@Lilly, Mauricio F Tohen/AM/LLY@Lilly, Gary D Tollefson/AM/LLY@Lilly, Denice M Torres/AM/LLY@Lilly, Albertus VanDenBergh/AM/LLY@Lilly
Subject: update on Zyprexa Dementia Program

John,

Following is an update on our Alzheimer's psychosis program:

Zyprexa Product Team conducted 4 clinical trials with mixed results to support an indication for Alzheimer's psychosis:

- HGOA (8-week, placebo controlled, 238 outpatients, olanz doses: 1 to 8mg), completed: May 1995
  Results: numerically but not statistically superior to placebo
- HGEU (6-week, placebo controlled, 206 inpatients, olanz doses 5, 10, 15 mg), completed: June 1998
  Results: 5mg and 10 mg significantly superior to placebo, some saftey concerns (eg, abnormal gait)
- HGGU (placebo vs. olanz. vs risperidone, acute and long-term treatment periods, 494 outpatients, flexible dosing), completed: November 2002
  Results: no separation between olanz vs placebo, olanz vs. risp., or risp. vs. placebo (large placebo response may explain negative results)
- HGIV (placebo vs. multiple fixed doses of olanz beginning at 2.5 mg; 575 inpatients planned) the trial is currently ongoing with 450 patients enrolled by year's end, last patient to be enrolled in March 2002.

For an indication, HGIV must be positive and another (new) global trial would need to be initiated

Safety Issues are inherent in this population because of their advanced age and poor health

JACK JORDAN DEPO P.236

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF NEW YORK

IN RE: MDL-1596

ZYPREXA PRODUCTS

LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

ALL CASES

C O N F I D E N T I A L

- - -

October 26, 2006

- - -

Videotape deposition of

JACK E. JORDAN

- - -

GOLKOW LITIGATION TECHNOLOGIES
1600 John F. Kennedy Boulevard
Suite 1210
Philadelphia, Pennsylvania 19103
(877) DEPS-USA

different phases of bipolar disorder. But mood stabilizer, again, is just a general term that can cover a number of classes.

Q. Yes, sir. Just so the record is clear, Zyprexa was never indicated for bipolar disorder, was it, sir?

A. No, it wasn't. No.

Q. It was only indicated for bipolar mania only, correct, sir?

MR. FAHEY: Objection. Foundation.

A. During the time I was there, yes.

Q. Okay. Now, back to my question. Let me see if we can approach it a different way if I need to. Was Zyprexa approved by the FDA for anything other than bipolar mania and schizophrenia?

THE WITNESS: During my time?

MR. ALLEN: Yes, sir.

A. Okay. So we're still on my time.

Besides the combination therapy, no, it wasn't.

Start (Page:Line)	End (Page:Line)
420:14	420:21
445:24	446:8
446:12	446:13
446:17	446:24
448:21	449:4
449:16	449:24
450:1	450:7
453:18	454:6
504:13	504:15
504:18	504:21
514:22	515:1
515:6	515:12
522:14	523:2

include

include

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial Deposition Designations for Michael Bandick:

Start (Page:Line)	End (Page:Line)	Objection
130:18	131:6	Vague (Alaska R. Evid. 611)
164:20	165:8	Relevance; Probative value outweighed by danger of unfair prejudice; Compound; Motion for Summary Judgment – Off-label (Alaska R. Evid. 401, 402, 403)
169:1	169:7	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label (Alaska R. Evid. 401, 402, 403)

overruled

sustained

sustained

Start (Page:Line)	End (Page:Line)	Objection	
201:24 202:14	202:11 202:14	Foundation; Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 602, 701)	overrul
373:7	374:4	Hearsay – Admit for Notice (Alaska R. Evid. 802)	admit-notice
376:23	377:9	Hearsay – Admit for Notice (Alaska R. Evid. 802)	
378:4	378:19	Hearsay – Admit for Notice (Alaska R. Evid. 802)	
379:14	380:5	Hearsay – Admit for Notice (Alaska R. Evid. 802)	
398:16	399:5	Hearsay – Admit for Notice (Alaska R. Evid. 802)	
408:8	409:3	Hearsay – Admit for Notice (Alaska R. Evid. 802)	
411:8	412:2	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Foreign Regulatory Actions; (Alaska R. Evid. 401, 402, 403)	overrule
415:14	416:13	Hearsay – Admit for Notice; Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Foreign Regulatory Actions (Alaska R. Evid. 401, 402, 403, 802)	overrule
418:21	419:17	Hearsay – Admit for Notice; Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Foreign Regulatory Actions; (Alaska R. Evid. 401, 402, 403, 802)	overrule
419:18	419:22	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Foreign Regulatory Actions (Alaska R. Evid. 401, 402, 403)	overrule
421:17	422:1	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Foreign Regulatory Actions (Alaska R. Evid. 401, 402, 403)	overrule
435:2	435:4	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Motion in Limine – Foreign Regulatory Actions (Alaska R. Evid. 401, 402, 403, 602, 701)	overrule

Start (Page:Line)	End (Page:Line)	Objection	
435:10	435:10	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Motion in Limine – Foreign Regulatory Actions (Alaska R. Evid. 401, 402, 403, 602, 701)	Overrul
435:15	435:16	Commentary by Counsel; Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 611)	Overrul
435:17	435:18	Relevance; Probative value outweighed by unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Overrule
436:15	435:17	Relevance; Probative value outweighed by unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Overrule
438:23	439:5	Relevance; Probative value outweighed by unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Overrule
443:12	444:4	Relevance; Probative value outweighed by unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Overrul
450:22	451:4	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Foreign Regulatory Actions (Alaska R. Evid. 401, 402, 403)	Overrul
451:7	451:10	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Foreign Regulatory Actions (Alaska R. Evid. 401, 402, 403)	Overrul
451:13	451:15	Relevance; Probative value outweighed by danger of unfair prejudice; Motion in Limine – Foreign Regulatory Actions (Alaska R. Evid. 401, 402, 403)	Overrule
452:21	452:22	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
452:23	453:8	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
453:9	453:14	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain

Start (Page:Line)	End (Page:Line)	Objection	
457:24	458:7	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
461:17	462:1	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
462:3	462:19	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
462:20	462:23	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
463:12	463:16	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
464:6	464:16	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
470:10	471:16	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
472:10	472:23	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
476:5	476:15	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Sustain
478:8	478:19	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Sustain
479:2	479:5	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain

Start (Page:Line)	End (Page:Line)	Objection	
479:24	480:6	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing; Motion in Limine – profit/net worth/price (Alaska R. Evid. 401, 402, 403)	Sustain
480:9	481:1	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing; Motion in Limine – profit/net worth/price (Alaska R. Evid. 401, 402, 403)	Sustain
489:3	489:14	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
491:10	491:19	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
491:24	492:11	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
493:3	493:12	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Sustain
496:9	497:3	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	Sustain
499:14	499:18	Foundation; Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 602, 701)	Sustain
504:6	504:12	Foundation; Hearsay – Admit for Notice (Alaska R. Evid. 602, 701, 802)	Overrule
506:1	506:12	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Overrule
510:11	510:18	Relevance; Probative value outweighed by danger of unfair prejudice; Misstates Evidence (Alaska R. Evid. 401, 402, 403, 611)	Overrule

Start (Page:Line)	End (Page:Line)	Objection	
511:3	511:11	Relevance; Probative value outweighed by danger of unfair prejudice; Assumes facts not in evidence (Alaska R. Evid. 401, 402, 403, 611)	overrul
516:2	516:	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	susta
516:6	516:9	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label marketing (Alaska R. Evid. 401, 402, 403)	susta
516:24	517:13	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label (Alaska R. Evid. 401, 402, 403)	susta
519:17	519:19	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label (Alaska R. Evid. 401, 402, 403)	susta
521:13	521:15	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label (Alaska R. Evid. 401, 402, 403)	susta
521:21	522:9	Relevance; Probative value outweighed by danger of unfair prejudice; Motion for Summary Judgment – Off-label (Alaska R. Evid. 401, 402, 403)	susta

Lilly also objects to Plaintiff's exhibits for use during the testimony of Michael Bandick:

Plaintiff's Exhibit	Objection(s)	
Zyprexa MDL Plaintiffs' Exhibit No 01926 (Bandick Exh. 17)	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)	overuld

...iff's Exhibit	Objection(s)
...yprexa MDL Plaintiffs' Exhibit No 09807 (Bandick Exh. 18)	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing upcoming programs related to Zyprexa's efficacy Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document
Zyprexa MDL Plaintiffs' Exhibit No 04104 (Bandick Exh. 19)	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

Not included with Motion

Overruled

Lilly reserves the right to object to these exhibits, and any others that may be introduced by Plaintiff, under the Alaska Rules of Evidence or any other applicable rule of law, based on this Court's rulings or the purposes for which Plaintiff seeks to use the exhibits at trial.

Respectfully submitted,

LANE POWELL, PC

By:_____

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Attorneys for Defendant
Eli Lilly and Company

Dated: March 8, 2008

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

JUDGES RULING

Mark Rindner

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

CHARLES BEASLEY

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for Charles Beasley (July 26, 2006):

√= Lilly include in cross or own ca

Start	End	
58:22	59:1	✓
81:16	81:18	✓
81:20	81:24	✓
82:1	82:10	✓
83:2	83:8	include for completeness
111:14	111:24	✓
112:8	114:24	✓
142:24	143:7	✓

Start	End	
143:21	143:23	✓
144:1	144:12	✓
148:5	148:18	✓
149:20	149:24	✓ include
150:18	151:10	✓ include
157:11	158:7	✓
184:23	185:15	✓ include
186:24	187:4	✓
187:6	187:10	✓
202:17	203:9	✓ include
208:20	209:10	✓
210:2	210:11	✓
210:16	211:13	✓
218:9	218:11	✓ include
243:24	243:24	✓ include
248:5	248:10	✓ include
253:8 253:15	253:13 253:16	✓ include
256:17	257:5	✓ include
260:20	263:13	already in PI designation.
272:18	272:22	✓
272:24	273:8	✓
296:11	297:8	✓

Start	End
298:8	298:20
301:23	302:4
391:3	391:7
391:10	391:18

already in Pl designations
✓ include

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial Deposition Designations for Charles Beasley (July 26, 2006):

Start	End	Objection	
78:17	79:6	Hearsay (Alaska R. Evid. 802)	overruled
80:22	81:12	Foundation; (Alaska R. Evid. 602, 701)	overruled
84:9	85:1	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled
95:23	96:12	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled
111:2	111:13	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled
135:15	136:2	Foundation; Ambiguous (Alaska R. Evid. 403, 602, 611, 701)	overruled
142:3	142:15	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled
147:19	148:4	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled
149:12	149:19	Foundation; Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 602, 701)	overruled
150:7	150:17	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled

161:18	162:1	Foundation (Alaska R. Evid. 602, 701)	overruled
162:22	163:11	Foundation (Alaska R. Evid. 602, 701)	overruled
186:16	186:23	Ambiguous; Misstates the evidence (Alaska R. Evid. 403, 602, 611)	overruled
191:8	191:17	Ambiguous; Misstates the evidence (Alaska R. Evid. 403, 611)	overruled
193:21	194:3	Motion in limine – foreign regulatory agencies (Alaska R. Evid. 401, 402, 403)	overruled
194:12	194:18	Motion in limine – foreign regulatory agencies; Foundation (Alaska R. Evid. 401, 402, 403, 602, 701)	overruled
194:19	195:4	Motion in limine – foreign regulatory agencies; Foundation (Alaska R. Evid. 401, 402, 403, 602, 701)	overruled
195:5	195:13	Motion in limine – foreign regulatory agencies; Foundation (Alaska R. Evid. 401, 402, 403, 602, 701)	overruled
195:14	195:18	Motion in limine – foreign regulatory agencies; Foundation (Alaska R. Evid. 401, 402, 403, 602, 701)	overruled
195:19	196:1	Motion in limine – foreign regulatory agencies (Alaska R. Evid. 401, 402, 403)	overruled
196:2	196:5	Motion in limine – foreign regulatory agencies; Authentication (Alaska R. Evid. 401, 402, 403, 901)	overruled
196:6	196:15	Motion in limine – foreign regulatory agencies (Alaska R. Evid. 401, 402, 403)	overruled
223:15	223:20	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled
223:21	223:23	Foundation; Misstates the evidence; Asked and answered (Alaska R. Evid. 602, 611, 701)	overruled
223:24	224:4	Foundation (Alaska R. Evid. 602, 701)	overruled
232:6	232:20	Hearsay (Alaska R. Evid. 802)	overruled
233:17:	233:23	Hearsay (Alaska R. Evid. 802)	overruled

	End	Objection	
247:7	247:17	Misstates the evidence; Argumentative (Alaska R. Evid. 611)	overruled
252:22	253:6	Compound; Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled - but no answer to question stands at 252:22
254:13	254:21	Asked and answered (Alaska R. Evid. 611)	overruled
259:3	259:22	Argumentative; Compound; Misstates the evidence (Alaska R. Evid. 611)	overruled
259:23	260:10	Foundation (Alaska R. Evid. 602, 701)	overruled
262:22	263:6	Foundation (Alaska R. Evid. 602, 701)	overruled
263:7	263:12	Foundation (Alaska R. Evid. 602, 701)	overruled
263:24	264:5	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overruled
267:23	268:2	Asked and answered (Alaska R. Evid. 611)	overruled
270:1	270:8	Asked and answered (Alaska R. Evid. 611)	overruled
270:22	271:3	Hearsay (Alaska R. Evid. 802)	overruled
271:4	271:10	Hearsay (Alaska R. Evid. 802)	overruled
271:11	271:19	Hearsay (Alaska R. Evid. 802)	overruled
271:20	272:7	Hearsay; Foundation; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 602, 701, 802)	overruled
272:8	272:13	Foundation; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 602, 701)	overruled
272:14	272:17	Foundation; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 602, 701)	overruled
277:1	277:18	Hearsay (Alaska R. Evid. 802)	overruled
283:19	284:16	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)	overruled
285:5	285:11	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)	overruled

	End	Objection	
285:12	285:24	Hearsay (Alaska R. Evid. 802)	overd
286:15	287:1	Foundation (Alaska R. Evid. 602, 701)	overrld
287:10	288:1	Hearsay; Foundation (Alaska R. Evid. 602, 701, 802)	overrul
288:6	288:13	Hearsay; Foundation (Alaska R. Evid. 602, 701, 802)	overrul
288:14	288:21	Hearsay; Foundation (Alaska R. Evid. 602, 701, 802))	overrld
293:6	294:8	Hearsay (Alaska R. Evid. 802)	overruled
295:10	295:22	Foundation (Alaska R. Evid. 602, 701)	overrul
296:3	296:10	Foundation (Alaska R. Evid. 602, 701)	overrul
297:14	297:20	Hearsay; Foundation (Alaska R. Evid. 602, 701, 802)	overrul
297:21	298:7	Foundation (Alaska R. Evid. 602, 701)	overrul
304:21	305:8	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)	overrl
305:9	305:11	Hearsay; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 403, 602, 701, 802)	overrul
305:12	306:1	Hearsay; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 403, 602, 701, 802)	overrul
306:19	307:3	Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403)	overrul
307:4	307:21	Probative value outweighed by danger of unfair prejudice; Argumentative (Alaska R. Evid. 403, 611)	overrul
310:1	310:15	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)	overrul
310:16	310:19	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)	overrul
310:20	311:5	Hearsay; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 403, 802)	overrul

		Objection	
	311:19	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overruled
317:20	318:9	Hearsay (Alaska R. Evid. 802)	overruled
345:22	346:8	Compound; Misstates the evidence (Alaska R. Evid. 611)	overruled
346:18	347:5	Compound (Alaska R. Evid. 611)	overruled
347:6	347:14	Compound (Alaska R. Evid. 611)	overruled
347:15	347:18	Compound; Ambiguous; Comment by counsel (Alaska R. Evid. 403, 611)	overruled
347:19	347:23	Compound; Ambiguous (Alaska R. Evid. 403, 611)	overruled
347:24	348:13	Compound; Ambiguous; Comment by counsel (Alaska R. Evid. 403, 611)	overruled
386:4	386:16	Hearsay (Alaska R. Evid. 802)	overruled
386:17	386:22	Hearsay; Argumentative (Alaska R. Evid. 611, 802)	overruled
390:9	390:20	Hearsay; Compound; Misstates the evidence; Asked and answered (Alaska R. Evid. 611, 802)	overruled
390:21	391:2	Hearsay; Compound; Misstates the evidence; Asked and answered (Alaska R. Evid. 611, 802)	overruled
391:19	392:1	Hearsay; Asked and answered (Alaska R. Evid. 611, 802)	overruled
393:17	393:19	Hearsay; Asked and answered (Alaska R. Evid. 611, 802)	overruled
393:20	394:1	Hearsay; Asked and answered (Alaska R. Evid. 611, 802)	overruled
394:2	394:8	Foundation (Alaska R. Evid. 602, 701)	overruled
394:12	394:17	Hearsay; Asked and answered (Alaska R. Evid. 611, 802)	overruled
394:18	395:10	Compound; Misstates the evidence (Alaska R. Evid. 611)	overruled
395:11	395:18	Asked and answered (Alaska R. Evid. 611)	overruled

... hereby objects to Plaintiff's exhibits

for use during the designated deposition testimony of Charles Beasley (July 26, 2006):

Plaintiff's Exhibit	Objection(s)
Zyprexa MDL Plaintiffs' Exhibit N. 988	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 1345	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 6890	Not relevant to labeling claims (Alaska R. Evid. 401, 402). Prejudicial, confusing, waste of time (Alaska R. Evid 403). Lay witness opinion (Alaska R. Evid. 701).
Zyprexa MDL Plaintiffs' Exhibit No. 8042	No foundation as to page 3 (Alaska R. Evid. 901).
Zyprexa MDL Plaintiffs' Exhibit No. 4858	Subject to motion in limine regarding adverse events (hearsay – notice).
Zyprexa MDL Plaintiffs' Exhibit No. 195	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 6998	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 1449	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 1453	Hearsay – any purpose except to show notice.
Zyprexa MDL Plaintiffs' Exhibit No. 6128	Admitted except for portion discussing OUS marketing efforts. Object as not relevant to labeling claims (Alaska R. Evid. 401, 402).
Zyprexa Plaintiff's Exhibit No. 10004; Beasley Dep. Exh. 1.	Not relevant to Phase I (Alaska R. Evid. 401), Hearsay, Foundation, Unfairly prejudicial.

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Page 3
overruled
prev. admitted
allowed for notice
allowed for notice
prev. admitted
will admit
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object to OUS effort
overruled

Lilly reserves the right to object to these exhibits, and any others that may be introduced by Plaintiff, under the Alaska Rules of Evidence or any other applicable rule of law, based on this Court's rulings or the purposes for which Plaintiff seeks to use the exhibits at trial.

Respectfully submitted,

Dated: March 8, 2008

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By:_____

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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.	)	

DEFENDANT ELI LILLY AND COMPANY'S MOTION FOR RECONSIDERATION OF RULINGS ON OBJECTIONS TO AFFIRMATIVE DEPOSITION DESIGNATIONS OF JOHN LECHLEITER AND DENICE TORRES

Defendant Eli Lilly and Company ("Lilly") respectfully requests that the Court reconsider its rulings regarding the admissibility of the following excerpts from the depositions of John Lechleiter and Denice Torres. Each of these designations by the State reflect its allegations that Lilly engaged in off-label promotion—allegations which the Court has deemed irrelevant to, and beyond the scope of, any claim that State asserts. Consistent with the Court's rulings regarding other designated testimony in these same depositions, Lilly's objections set forth below should be sustained. Relevant pages of the transcripts are attached.

1. John Lechleiter, Ph.D. (TAB A)

The Court sustained Lilly's objection to testimony at 360:3 to 360:6, in which the State, as a prelude to discussing Exhibit 29 (Plaintiff's Exhibit 10041), asked, "Dr. Lechleiter, you went out to try to promote Zyprexa off label yourself, did you not?" and Dr. Lechleiter responded, "No, I did not." Despite sustaining Lilly's objection, the

Court overruled Lilly's later objections to specific testimony regarding Exhibit 29, the very testimony elicited by the State in support of its premise. These rulings are also contrary to those made on objections to testimony designated from the deposition of Ms. Torres. In those rulings, the Court *sustained* Lilly's objections to testimony concerning the very same document (identified as Plaintiff's Exhibit 10068). The following segments of testimony address Lechleiter Exhibit 29, which has no relevance to this case in light of the exclusion of the off-label issue:

Start (Page:Line)	End (Page:Line)	Objection
361:4	361:20	Relevance (testimony concerns off-label issue).
363:3	363:16	Relevance (testimony concerns off-label issue).
363:19	364:2	Relevance (testimony concerns off-label issue).
364:3	365:23	Relevance (testimony concerns off-label issue).
366:7	367:11	Relevance (testimony concerns off-label issue).

will sustain

2. Denice Torres (TAB B)

The Court's sustained Lilly's objections to several of the State's designations of the testimony of Ms. Torres because they concern the off-label issue. Nevertheless, the Court overruled Lilly's objections to the following similar segments of testimony, each of which specifically concerns indications, and which have no probative value in a case from which off-label issues have been excised:

Start (Page:Line)	End (Page:Line)	Objection
150:8	150:11	Relevance (testimony concerns off-label issue).

ND

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document has been served via email upon counsel listed below, and by hand delivery and email upon Mary Beth Rivers, Room 532, Tower Two, Captain Cook Hotel.

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Date: March 8, 2008

THIRD JUDICIAL DISTRICT

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

JUDGES RULING

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

Defendant Eli Lilly and Company ("Lilly") counter-designates for trial the following deposition transcript excerpts in response to Plaintiff State of Alaska's Trial Deposition Designations for Robin Pitts Wojcieszek.

include all in Single playing. per Evidence Rule 611(a)(1)(2)

Start (Page:Line)	End (Page:Line)	
17:2	17:22	~~include~~ OK *
23:9	23:15	~~include~~ OK *
23:21	24:1	OK *
27:25	28:12	OK
83:14	83:19	OK include *
95:2	95:17	OK
98:9	98:18	OK

Lilly objects to the following pages and lines of Plaintiff State of Alaska's Trial Deposition Designations for Robin Pitts Wojcieszek:

...iff's Exhibit ...0108	Relevance; probative value is outweighed by prejudice, delay and confusion, subsequent remedial measures, hearsay (Alaska R. Evid. 401, 402, 403, 407, 801, 802). Subject to Motion in Limine re: recent regulatory events.	Overruled
Zyprexa Plaintiff's Exhibit No. 10109	Relevance; probative value is outweighed by prejudice, delay and confusion, subsequent remedial measures, hearsay (Alaska R. Evid. 401, 402, 403, 407, 801, 802). Subject to Motion in Limine re: recent regulatory events.	overruled
Zyprexa Plaintiff's Exhibit No. 10110	Relevance; probative value is outweighed by prejudice, delay and confusion, subsequent remedial measures, hearsay (Alaska R. Evid. 401, 402, 403, 407, 801, 802). Subject to Motion in Limine re: recent regulatory events.	overruled

Lilly reserves the right to object to these exhibits, and any others that may be introduced by Plaintiff, under the Alaska Rules of Evidence or any other applicable rule of law, based on this Court's rulings or the purposes for which Plaintiff seeks to use the exhibits at trial.

Respectfully submitted,

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Attorneys for Defendant Eli Lilly and Company

Dated: March 8, 2008

424:9	424:16

Not disputed

2. John Lechleiter, Ph. D.

Start (Page:Line)	End (Page:Line)	
120:14	121:7	Not disputed
122:2	122:18	Include
149:3	149:12	Not include - can be played by Lilly
267:12	268:11	not included Lilly can play
277:9	277:17	Not disputed
300:11	300:21	not include - Lilly can play

Was non responsive →

Was non responsive →

3/28/08

Mark Rush

Page 120, Lines 22-25
Page 121, Lines 9-15
Page 121, Line 18 through Page 122, Line 5
Page 122, Lines 19-21
Page 123, Lines 3-7
Page 123, Lines 15-18
Page 124, Line 25 through Page 125, Line 12
Page 126, Lines 7-20
Page 127, Lines 11-16
Page 133, Lines 7-13
Page 134, Lines 7-11
Page 146, Lines 14-19
Page 157, Lines 8-11

(See Attachment A)

As reflected above, and as reflected in Lilly's cross-examination of Dr. Brancati, Lilly is relying heavily in this trial on the fact that Zyprexa was prescribed to "23 million patients" in "80 countries" and has affirmatively told the jurors that Zyprexa has saved people "with serious mental illness" and "schizophrenia" and "bipolar disorder" from all matters of "hell that most people cannot imagine" including being "robbed of their dignity," "lobotomies," "electric shock treatment," and "[freedom from] hospitals and prisons." They go on to state that "schizophrenic and bipolar patients are at risk of diabetes regardless of what medication they use." There is only one problem with this argument --- it ignores and misstates the truth in order to gain tactical and improper advantage on the issue of "risk/benefit analysis."

For example, in the sworn deposition testimony of Denice Torres (Lilly's Head of Global Marketing), she has testified that 30-40% of Zyprexa's use in the U.S. was "off-label" (Deposition at Page 136, Lines 6-15; See Attachment B). Assuming ½ of the alleged 23 million patients worldwide were from the U.S. and 40% of those were "off-label," then approximately 4.6 million prescriptions of Zyprexa in the U.S. were for conditions other than schizophrenia and bipolar mania. This is further bolstered by the fact that approximately 38% of Alaska's Medicaid prescription payments were for non-schizophrenic and non-bipolar manic uses. (Evidence to be provided by trial testimony of David Campana, Medicaid Pharmacy Program Manager, State of Alaska, Department of Health and Social Services, Division of Health Care Services.) Thus, it is a complete distortion to suggest that Zyprexa is saving people from "prison," "hospitals," "lobotomies," "electric shock," and "suicide," etc….when in fact Lilly knows that such is not even remotely true. See e.g. Exhibit #8479 (Attachment C) where Lilly instituted a "Primary Care Strategy" that specifically stated "Zyprexa's primary indications – schizophrenia and bipolar – are not viewed as PCP-treated conditions, so there's not a specific indication for Lilly's reps to promote in the PCP segment."

Therefore, to suggest that when doctors "weigh the risks against the benefits" (Opening at Page 118, Line 20; Page 127, Lines 11-16; See Attachment A) when

er of the brain" (Page 122, Lines 20-21; See Attachment A)
s medicine for a serious disease" (Page 133, Line 8; See Attachment
complete misrepresentation to the jury about both: (a) the true risk vs. benefit equation needed for some 4.6 million Americans, excluding schizophrenia and bipolar mania and (b) the true risk vs. benefit equation for 38% of Alaskans who were prescribed Zyprexa.

Additionally, counsel for Lilly engaged in error or extreme inadvertence in opening when she continually referred to Zyprexa's use/approval in "bipolar disorder" (consisting of both mania/depression) when in fact Zyprexa has no such approval whatsoever. Counsel's reference can be found many times at the following locations:

Page 117, Lines 8-11
Page 124, Lines 16-17
Page 124, Line 25 through Page 125, Line 5
Page 125, Lines 6-18
Page 126, Lines 7-10
Page 126, Line 22 through Page 127, Line 5
(See Attachment A)

Counsel for the State is confident that he could locate deposition references to this fact (he is busy preparing for other witnesses) but is also confident that if the court questions Lilly counsel they will candidly admit there is no "bipolar disorder" indication for Zyprexa. Counsel for the State objected to such "bipolar disorder" reference during the Opening and was told by your Honor "you can point that out down the road."

Further, counsel for Lilly went so far as to tell the jury that "...when Lilly received approval from FDA in 2000 for Zyprexa to be used in bipolar disorder, that's why it started to move into calling upon primary care physicians." The facts are to the contrary, e.g. Exhibit #8479 (See Attachment C) and #5846 (See Attachment D), which specifically state that the PCP launch was for "mood, thought and behavioral disorders" which was "intentionally vague" in order to provide "latitude" to "frame the discussion around symptoms and behavior rather than specific indications." This was part of the "3x3" strategy of VIVA Zyprexa, the first "3" being "mood, thought and behavior."

The Court said the State could "point this out down the road" and the State respectfully requests that now is the time. All of the evidence currently barred by the Court is relavant and needed to:

(a) Rebut Lilly's "risk/benefit analysis";

(b) Rebut Lilly's defense of saving people from "hell," "prisons," "hospitals," "lobotomies," "electric shock," and "suicide;"

(c) Rebut Lilly's inference that 23 million prescriptions have been for schizophrenia and "bipolar disorder;"

because the judge told me to wrap it up. These were experts from American College of Endocrinology, the American Psychiatric Association, the North American Association of Obesity and they determine, looky here, look whose drug carries the greatest risk, Clozapine and olanzapine. Remember the drugs that are similar that they knew were similar. Three pluses, they had the risk for diabetes. All the other ones in the class, all the other ones, no.

Zyprexa -- and when do they knew this, they knew it in January, 2004 before they ever notified the doctors in a March letter.

Ladies and gentlemen, facts on the table. They bet the farm. They were worried about money. They denied and never put a warning on the label. When they finally did in 2003, they were made to do so, but it was still not sufficient, because they still didn't tell all they knew. You saw that the first, your Attorney General was right, the FDA told them it's right. All the evidence is in. These people didn't warn. They chose to bet the farm, ladies and gentlemen. Chose to bet the farm. It's time to call their bet.

Thank you very much.

THE COURT: Ladies and gentlemen of the jury, we're going to take a 15-minute break while we reorganize the courtroom and have Lilly's opening statement. Again, we'll go a little bit late so we can finish these opening statements today and get right to the evidence tomorrow. And so I'd ask you now to return to the jury room again. Please don't discuss this case among yourselves or let anyone discuss it with you. We'll be in recess for about 15 minutes.

THE CLERK: Rise. The Superior Court now stands in recess.

Off record.

(Break.)

THE COURT: Please be seated.

We're back on record. All members of the jury panel are present.

Ms. Gussack.

MS. GUSSACK: Thank you, Your Honor.

Can you imagine how hard it is to sit waiting for your chance to get up and speak after a long presentation like Mr. Allen's? I

wanted to jump up, but I have to wait my turn and now you can appreciate why we took such care to pick a jury that could commit to doing exactly what Judge Rindner said, which is to keep an open mind until all of the evidence is in. And, of course, these opening statements are not evidence; you've heard that. We have a ways to go to put that evidence in.

But we appreciate that you made that commitment to keep an open mind and listen to the evidence. There is going to be some very important evidence coming from Eli Lilly and Company, its employees, its expert witnesses and we're looking forward to bringing it to you. Never, in all the time that I thought about coming to try a case in Anchorage, did I think I would feel warm in Anchorage. And here I am feeling warm because I'm ready to go. And I want to really express my appreciation for your time and for your attention.

Let me do a little bit of background, again, since it's been a while since we got a chance to speak. My name is Nina Gussack, and I am proud to be here on behalf of my client, Eli Lilly and Company. And my trial

team partners who are sitting over here, George Lehner, John Brenner, Andy Kantra and Brewster Jamieson are going to be working right alongside of me as we try this case and in fact, George will join me in making these opening comments to you this afternoon.

I want to talk with you this afternoon about Zyprexa, a prescription medicine made by Lilly for serious mental illnesses that you've heard described already, schizophrenia and bipolar disorder. This is no lifestyle drug. This is not about allergies. This isn't about erectile dysfunction. This is about serious mental illness.

When the Food & Drug Administration approved this medicine in 1996, doctors understood it was a breakthrough medicine, something that could help restore meaningful life to patients who were robbed of their dignity and their lives by their serious mental illness. Were there other medicines available before Zyprexa was brought to the market in 1996?

Yes. But those medicines had side effects that made patients unwilling to stay on them. And you're going to hear about some of

...ose side effects including tardive dyskinesia and very jerky physical movement.

Here's one thing you need to understand: No medicine can help people with serious mental illness unless they're going to take it, right? You have to take your medication to benefit from it. And Zyprexa was a breakthrough medicine for a lot of reasons, but not the least of which was that it had a better side effect profile on the kind of side effects that made it very difficult for patients to stay on.

But let's get something straight right now. It's a prescription medicine. There is no prescription medicine that doesn't have side effects. Every prescription medicine has side effects.

So what it is that our physicians are doing when they prescribe medicines for us? They are weighing the risks against the benefits. There is no one medication that is perfect for everybody, and there is no medication that doesn't have risks. But our physicians are making that hard choice every day to try to make sure that the prescription they're making is the

best one for us. And we're going to talk about that and this case is going to involve a lot of information about how doctors make those choices.

How important is Zyprexa as a medicine? You do not have to listen to me. You don't have to listen to Eli Lilly and Company about that. You have to listen to the State's expert witness, Dr. Wirshing, who Mr. Allen mentioned to you. The expert psychiatrist for the State of Alaska has said: The second-generation antipsychotics, including Zyprexa, are among the most powerful disease modifiers in all of medicine. They are a Godsend to most people. A Godsend.

And if you have a family member, you know someone or you know anything about serious mental illness, you can appreciate that the -- the class of medications that we're talking about, these atypical antipsychotics are what we call the second-generation of them, because there was an older group. And Zyprexa belongs to the more current group, are a Godsend.

I want to show you what Dr. Wirshing said when he testified before this trial, and he's going to come to trial.

Video: "They're the closest thing to magic that I have ever experienced in my professional life."

MS. GUSSACK: They're the closest thing to magic that I've experienced in my professional life. From Dr. Wirshing, the State of Alaska's psychiatrist who has made his career treating schizophrenic patients at the VA Hospital in California.

Before there were medications like Zyprexa to treat schizophrenia, and these -- and bipolar disorder, you know what treatment consisted of? Lobotomies, imprisoning people, electric shock treatment.

In the 1950s scientists discovered what we call the first generation of antipsychotics, and you saw them on the easel before, including Haldol, and you're going to hear a little bit more about Haldol. These medications were valuable because they were helpful, but they were not -- but the next generation of medications has proven. And these atypical antipsychotics, the second generation were a great leap forward in the treatment of these very serious diseases.

Scientists have been searching for more effective medications for serious mental illness for years. And over 20 years ago, 20 years ago, two Lilly scientists discovered a molecule and researched it and developed it, and the company invested in it, and in -- all in the hopes that it would make a difference in the lives of millions of people. That molecule is the medicine Zyprexa. That medicine has been prescribed to 23 million people since it was brought to market.

It is approved for use in over 80 countries. It is approved by the FDA in the U.S. It is used every day by the physicians who prescribe for patients in Alaska.

Why does Dr. Wirshing say they're the closest thing to magic that he's ever experienced in his professional life? Because he knows, as all physicians who treat these diseases know, there is no cure for schizophrenia. There is no cure for bipolar disorder. But we are searching every day to give people back a quality of life that will allow them to be with their families, to not be in hospitals, to not be in prisons, to have a quality of a life that allows

primary-care physicians or nurse practitioners, and we are lucky because every time a physician who is trained and educated to identify serious mental illness does and then treats it, people are on the road to reintegrating the quality of their life with what they are capable of.

That is why when Lilly received approval from FDA in 2000 for Zyprexa to be used in bipolar disorder, that's why it started to move into calling upon primary care physicians.

MR. ALLEN: Your Honor, could we approach?

THE COURT: Please.

(Bench discussion.)

MR. ALLEN: There's no -- evidence. It's not approved for bipolar disorder. It's approved for bipolar I disorder. It's a major difference.

THE COURT: This is opening statement. You can point that out down the road.

(End bench discussion.)

MS. GUSSACK: Patients with bipolar disorder need help, and we want to make sure they get help wherever they can. That may be a primary care office; that may be a primary care

office; that may be in a nurse practitioner who can prescribe's office. We want to make sure that physicians and nurse practitioners have the information that they need to make those kind of diagnoses and make good prescribing decisions.

Physicians like Dr. Kahn, as well as the physicians in the State of Alaska, trust Zyprexa to help their patients who suffer from these diseases. That's why Lilly is proud to say we make Zyprexa. It is affecting the quality of life for countless patients. What doctors do every time they write a prescription, whether for an antibiotic, a cancer medication or for Zyprexa, is to balance the risks against the benefits. That's what doctors do. That's what you're going to hear about.

There is no question that this medicine is effective. As I said, not for everybody. And you're going to hear that and, of course, sometimes you have to take one or two medications until you find the one that works. It is not always so simple to say, you have this problem, therefore, you take this medication. You will hear about that.

The State has said that -- that

Lilly's label for Zyprexa was misleading or deceptive. But let's be clear, they are not saying that this medicine doesn't work.

Instead, they want you to believe that the label failed to warn doctors about the risks of Zyprexa even though Lilly's label for Zyprexa has been reviewed, approved, revised, amended, approved again by FDA on numerous occasions as more and more scientific information became available.

So in 1996 the medicine was first approved to treat patients. It received the approval again after Lilly submitted more information to FDA for bipolar mania four years later in 2000. It -- Lilly submitted more data later and asked for approval to market it for the maintenance of schizophrenia relief and received approval again. Lilly submitted data to FDA. All of the information it had about how effective Zyprexa was about used with other medications for bipolar disorder. And FDA approved it again in July, 2003. And then, again, in January, 2004.

And each time FDA made the decision that it was approved for these new uses, FDA looked at all of the information that Lilly

submitted and said, yes, we believe it is safe and effective for those medications. Not guaranteed safe. Safe and effective for the medications as described in the label.

And let's be clear, as we're talking about the label, we're not talking about the label on the bottle that you get from the pharmacy. We're not talking about that little piece there. We're not talking about the summary sheet that your family physician may give you. We're talking about that detailed small-print, lengthy requirement that FDA requires every manufacturer to use to develop, reporting all of the information about its medicine that has to accompany that medicine when it is provided to the pharmacy or to the physician.

But we know that doctors aren't taking out their magnifying glass to look at each section of this label. Where do these labels appear? In lots of places. In the Physicians' Desk Reference that you saw before, on web sites, in their handheld computers that they can type in the name of the medicine and find it. But each portion of this label is regulated by FDA. The size of the print is regulated by FDA. The

sections of the label and warnings is one section, adverse reactions is another, precautions is another, clinical pharmacology is another. Each of those sections are requirements that FDA has, and only when you have satisfied FDA's requirements for where the information goes and what you say are you allowed to market your medicine. That's what Lilly did starting in 1996 with Zyprexa.

I want you to think about for a minute what the State is asking you to do. The State wants you to believe that Lilly has fooled doctors in Alaska; doctors who are trained in the practice of medicine, doctors who use their best judgment every day to treat serious illness; doctors whose own patients tell them this medicine works. The State wants you to believe that for the past 11 years Lilly has pulled the wool over the eyes of physicians in the State of Alaska.

And the question you should be asking yourself is: What physician is the State of Alaska bringing to this courtroom to tell us how the State got bamboozled? Because I didn't hear anything about anybody coming from the

physician, no psychiatrist coming from the State to tell you how they were fooled by Lilly's label, about how it was misleading.

That's because the State is not bringing any doctors from Alaska to court to tell you that they were misled, that the label's inadequate or that they were tricked into prescribing Zyprexa.

Lilly is going to bring you the doctor from Alaska. In fact, you might think of him as the head doctor for Alaska, Dr. Duane Hopson, because Dr. Hopson is a psychiatrist. He is the president of the Alaska Psychiatric Association. He is also the medical director of the Alaska Psychiatric Institute, the only state-run psychiatric hospital in Anchorage, and he is an employee of the State of Alaska. And Lilly will bring Dr. Hopson to court.

You might think that the State would have brought him as a witness in their case, but they won't and we will.

And Dr. Hopson will tell you that he and others on his staff use Zyprexa regularly to treat patients at the Alaska Psychiatric Institute, and he will tell you that he has and

continues to prescribe Zyprexa to patients right here in Alaska.

He's also going to tell you that Alaska has no restrictions, no restraints on the use of Zyprexa. Two years this lawsuit has been pending and for two years the State has not imposed any restriction, any restraint, any limit on the use of Zyprexa. Does that sound like somebody who has been bamboozled? If they had a complaint two years ago, you need to be asking yourself, I think, well, why haven't they done something?

MR. ALLEN: Your Honor -- I object. It's argumentative. We're right here filing a lawsuit.

THE COURT: Again, these are statements of counsel. You'll hear evidence about things and you're going to determine facts based on the evidence. This is argument of Counsel. It's entirely proper.

MR. ALLEN: Okay, Your Honor. I just wanted you to know we filed a lawsuit.

MS. GUSSACK: You're going to hear from Dr. Hopson when he comes to court that he considers and evaluates each patient on an

individual basis just like Dr. Kahn's going to talk to you. And that the doctors on the staff of the Alaska Psychiatric Institute, State of Alaska employees in many cases, turn to Zyprexa in many cases after considering all the risks and benefits of the medicine.

You're also going to learn, because it's a serious medicine for serious disease, it's not advertised on television. You will not find it in magazines at the supermarket. It's not on the radio. It is a medicine that is prescribed by physicians and Lilly communicates its information about Zyprexa to physicians. Like I said before, Lilly cannot sell this medicine until the FDA has evaluated and studied it to determine whether the risks and benefits are appropriate and when they have approved the label for the medicine.

You will also hear, not just from Dr. Hopson, that people who work for the State of Alaska have not limited or restricted the use of Zyprexa. Not in State hospitals, not by doctors employed by the State, not by Medicaid patients, even though the State has the power and authority if they wanted to. You will hear that lawyers in

the office of the State Attorney General where Mr. Sniffen and his counsel have authority go to court on occasion and ask judges to order that certain psychiatric patients be administered medications, including Zyprexa, when the patient won't willingly take the medication themselves. The State comes and asks the judge to administer Zyprexa to patients when the patient won't take it themselves in certain circumstances.

That's how valuable the State thinks this medicine is. And why does the State do this? Because the medicine works. And two years ago when Alaska filed this lawsuit saying the label was deceptive or misleading, you might have thought something would have changed, but it hasn't. The State of Alaska's doctors continue to prescribe Zyprexa, and the State has done nothing to discourage it.

Why are we so sure that doctors haven't been misled? Because the label and all of the information that Lilly shares with physicians tells them about the side effects and the risks with -- associated with Zyprexa.

Since Day One that this product was marketed in the U.S., weight gain was described

in the label in the adverse reaction section. Doctors know the risks.

Before the FDA approves a medicine for sale -- and that label, I want to talk just a minute about the process, and you're going to hear much more about this, but the process that goes into developing a medicine and having it approved by FDA. Because it's not just a molecule that goes into becoming a medicine and gets accompanied by a label. There are studies that are done in the laboratory and then in clinical trials, and when the product comes to market as Zyprexa did, what is being labeled is what is learned from all of those studies. And that's what FDA is looking at, all of the information that Lilly submitted about what it learned from its clinical trials with Zyprexa.

Now, the FDA is not dumb or stupid, nor are they all-knowing. They are simply the cop on the beat. And when FDA says green light, that means we get to go ahead and market the medicine. And when they say stop, we stop. And you will hear both -- both times when FDA said stop, we don't think you should put that in your label, and you will hear times when they said, go

ahead, your label looks good. And you will hear about times that we have had communications with FDA and said, we see the data, the information this way, what do you think? But when FDA speaks, that's final. We can have views, but FDA is the cop on the beat and we listen to what FDA says.

FDA said when we first came to market in 1996 with Zyprexa that the weight gain information needed to be in the label, and ultimately they approved that label with that weight gain in the adverse reaction section.

Let's look at the label. Here's the label that was available in 1996, and as I mentioned earlier, it has lots of different sections to it. Let's look at the adverse reaction section, which is from the first time this product was approved. Lilly was explaining to physicians where weight gain was observed, and they told physicians in short-term clinical trials, meaning six-week trials, patients on olanzapine or Zyprexa gained 6 percent compared to those patients on placebo or sugar pill.

But that's not all they told doctors about weight gain. They also told

doctors that in long-term treatment with olanzapine, which is the generic name for Zyprexa, in long-term treatment, more than 50 percent of patients met the criteria for having gained a lot of weight. So everybody can just close their eyes for a minute and say, what's 7 percent of their weight? That's what doctors were told. Your patients, when they come in, may gain 7 percent of their existing weight. Significant weight gain, and doctors knew.

Did Lilly have an obligation to tell doctors what weight gain does? No, because doctors have gone to medical school and doctors know. All of us have had doctors tell us we need to lose weight or be mindful of our weight because weight gain or being obese or being overweight is a risk factor for a lot of diseases; diabetes, cardiovascular risk. Lilly was telling physicians, here's what we saw from our clinical trials about weight gain.

But that's not all. What else did the label say in 1996? It said: In other adverse events we saw infrequently hyperglycemia and diabetes. Infrequently meaning -- and that's a defined term by FDA -- 1 in 100 to 1 in 1,000

could express a certain level of implied safety. What they said is, before we understand this more, before we can approve ultimately this language being in the label, we want to have more information from you. It was clear to -- it was clear to Lilly that the FDA had taken control of this issue.

Now, as a result of the FDA's interest, Lilly continued to submit annual and periodic reports to the FDA. In May, 2001, Lilly submitted its analysis of clinical trial data and two epidemiological studies. This is the report that they submitted in May, 2001. In October of 2002, Lilly provided a briefing document and this showed new Lilly studies and now talked about the kind of spontaneous adverse events that were reported after now 9 million exposures to the drug. Nine million patients had taken this drug by October, 2002.

In March, 2003, Lilly again updated and supplemented its prior reports. They did the same thing in June of 2003 with a new submission of data. And also reviewed all the literature that had been accumulated on diabetes and antipsychotics. That's what the evidence will

show. Lilly was forthcoming, Lilly was opening the books and saying here's what we know about this relationship that may or may not exist between our product and this condition.

Now, September, 2003 marked a very significant milestone in the life of this label. I've been talking about how the label evolved and changed when the FDA told all the manufacturers of the second-generation antipsychotics to add new information to their label. After three years of review and analysis of the data, remember, they sort of began this process in May of 2000 and it's now September of 2003, after three years of review and analysis of all the data that had been submitted by all the different manufacturers, the FDA told Lilly and all these other companies it's time to add some new information to the label. And what did they do? They said here's the information we want you to put in the label and, of course, Lilly did.

They wanted to put into the label that there is a increased risk of diabetes among schizophrenics. The label said and pointed to certain studies, epidemiological studies which suggest an increased risk of

hyperglycemia-related adverse events in patients treated with atypical antipsychotics.

They said, however, there's not enough data to show whether there is a difference of risk among the various antipsychotics. They said doctors, we want you to do some monitoring of your patients and, last, and hardly least, the FDA said: The relationship between atypical antipsychotics use and hyperglycemia-related adverse events is not completely understood. It's not Lilly's language, that's not Lilly trying to hedge its bets. That's the FDA language.

This is the FDA saying we don't really understand this, we don't know what this relationship may be if any. But we want to at least alert doctors that something may be going out there, put it in the label; and we did. It doesn't say whether or not it caused, it didn't say whether it didn't cause, it said you may be alert to the fact that there may be this relationship out there, but we really don't know what it's all about.

At the same time that the FDA made the label change request, it sent a letter to all

manufacturers that accompanied that request in September 1990 -- September 2003 and it told the companies what the FDA wanted to do next.

And that letter said in essence, that while the FDA believed that the language that it had just recommended to be put in the September, 2003 label adequately described the available information that then existed on antipsychotics and the use of diabetes (sic), it said we, meaning the FDA acknowledge -- acknowledge that additional labeling changes may be required as new information becomes available.

This is important because the FDA was telling manufacturers that the 2003 label isn't the last chapter, it's likely that this label is going to change again as more information becomes available. And what the FDA did was made it crystal clear what new information that it wanted to receive from the manufacturers. In essence the FDA said we're really on top of all this, we're all over this, and here's what we want you to provide us so that we can make the kind of decision we need to make about what should go in the label.

And so the 2 -- so in 2003, the FDA

factors as well, events that might help us predict who might get diabetes, when, in fact, nobody really knows what causes diabetes.

What do we know about Zyprexa? We know and as you have seen that Zyprexa and we have told doctors Zyprexa causes weight gain, not in every patient, but in some. And in those who gain weight, some may gain a little, some may actually gain a lot. It's a doctor's decision to decide whether or not he or she is going to keep a particular patient on the medication while that person may be gaining weight gain. By the wail, it's very hard to hide weight gain, particularly substantial weight gain as you're visiting your doctor. As I said, weight gain also does not cause diabetes. We also know there appears to be an association with elevated blood sugar levels and second-generation antipsychotics. But, again, elevated blood sugar levels do not equal diabetes.

Elevated blood sugar levels are not even necessarily a natural next step to having diabetes.

Between 1996 and October, 2007, the Zyprexa label changed several times to add more

information to help doctors better understand the relationship between blood sugar levels and people who take Zyprexa. You've seen two of these changes. But the fact that a label changes over time does not mean that it is misleading, it does not mean that it is deceiving, does not mean that the label that came before that was necessarily misleading or deceiving either. What it means is that Lilly is gathering more information, communicating that information to physicians, trying to respond to the concerns of its customers and to the concerns of its author, the FDA. When you have heard all of the evidence, I think you will come to the conclusion that the right answer is not to say that Zyprexa causes diabetes. I believe that the right answer is what the evidence will show. It's namely that what Lilly has been doing over the last decade and is doing today; studying, monitoring, reporting, probing answers to hard questions.

Let me address for a minute some of the allegations that the State has made for you. You're going to hear a lot of our responses during the various witnesses that will come here today. You saw a lot of witnesses and I'm going

to address one or two to tell you what they didn't tell you. You heard Mr. Allen say that when the regulatory authorities in Japan told Lilly to change the label, Lilly made a change to this label in Japan. Lilly didn't agree with that change but it made it nonetheless.

What the State didn't tell you was that as soon as Lilly changed the label in Japan, it told the FDA. Called the FDA on the phone and said we're making a label change, this is a note to file from Lilly are from two doctors at Lilly talking to the FDA and saying we made a change in Japan to our label. That's not all Lilly did. Lilly promptly provided, yes, another report to the FDA, this time a comprehensive report analyzing everything that they had learned about why Japan had changed the label and it told the FDA why it disagreed with the conclusions that the Japanese regulators came to. Lilly also told the FDA, but you'll hear that Lilly told its sales representatives to go out and tell doctors that a label change had been made in Japan. The label change in Japan was no secret, but it was something that Lilly disagreed with. You will hear from Dr. Cavazzoni again, who went to Japan,

who analyzed the data, and who reached the conclusion that the label change that Japan made was not warranted because the data did not support the conclusion that the Japanese regulators for their own regulatory reasons, reached with respect to how the label should look in Japan. And that's not surprising.

Ms. Gussack said that this product has been used by 23 million people over the last 11 years; it's been approved for use in over 80 countries. Different countries have different regulatory regimes. The label that Mr. Allen showed you is not the label that is used in Japan. It's not the label that is used in Europe. It's not the label that is used in India. It's not the label that is used in South Africa. Different countries have determined what kind of information should go on labels and how those labels should be structured. Mr. Allen also told you about the ConSensus statement. He described that meeting where a number of scientists came together to look at whether or not and to examine this question of the relationship between second-generation antipsychotics and hyperglycemia and diabetes and

ATTACHMENT B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE: ZYPREXA PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES: TO ALL CASES	:	MDL-1596
TERRY L. DEPEW	:	UNITED STATES DISTRICT COURT
V.	:	SOUTHERN DISTRICT
ELI LILLY et al.	:	OF OHIO NO. 06-CV-00426
JAMES TSIKAS	:	UNITED STATES DISTRICT COURT
V.	:	SOUTHERN DISTRICT
ELI LILLY et al.	:	OF OHIO NO. 1:06-CV-00505
WILLIAM LEGGETT	:	UNITED STATES DISTRICT COURT
V.	:	CENTRAL DISTRICT
	:	OF CALIFORNIA
	:	CV-064323 ABC
ELI LILLY	:	(CTx)

- - -

December 15, 2006

- - -

C O N F I D E N T I A L

- - -

Videotape deposition of DENICE M. TORRES, held in the offices of Pepper Hamilton, 301 Carnegie Center, Princeton, New Jersey, commencing at 9:43 a.m., on the above date, before Linda L. Golkow, a Federally-Approved Registered Diplomate Reporter and Certified Shorthand Reporter.

- - -

GOLKOW TECHNOLOGIES, INC.
DEPS@GOLKOW.COM

the form.
THE WITNESS: I don't know what you're referring to with "collecting the chips."
BY MR. ALLEN:
Q. You said it offended you.
A. The way that you used it. I don't know what -- I guess I'll leave it at that because I don't know what you're talking about.
Q. That's fine. We've got two things that offended you so far today. One was bet the farm and number two was cashing chips, is that right?
A. In the way that you referred to them at the time, yes.
Q. Now, you said it would be improper, illegal for the sales rep to promote off-label use. Do you recall that?
A. To promote for use, yes.
Q. Off-label use?
A. Yes.
Q. Tell the jury -- define what

off-label use is.
A. Off-label use is if a prescribing physician used a drug for something other than it was indicated or approved by the FDA, that would be referred to as off-label use.
Q. Wasn't the majority of the use of Zyprexa in the United States off label?
A. I don't -- I don't know if it was the majority, but a good portion of use of all antipsychotics are used off label.
MR. FIBICH: Objection, nonresponsive.
BY MR. ALLEN:
Q. Listen to my question. I'm not here to talk -- I'll let you know when I want to talk about Risperdal, Seroquel, Geodon, Abilify. I'll let you know that. You're here for Eli Lilly on behalf of the marketing of Zyprexa, right?
A. Yes.

Q. Okay.
So, I'm going to limit my questions to Zyprexa unless I tell you otherwise. All right?
A. Okay.
Q. Wasn't the majority of the use of Zyprexa in the United States off label?
A. There was a good portion. I don't -- I don't remember the exact numbers. I don't remember it being the majority.
Q. Can you give the jury your best estimate, please.
A. Maybe 30 to 40 percent.
Q. Right.
Isn't it also true --
Do you recall the primary care physician launch, Viva Zyprexa, in the fall of 2000 in Orlando, Florida? Do you recall that?
A. No. I wasn't on the team at the time.
Q. I understand you weren't on

the team, but do you recall it?
A. No.
Q. Okay.
As you became involved in global marketing for Zyprexa, you certainly knew that a substantial portion of Zyprexa sales both in the United States and around the world was related to off-label prescriptions?
A. When I joined the team? Yes.
Q. Yes, ma'am.
And, in fact, did you not and weren't you one of the individuals at Eli Lilly along with others that used different channels and methods to promote and facilitate off-label prescriptions of Zyprexa?
A. Absolutely not, no.
Q. You never would do that?
A. No.
Q. Didn't John Lechleiter do that?
A. I'm not familiar with John

ATTACHMENT C

Implementation: Market research, message development, medical support and the creation of a training calendar is in progress. Logistical details surrounding a proposed single-site launch meeting, sampling considerations, the communications plan, sales metrics and incentives, customer targeting and direct-to-physician initiatives are also underway. Additional pre-launch activities (sales force integration, sales support items) are planned. Detail sequence will be determined by whether or not a key customer is identified as a Zyprexa target; redacted

redacted

Financial Impact:

	2000	2001	2002	2003
Absolute				
Sales*	**$16.8M**	**$156.5M**	**$203.8M**	**$259.6M**
Opex**	**$ 9.2M**	**$ 46.9M**	**$ 93.9M**	**$ 50.8M**
BUC	**$ 7.6M**	**$109.6M**	**$109.9M**	**$208.8M**

* *Note: Absolute PCP sales include spillover from LTC.*
** *Note: OPEX includes Sales Force Allocation.*

Incremental versus 2000 Forecast and 3/1 Year Plan Target

Sales	**$ 1.7M**	**$60.3M**	**$100.8M**	**$148.5M**
Opex	**$ 9.2M**	**$16.5M**	**$ 14.3M**	**$ 14.3M**
BUC	**$(7.5M)**	**$43.8M**	**$ 86.5M**	**$134.2M**

Mike Bandick, Brand Manager

August 2000

ATTACHMENT D

ZYPREXA Olanzapine

Zyprexa Launch Meeting

Lilly

Answers That Matter.

ZYPREXA Primary Care Vision and Strategy

Zyprexa Olanzapine

Vision: Expand Zyprexa's market by redefining how primary care physicians treat mood, thought, and behavioral disturbances

Strategy: Establish position of "Safe, proven solution for mood, thought and behavioral disturbances."

* Strong emphasis on direct-to-physician marketing; establish Zyprexa as next incremental step in PCP's treatment and Rx orbit
* Broad targeting among office-based PCPs
* Message based on patients' symptoms and behaviors (rather than diagnoses)

ZYPREXA
Olanzapine

Psychiatric symptoms in Primary Care

Mood disturbances	Thought disturbances	Behavioral disturbances
• Anxious	• Psychosis	• Restlessness / agitation
• Depressed	• Memory	• Aggressiveness / hostility
• Euphoric / manic	• Orientation	• Apathy / social withdrawal
• Irritable / angry / hostile	• Attention	

ZYPREXA Primary Care
Core folder: Back cover

Key takeaways:

Foundation of Zyprexa 3 x 3

Broad efficacy: Mood, Thought, Behavioral disturbances

Safety: Low risk for certain serious medical complications

Ease of use: 5mg starting dose, QD, no blood monitoring

Creates platform for creating action in specific patient type

ZYPREXA Primary Care
Core folder: Inner spreads

Key Takeaways:

Each spread addresses distinct area:

- Inside front - Introduces Zyprexa; conversational
- Behavior - Data to support efficacy in agitation et al
- Mood - Data to support efficacy in depression, mania
- Thought - Data to support efficacy in cognition
- Safety / Ease of Use - Data on EPS; flexible dosing
- Low risk - Most important of inner spreads; reinforces safety, frames adverse events with discontinuation rate = placebo

Designed to support data on demand, or extended message

ZYPREXA Primary Care Medical support

Medical slide kit

"Primary Care for Mood, Thought and Behavioral Disturbances"
Available to speakers by Nov. 4

- No additional training required; extensive speaker notes

Medical letters - Available now

- Extrapyramidal symptoms
- Anticholinergic effects
- Body weight changes
- Tardive dyskinesia (2)
- Blood glucose changes

Medical letters - Available soon

- Dizziness & Sedation
- Negative symptom efficacy
- Positive symptom efficacy

ZYPREXA Primary Care Message Recall: add'l priorities

Zyprex
Olanzapine

1) Which symptoms / behaviors are considered "appropriate"?
(unprompted / prompted)

Agitation	Hostility	Depression
Anxiety	Confusion	Elevated Mood
Mood Swings	Manic symptoms	Suspiciousness
Paranoia	Anger	Psychotic symptoms

2) Do customers describe Zyprexa as "easy to use"
QD, w/o regard to meals, no blood monitoring, well tolerated

3) Do customers recall: "EPS and Discontinuation Rate comparable to placebo"

4) Do customers recall "4 years, 4 million patients"

5) Do customers have a "neutral" view on Zyprexa's weight gain

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

MOTION TO LIMIT TESTIMONY OF PLAINTIFF'S EXPERT WITNESS JOHN L. GUERIGUIAN

INTRODUCTION

Lilly requests that the Court limit the testimony of plaintiff's expert, Dr. John L. Gueriguian by barring him from opining on the following subjects: (1) the adequacy of the Zyprexa labels; (2) the meaning of federal regulations; and (3) whether Lilly acted as a "reasonably prudent" drug manufacturer.

ARGUMENT

I. DR. GUERIGUIAN SHOULD BE BARRED FROM OPINING ON THE ADEQUACY OF THE ZYPREXA LABELING

Dr. Gueriguian admitted in his deposition that he has never actually seen the Zyprexa label:

> "No. Label, per se, I don't have. … I have not seen."[1]

> "I told you earlier that I didn't read the labels and that the only thing I know about the labels are the references that I found in the various documents."[2]

[1] Gueriguian Dep. at 143 (attached hereto as Exhibit A).

[2] *Id.* at 199.

Additionally, when Dr. Gueriguian was deposed on April 12, 2007, the October 2007 revisions to the Zyprexa label had not yet occurred, and so he could not have reviewed that revised label, either (nor any submissions by Lilly to the FDA after his deposition). Dr. Gueriguian has not supplemented or updated his report or any of the testimony he gave in his deposition, and should not be permitted to testify regarding documents or events after his deposition.

Because Dr. Gueriguian has never seen the Zyprexa labels and disclaimed first-hand familiarity with them at his deposition, he has no basis for opining about the adequacy of the labels. Nor has Lilly had an opportunity to meaningfully depose him about the actual content of the labels. To the extent he may claim at trial to have reviewed the labels since his deposition, those opinions have not been disclosed to Lilly and should be excluded on that basis.

II. DR. GUERIGUIAN SHOULD BE BARRED FROM OPINING ABOUT THE MEANING OF FEDERAL REGULATIONS.

Based on his report and deposition testimony, Dr. Guerigian proposes to offer his opinion about what is the proper interpretation and application of various federal regulations. These opinions should be excluded because the "meaning of … regulations" is not a proper subject of expert testimony: "That's a subject for the court, not for testimonial experts. The only legal expert in a … courtroom is the judge."[3] "The meaning of federal regulations is not a question of fact, to be resolved by the jury after a battle of experts. It is a question of law, to be resolved by the court."[4] "[W]hen the purpose of testimony is to direct

[3] *United States v. Caputo*, --- F.3d ---, 2008 WL 509177, *6 (7th Cir. 2008) (affirming exclusion of proposed expert testimony on meaning of FDCA and implementing regulations) (emphasis added).

[4] *Bammerlin v. Navistar Intern. Transp. Corp.*, 30 F.3d 898, 900 (7th Cir. 1994).

the jury's understanding of the legal standards upon which their verdict must be based, the testimony cannot be allowed. In no instance can a witness be permitted to define the law of the case."[5] For these reasons, numerous courts have excluded proposed "expert" testimony by witnesses who would have usurped the role of the Court by opining about the proper interpretation of federal regulations.[6] The Court here should likewise bar Dr. Gueriguian from offering opinions about the proper interpretation or application of FDA regulations.

III. DR. GUERIGUIAN SHOULD BE BARRED FROM OPINING ON WHAT A "REASONABLY PRUDENT" DRUG MANUFACTURER WOULD DO.

Based on his report, Dr. Guerigian proposes to summarize record evidence about which he lacks personal knowledge, and to preview plaintiff's closing argument by telling the jury what inferences should be drawn from those facts. For example, he proposes to offer the following opinions based on his review of Lilly documents:

- "Lilly documents demonstrate that the company delayed communicating essential data to regulatory agencies and resisted their requests to change the OL label."[7]
- "Lilly documents demonstrate that the company did not act as a reasonably prudent manufacturer in that it did not take the initiative of voluntarily adding to the label information needed

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[5] *Specht v. Jensen*, 853 F.2d 805, 810 (10th Cir. 1988).

[6] *See, e.g., Aguilar v. Int'l Longshoremen's Union Local #10,* 966 F.2d 443, 447 (9th Cir. 1992) (upholding trial court's exclusion of expert legal opinion as "utterly unhelpful"); *Police Retirement System of St. Louis v. Midwest Investment Advisory Service, Inc.*, 940 F.2d 351, 357 (8th Cir. 1991) ("More troubling is the System's allegation that one of the defendants' experts, Lee Pickard, a former head of the Securities and Exchange Commission's Division of Market Regulations and a lawyer, was allowed to explain the reach and meaning of § 28(e) to the jury. This was error. Explaining the law is the judge's job. Pickard's extensive law-related expert testimony allowed him to usurp the judge's place."); *Ricker v. Southwind Trucking, Inc.*, 2006 WL 5157692, *8 (N.D. Ga. 2006) ("[I]t is inappropriate to allow [plaintiff's proposed expert witness] to testify as to what the Federal Motor Carrier Safety Regulations provide and mean, or to allow him to opine expressly that the conduct of Defendants violated certain Federal Motor Carrier Safety Regulations. … The Court therefore will not permit Mr. Morgan to testify as to what the regulations at issue mean, or to testify that Defendants violated those regulations.").

[7] Gueriguian Report, at 18 (copy attached hereto as Exhibit B).

by prescribers and indeed ignored internal and external expert advice to warn ...."[8]

- "Lilly documents demonstrate that the company trained its representatives to mislead prescribers...."[9]

Dr. Gueriguian's opinions on these matters are not expert testimony – they are simply factual assertions and inferences regarding matters that the jury is fully capable of understanding and deciding without the help of any expert, as another court made clear under analogous circumstances:

> [The expert's] view that [defendant] failed to disclose information to the FDA boils down to a contention that [defendant] "buried" certain lab results.... This opinion does not implicate [the expert]'s expertise in pharmacoepidemiology. It is a simple inference drawn from his review of two documents. . . , which, if admissible, plaintiff's counsel may present directly to the fact-finder while arguing his or her view as to their significance. Expert testimony interpreting [defendant]'s conduct in disclosing information to the FDA therefore will not assist the fact-finder in these cases.[10]

To be admissible under Alaska Rule of Evidence 702(a), "expert opinion testimony must be helpful to the jury. This helpfulness standard requires experts to 'stop short of stating their own conclusions' on points that the jury is at least equally capable of determining."[11] Expert testimony may not "merely reiterate arguments based on inferences that can be drawn by laypersons; those can properly be advanced by the parties in their

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[8] *Id.*

[9] *Id.*

[10] *In re Rezulin*, 309 F. Supp. 2d 531, 550 (S.D.N.Y. 2004).

[11] *Getchell v. Lodge*, 65 P.3d 50, 56 (Alaska 2003).

summations."[12] Experts do not assist the jury by characterizing documents, or setting forth their contents in narrative form.[13] Nor is it the role of an expert to place documents in a thematic context, as this "does no more than counsel for plaintiff[s] will do in argument, i.e., propound a particular interpretation of [defendant]'s conduct."[14] Factual and background material, "to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence," not through the testimony of an expert witness.[15] The jury does not need Dr. Gueriguian's "help" to decide whether Lilly documents show that Lilly acted in a reasonably prudent manner, and the Court should bar preclude Dr. Gueriguian from opining on this issue.

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[12] *Schwab*, 449 F. Supp 2d. 992, 1134. *See also, e.g., Highland Capital Management, L.P. v. Schneider*, 379 F. Supp. 2d 461, 468-69 (S.D.N.Y. 2005); *LinkCo, Inc. v. Fujitsu, Ltd.*, 2002 WL 1585551, *2 (S.D.N.Y. 2002); *Taylor v. Evans*, 1997 WL 154010, *2 (S.D.N.Y. 1997).

[13] *See City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 565 (11th Cir. 1998); *In re Rezulin*, 309 F. Supp. 2d at 551; *United States v. Mulder*, 273 F.3d 91, 101 (2d Cir. 2001) (requirement that expert testimony be of scientific, technical, or specialized knowledge protects against admission of supposed expert testimony about lay matters which a jury can understand and determine without an expert's assistance).

[14] *In re Rezulin*, 309 F.Supp. 2d at 551 (citation omitted); *GST Telecommunications, Inc. v. Irwin*, 192 F.R.D. 109, 111 (S.D.N.Y. 2000) ("the Court should not shift to [expert] witnesses the responsibility to give conclusory opinions and characterizations of the business conduct portrayed.").

[15] *In re Rezulin*, 309 F. Supp. 2d at 551.

DATED: March 6, 2008.

Respectfully submitted,

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By: _____
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Attorneys for Defendant

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE: MDL-1596

ZYPREXA PRODUCTS
LIABILITY LITIGATION
THIS DOCUMENT RELATES TO:
ALL CASES

\- - -

April 12, 2007

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C O N F I D E N T I A L

\- - -

Videotape deposition of JOHN L. GUERIGUIAN, M.D., held in the offices of Pepper Hamilton, 3000 Two Logan Square, 30th Floor, Philadelphia, Pennsylvania 19103, commencing at 9:43 a.m., on the above date, before Linda Rossi Rios, RPR, CSR and Notary Public.

\- - -

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ALSO PRESENT:

MIKE KUTYS, Videographer

- - -

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INDEX

- - -

EXHIBITS

EXHIBITS (cont'd.)

- - -

DEPOSITION SUPPORT INDEX

Direction to Witness Not To Answer
Page Line Page Line
None

Request For Production of Documents
Page Line Page Line
None

Stipulations
Page Line Page Line
None

Questions Marked
Page Line Page Line
None

- - -

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VIDEOGRAPHER: We are now on the record. My name is Mike Kutys. I'm a videographer employed by Golkow Litigation Technologies. This is a video deposition for the United States District Court for the Eastern District of New York, MDL Number 1596. Today's date is April the 12th, 2007, and the video time is 9:44 a.m. This deposition is being held at Two Logan Square, 30th Floor, Philadelphia, Pennsylvania 19103 In Re: Zyprexa Liability Litigation. The deponent is John L. Gueriguian, M.D. This deposition is being taken on behalf of the defendant.

All counsel will be noted on the stenographic record. The court reporter's name is Linda Rossi, and she will now swear in the witness.

- - -

JOHN L. GUERIGUIAN, M.D., after having been duly sworn, was examined and testified as follows:

- - -

(Exhibit Gueriguian-1, Report of Plaintiff's Expert John L. Gueriguian, M.D., was marked for identification.)

- - -

EXAMINATION

- - -

BY MR. FAHEY:

Q. Good morning, Dr. Gueriguian.

A. Good morning, sir.

Q. My name is Sean Fahey. We met before the deposition started. But I just wanted to start the deposition with a couple instructions. I know you've been deposed a number of times before, but just so we're on the same page. I'm going to ask you a series of questions, and it's no secret, they're designed to

make sure that I fully understand the opinions that you intend to offer in this case, and understand the basis for those opinions. Do you understand that?

A. I do.

Q. Okay. And I may ask questions that you don't understand, that's fine, just tell me that you're not sure what I'm trying to ask you, and I'll try to rephrase them. If you don't hear me, just tell me that, and I'll speak up. And then I'm going to assume that if you answer the question, you understood and heard my question. Is that fair?

A. That's very fair.

Q. Okay. When -- when were you contacted to serve as an expert in this case?

A. I don't recall exactly, but let me see. Probably the last part of 2006.

Q. Okay. We are now in April of 2007, so approximately five months ago?

A. About that or give or take a month.

Q. Okay.

A. Probably give.

Q. Okay. Who contacted you?

A. The first contact came from a Ms. Harrington, Esquire.

Q. Ms.?

A. Harrington --

Q. Harrington?

A. -- Esquire.

Q. Which firm is she with?

A. I don't know.

Q. How would you be able to figure out who Ms. Harrington is? Is there anything you could look to to tell us what firm she is with?

A. Not presently, but I can -- I have that information at home, and I can supply it to you, no problem.

Q. Okay. What did -- what did she tell you?

A. Well, she simply asked me, as I remember it, if I were interested to

Q. Okay. Can you think of other examples of -- and I don't want to get too far afield, because I still want to focus on your opinion number 1, but there -- are there other examples of situations where you feel that the FDA suggested that a label change occur and Lilly resisted those efforts?

A. Well, the resistance criteria or standard should be what is the state of the label today. That's the benchmark. To this day, to my information, there's still -- Lilly is adhering to the so-called class effect. So that's the benchmark. Good.

Now, addition, here is Exhibit 2663, FDA memo signed by FDA's medical officer team leader, Andreason, 2003. And as you can see, I took a part of the pdf and transferred it as such to this document of mine. And I direct your attention to the second bullet where it says, "Addition of Weight Gain and Metabolic Dysregulation to the WARNINGS

section of labeling." That's what -- the team leader's proposal. So there is at that point in time a difference of opinion about where to put that information. Where is that part?

Q. And just while you're looking for the next document, this is a document that you saw for the first time yesterday?

A. Yes, early yesterday.

Q. Okay.

A. Now, in addition, Exhibit 2534 in the middle of page 2 of my thematics, FDA memo by FDA's medical officer and epidemiologist, Mosholder, 2003, refers to studies that the medical officer, whom I know, cites from the literature. "Caro, et al...," reference 3, I'm quoting, "...showed a relative risk greater than one for olanzapine versus risperidone." So you see, this is a published literature. "Gianfrancesco et al..." -- I'm continuing to quote, "...concluded that among the atypicals

only risperidone was not associated with diabetes." "Given the preponderance of the evidence...," and I'm still quoting now, but from the next paragraph down there, "...given the preponderance of evidence showing an association of atypical antipsychotic use and diabetes, and the public health importance of diabetes, this concern seems appropriate for a risk management program." This is FDA lingo to say we'll go and establish some kind of committee which will then tell the company, Lilly, either you do the study or you change your label.

Q. Okay. Are there any documents you saw before yesterday that support your conclusion on this issue?

MR. SUGGS: Objection to form.

THE WITNESS: I had not received any regulatory opinion or FDA regulatory opinions before I came and got the thing -- the information yesterday early. And

maybe I'm wrong, but it was my understanding that these were obtained very late. And that what is not available, I cannot review. When it is available, I review it with the same attention and rigor and objectivity, and I stayed very -- I wake up very early at 5:30 in the morning and I worked hard till 11:00 at night. As I said, this is not French style working day.

BY MR. FAHEY:

Q. Okay. And based on what your disclosures -- based on your disclosures, you never looked at any of the Zyprexa labels themselves, did you?

MR. SUGGS: Objection to form.

THE WITNESS: I don't remember exactly what I saw in terms of label, but I must have looked at things because it -- when I say that to this day the

label is not satisfying to the FDA, I think I must have, and I have, a supporting documentation, and it may well be here.

BY MR. FAHEY:

Q. Okay. I'm just going to put another objection on the record. If you did look at the labels, that's just another thing that's been considered by you in connection with the report that hasn't been disclosed to us.

You would agree that on none of the disclosures --

MR. SUGGS: Counsel, there are documents -- there are documents that -- company documents that talk about what the content of the label is.

MR. FAHEY: I'm not talking about -- I'm asking him whether he has seen the Zyprexa labels.

MR. SUGGS: The label, per se?

MR. FAHEY: Yes.

THE WITNESS: No. Label, per se, I don't have.

BY MR. FAHEY:

Q. Okay.

A. I have not seen. But there were references in various places to specific labels. And that's what I'm talking about. And in particular, I'm trying to find out something written by the FDA in a review -- in a review of -- what was it, the combination drug between olanzapine and Prozac. I forgot the proprietary name. Where the FDA is saying we're still not in agreement with your label on olanzapine as well as the combination.

Q. That's a document you saw yesterday again --

A. Yes.

Q. -- for the first time?

MR. SUGGS: It was only -- it was only written March 27.

BY MR. FAHEY:

Q. I just want to confirm when

he saw it. You saw it for the first time yesterday. Right?

A. Yes.

Q. Okay.

A. I answered that, it's yes.

MR. FAHEY: It's probably a good time to take a break for lunch.

MR. SUGGS: Sure.

MR. FAHEY: Like I said, there's a cafeteria right next door.

Oh, we've got to go off the record.

VIDEOGRAPHER: The time is 12:41, and we are off the record.

- - -

(A recess was taken from 12:41 p.m. to 1:15 p.m.)

- - -

VIDEOGRAPHER: The time is 1:15, and we are back on the record.

MR. FAHEY: Can you mark

this as Gueriguian-5?

MR. SUGGS: Which one is that one?

MR. FAHEY: The weight gain.

MR. SUGGS: I'm sorry?

MR. FAHEY: Weight gain.

THE WITNESS: Thank you.

MR. FAHEY: And this is Gueriguian-6, which is the regulatory. Actually no, we've already marked regulatory -- let me take that back. Residual issues would be Number 6.

THE WITNESS: I don't know. There's something that -- that's your document.

MR. FAHEY: Oh, okay. Sorry. And then this as, I guess, 7. I'm just going to put it on the record. It's the sales rep summary.

MR. SUGGS: Okay.

THE WITNESS: This is yours, too. Forgive me. Here you go.

1602, page 3.
3680, page 3 and 4. And the document page proper is 165.
MR. SUGGS: Didn't he already list those?
MR. FAHEY: Well, this is a separate category that he separated out.
MR. SUGGS: Okay.
THE WITNESS: 2457, page 10 of my Thematic: Diabetes.
1605, page 5 of the thematics and page 11 of the document proper.
988, page 8 of the thematics.
3680, page 8 of the thematics, and pages 50 to 51 inclusive in the proper -- in document proper.
The same document 360 -- 3680, now page 9 of the thematic, and page 165 of the document proper.

1452, page 10 of the thematic.
BY MR. FAHEY:
Q. Okay. Now, are there any other documents or anything that you've looked at that support -- that you're going to rely on to support your position listed in opinion number 1 of Gueriguian Number 1?
A. Yes. And may I remind you that I said that olanzapine can cause or be a substantial contributing factor in the development of diabetes in some individuals. That is precisely what my opinion is.
Q. Okay. And are there -- what are the other documents other than the ones you've already identified that support your position, or that you're relying on to support your position?
A. That's it.
Q. Okay.
A. I gave the whole thing, and you will note that the same thing,

diabetes is also -- offers a second -- opinion number 2.
Q. So the same documents you've referenced thus far would be the documents that you used to -- or that you're relying on to support your conclusion listed in opinion number 2?
A. Well, let me read it carefully.
Q. Sure.
A. Increases the risk of diabetes and other antipsychotics (other than clozapine) and thus the risk of diabetes, and I'm quoting myself, with olanzapine is not "comparable" with other atypical antipsychotic drugs as claimed by Lilly.
Now, here, that opinion is supported as a background with everything that I gave you plus the documents that show that -- that I alluded to earlier where it was shown that the FDA was of the opinion that this was not class effect at some point in time, and to this

day the Eli Lilly didn't seem to have satisfied label-wise the FDA's requirement.
Q. Okay. And those are the documents, the regulatory documents you saw yesterday. Right?
A. Yes.
Q. Okay. And can we just pull out your regulatory thematic and have you identify which of those documents --
A. Okay.
Q. -- in particular are using -- that you're relying on to support opinion number 2?
A. Sure. Now, document 186, this is a review of 1996 by the FDA medical officer. In page 24 -- 27 -- no, I'm sorry. 24. It is stated that -- I didn't find any mention of hyperglycemia in that review by the medical officer.
Q. You know hyperglycemia was in the label from the very beginning. Right?
A. Well, I'm concentrating here

now. If you want me to look at the label and reshape, refocus my attention, fine. But I can't answer cold like this.

Q. So let's just stop for one second then, and just -- because you referenced it before, and I just wanted to follow up. You said there was no reference in the NDA to hyperglycemia.

MR. SUGGS: Objection.

THE WITNESS: I didn't say that.

BY MR. FAHEY:

Q. Well, it's not necessary for my question, so --

A. Still --

MR. SUGGS: It's the preface to your question.

THE WITNESS: That's not what I said.

BY MR. FAHEY:

Q. The -- I think the record will show, if there's any confusion, what you said. So I'm not going to argue about that. But the simple question is,

you are aware, are you not, that hyperglycemia was in the Zyprexa label from -- from the very beginning?

A. I told you earlier that I didn't read the labels and that the only thing I know about labels are the references that I found in the various documents.

Q. Okay.

A. That's very clear.

Q. Okay. All right. Why don't -- I'm sorry to divert your attention. Why don't we go back to the --

A. Okay. Well, as I said, page 24 of document 196 doesn't show any mention of hyperglycemia. I didn't say it was in the label. I just said that the document itself didn't contain it.

Q. Okay.

A. Now, page 2, document 2169, an FDA review completed 2001 under the heading of olanzapine, the review says that at that point in time, obviously the

FDA came to the following conclusion. And I'm quoting. Although the risk for particular glucose-related adverse events, serious adverse events, discontinuations and treatment-emergent adverse events were numerically greater among olanzapine-treated subjects compared to controls in the NDA trials, these events were rare.

Now, that supports my -- that part of the opinion that says it's very clear that the FDA had an inkling, very serious inkling that something was happening and that it needed additional information. And the only person or institution to supply that information was Eli Lilly. And to the best of my knowledge, that definitive study was never performed or provided or both.

Okay. Then the paragraph 3 -- 4 of that document, same document, it says, clozapine, and this was by a Dr. Wysowski, who is an epidemiologist at the FDA that I worked with often.

Q. What department was he in?

A. Epidemiology. Safety.

Q. Okay.

A. Safety division.

Q. Okay.

A. The same thing where Dr. David Graham is, just for reference.

It says, and I'm quoting her. "Clozapine and olanzapine had reporting rates at least two times and up to 15 times that of risperidone..." This is a review dated 2001. So the drug is approved. "A prospective cohort study may help to answer some questions..." Again, this supports what I just told you a moment ago, that the FDA knows that there's something -- that has to be addressed, they don't have conclusive evidence, and they're saying a prospective cohort study may be -- help to answer some questions.

Let me tell you why this is important. Before the approval of a drug, the FDA has all the powers. And it

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION — MDL 1596 (JBW)

REPORT OF PLAINTIFF'S EXPERT

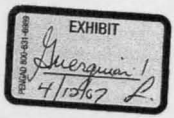
JOHN L. GUERIGUIAN, M.D.

My name is John L Gueriguian. I am a resident of Rockville MD. My address is 14513 Woodcrest Drive, Rockville, MD 20853-2371. I am a medical doctor and have been retained by the plaintiffs in the above styled case to review documents and materials concerning the drug Olanzapine which is manufactured by Eli Lilly Co. This drug is also known as Zyprexa.

EDUCATION AND WORK EXPERIENCE

Positions Held

1998-present	President, and General Manager, PharmaGenesis, Inc.
1978-1998	Medical Officer, Food and Drug Administration.
1976-1978	Tenured Associate Professor, Pharmacology, Univ of Minnesota, Medical School, Duluth, Minnesota.
1973-1976	Assistant Professor, Pharmacology, Univ of Minnesota, Medical School, Duluth, Minnesota.
1971-1973	Assistant Professor, Pharmacology, Univ of North Carolina, Medical School, Chapel Hill, North Carolina.
1969-1971	Instructor, Pharmacology, Univ of North Carolina, Medical School, Chapel Hill, North Carolina.



1967-1969	Research Associate, INSERM (French National Institutes of Health) & Head of Laboratory, Dept of Biochemistry, Medical School, Paris.
1965-1967	Post-doctoral Research Fellow, Harvard Medical School Associate Staff, Endocrinology, Peter Bent Brigham Harvard Medical School & Peter Bent Brigham Hospital, Boston, Massachusetts.
1961-1965	Teaching Assistant, Biochemistry, University of Paris, Medical School.

Education & Training

1956	Diplomat, French Baccalaureate, series M (Experimental Sciences)
1956-1957	University of Paris, Faculty of Sciences, Premed courses
1957	University of Paris, Faculty of Sciences, PCB degree*
1959	University of Paris, Faculty of Sciences, SPCN degree**
1965	University of Paris, School of Medicine, Doctoral Thesis
1965	University of Paris, School of Medicine, MD (State Diploma)
1959	University of Paris, Faculty of Sciences, BS in Biology
1960-1965	University of Paris, Faculty of Sciences, graduate education
1964	University of Paris, Faculty of Sciences, Licencié-es-Sciences***
1962-1965	Internship & Residency, Hospital of Mantes-la-Jolie, Internal & Pediatrics.
1966	Diplomat, Biochemical Technology - a Graduate Course, Harvard Medical School, Boston, Massachusetts
1978	ECFMG certification of Medical Doctorate degree in the United States

* French Medical School entrance qualifying examination
** Equivalent to the BS degree, Biology
*** Equivalent to the MS degree, Chemistry & Endocrinology

Awards & Grants

Commendable Service Award, Food and Drug Administration, Rockville, Maryland.
On-the-Spot Award, Food & Drug Administration, Rockville, MD..
Principal Investigator, NIH, USPHS grant HD0849.
Co-principal awardee, Media Production Fund Grant 5050, Univ of Minnesota, Minneapolis.
Co-principal awardee, Media Production Fund Grant 7126, Univ of Minnesota, Minneapolis.Principal Investigator, Miller Dwan Medical Fndn, Duluth, Minnesota.
Principal Investigator, Minnesota Medical Fndn grants DMRF-5-76 and DMRF-78.
Principal Investigator, Am Cancer Soc Institutional Research Grant 2917.

Recognitions

Memberships: Am Assoc for the Advancement of Sciences (past)
Am Soc Pharmacology & Experimental Therapeutics (past)
New York Academy of Sciences (past)

of important drugs. I have organized several international medical/pharmaceutical meetings, edited several scientific volumes, have held a tenured Associate Professorship in pharmacology, co-discovered the sex hormone-binding globulin and discovered, a ligand-ligand partition assay methodology. I participated in the development and worldwide introduction of the first recombinant DNA drugs by initiating early interactions with industry, defining the minimal requirements for approval, and approving submitted New Drug Applications.

I have contributed to the development of LHRH analogues for the treatment of prostatic cancer, benign prostatic hypertrophy, endometriosis, and precocious puberty by assisting industry towards viable clinical indications, defining for each indication the safety and efficacy parameters, and recommending approval of submitted NDAs.

I have participated in initiatives in the development of Growth Hormone Releasing Factor (GRF) through early interaction with discoverers, approving initial IND, informing industry of the discovery, defining safety and criteria parameters.

Much of my professional experience has been in the area of drugs and research concerning diabetes. I participated in the introduction of metformin (Glucophage) in the United States through early interactions with industry, defining protocols to confirm hypothesized synergism with sulfonylureas, and recommending approval of the submitted NDA. I organized and convened two international conferences for the purpose of developing an expert consensus around novel efficacy criteria for all anti-diabetic drugs, particularly those tested to retard or prevent the advent of the various diabetic complications. I organized and convened several international conferences to aid the development of biotechnological products.

I am co-founder of IDRAM, a non-profit public interest international organization, regrouping scientists from Academia, Industry, and Government; to define and implement safety and efficacy criteria for new drugs.

My training and experience with the requirements of drug safety and efficacy resulted in a recommendation of non-approval of Ayerst's aldose reductase inhibitor: An unsafe and inefficacious drug. This recommendation was successful in convincing various pharmaceutical companies to withdraw unsafe drugs from FDA consideration. My work also contributed to affirming causality between Creutzfeld-Jacob disease and cadaveric pituitary growth hormone which resulted in obtaining the voluntary withdrawal by industry of such preparations.

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Gueriguian JL, "The endocrine function of the ovary during an ovulatory cycle in sexually mature woman," A self-instructional program, Health Sciences Consortium Catalogue, 29 pp., Chapel Hill, NC, 1973.

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Gueriguian JL, "Introduction to the pharmacology of estrogens" A self-instructional program, Health Sciences Consortium Catalogue, 17 pp., Chapel Hill, NC, 1973.

Burford H & Gueriguian JL, "Oral Contraceptives: Hormonal control of ovulation and menstrual cycles," Medical Television Ctr, Chapel Hill, NC, 10 min movie, color & sound, 1973.

Gueriguian JL, "Immunosuppressive agents and human therapy," A self-instructional program, Health Sciences Consortium Catalogue, 13pp., Chapel Hill, NC, 1974.

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Gueriguian JL, "Antiprotozoal and antimetazoal drugs, Pt 2" A self-instructional program, Health Sciences Consortium Catalogue, 15pp., Chapel Hill, NC, 1974.

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Gueriguian JL, "The androgens, Pt 2" A self-instructional program, Health Sciences Consortium Catalogue, 25pp., Chapel Hill, NC, 1975.

Gueriguian JL et al., "Audiovisual Self-Instructional Programs: Introduction to Male Reproductive Pharmacology," Media Resources Center, University of Minnesota, Minneapolis, 40 slides, 1977.

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Greppin JAC, Savage-Smith E & Gueriguian J L (eds): The Diffusion of Greco-Roman medicine into the Middle East and the Caucasus," (Delmar, NY: Caravan Books, 1999)

Gueriguian JL, "An algorithm for the rediscovery of old yet effective medications of botanical origin with special reference to Armenian pharmacology," in Greppin JAC et al., (eds): The Diffusion of Greco-Roman medicine into the Middle East and the Caucasus," (Delmar, NY: Caravan Books), 1999, pp. 265-85.

Gueriguian JL, "The language of Amirdovlat Amasiatsi," in Greppin J (ed): Proceedings of the 4th International Conference on Armenian Linguistics (Delmar, NY: Caravan Books, 1992), pp. 77-100

Gueriguian JL, Insights into the Orbelian Principality, part II, J Arm Studies (Boston) 1990-1991, 5(1):13-36

Gueriguian JL, "Amirdovlat' Amasiats'i: His life and contributions," J Soc for Armenian Stud 3: 63-91, 1987

Gueriguian JL, Insights into the Orbelian Principality, part I. J Arm Studies (Boston) 1985-6, 2(2):27-42

INVITED LECTURESHIPS & CONSULTANCIES (a representative sampling)

Opening address, Session 2, 4th Meeting of the International Study Group for Steroid Hormones, Rome, 1969.

Invited speaker, "Progesterone-binding Proteins," Dept. of Obstetrics & Gynecology, University of Michigan, School of Medicine, Ann Arbor, Michigan, 1971.

Consultant and Keynote Speaker , IVth Regional Meeting on Family Health, Dakar, Senegal, 1973.

Visiting Lectureship, Univ of Santo Tomas, Faculty of Medicine & Surgery, Manila, the Philippines, 1979.

Invited speaker, "Lipid-altering drugs: Scientific & regulatory viewpoints," New York Lipid Research Club, The Rockfeller University, New York, 1980.

Invited Speaker, "Proposed guidelines for the uses of LHRH agonists and antagonists in humans," NIH, Contraceptive Development Branch, 1981.

Invited Speaker, "Regulatory aspects on biosynthetic polypeptides," National Board Of Health & Welfare, Dept. of Drugs, Uppsala, Sweden, 1981.

Invited speaker, " Amirdovlat': His life and contributions to Medieval Armenian Medicine," University of Chicago, Humanities Division, 1986.

Invited speaker, "Regulatory categorization of drugs in the USA," Droit et Pharmacie, Paris, 1990.

Invited speaker, "FDA-Industry Interactions: Recent Trends," George Washington University, Center for Health Services Research & Policy, 2002.

Organizer & Invited Speaker, "New Trends in Regulatory Affairs on Medical Products for Human Use," Catholic University of Brussels, 2002

ORGANIZER OF INTERNATIONAL SCIENTIFIC & MEDICAL CONFERENCES

State-of-the art conference on insulins & growth hormone, Bethesda, MD 1981
Hormone Drugs, Rockville, MD, 1982.
Biotechnologically-derived agents. The scientific basis of their regulation, Paris 1987
Physio-pathology & natural history of the diabetic complications, Lisbon 1990.
Efficacy criteria of new drugs for the treatment of the diabetic complications, Gaithersburg, 1991.

PHARMACEUTICAL CLIENTS (A selected list)

Bristol-Myers, Johnson & Johnson; Sanofi-Aventis;

DEPOSITIONS, WITNESSING & LEGAL CONSULTATIONS

For Plaintiff, versus Lariam, by Defendant's Counsel.
Advising Plaintiff's' Counsels, Lariam
Advising Plaintiff's' Counsels, Baycol
For Plaintiff, versus Fenfluramines, by Plaintiff's Counsel.
For Plaintiff, versus Loestrin, by Defendant's Counsel.
For Plaintiff versus Cylert, by Defendant's Counsel.
Advising Defendant's Counsels, Thyroid hormones.
Depositions for Plaintiff vs. Rezulin, by Plaintiff's Counsel. In Rockville, and Baltimore, MD
Witnessing for Plaintiff vs. Rezulin, in Rockville, MD; Liberty, MO, Tulsa, OK; Forth Worth, TX; and San Antonio, TX

COMPENSATION

My compensation in this case is Five Hundred dollars an hour. This is the ordinary hourly rate I charge any client for whom I am asked to review matters or consult. To date I have worked sixty one hours on this matter.

I have reviewed the confidential internal company documents listed in attachments A which are documents provided to me by the plaintiff obtained through discovery. In addition to exhibit A, I have conducted my own independent review of the published literature concerning the safety and efficacy of the drugs known as atypical antipsychotic medications. A list of this literature is included as attachment B to this report.

OPINIONS REGARDING OLANZAPINE (ZYPREXA) AND ITS DIABETOGENIC EFFECTS

1. Olanzapine overview

Olanzapine (henceforth, OL) has been approved by the FDA for the treatment of schizophrenia, acute mania in bipolar disorder, agitation associated with schizophrenia and bipolar disorder and as maintenance treatment in bipolar disorder. Olanzapine is manufactured and marketed by the pharmaceutical company Eli Lilly and Company (henceforth, Lilly). It is available as a pill and orally disintegrating tablets of various dosages. It is also available as a rapid-acting intramuscular injection for short term acute use.

OL is structurally similar to clozapine and they both belong to the pharmaceutical class of thienobenzodiazepines, also known as "atypical antipsychotic drugs." The main characteristic that distinguishes them from "traditional antipsychotics" is the fact that they bind to many more receptors than the traditional drugs. However, drugs with affinities for an unusually high number of receptors have been often shown to present unusual and unpredictable toxicities.

2. Diabetes overview

Insulin is produced by specialized pancreatic cells followed by its release in the blood. Diabetes comes in two varieties: type 1 and type 2—the former due to a total lack of insulin production, the latter being a relative insulin insufficiency, or insulin inability to properly perform its function. Blood glucose is derived from starchy food and is stored in the liver, whence it can be released into the blood steam. Glucose is the only nutrient used by the brain. It also serves to maintain bodily organs and functions. In all organs, and particularly in the muscles, glucose must penetrate the cell before it can be metabolized to produce the energy needed for their maintenance and their function.

Insulin allows the penetration of glucose into the cells. In its absence or relative ineffectiveness, not enough energy is produced, organs and functions are not working properly, less utilized blood sugar increases in titer (hyperglycemia) and a number of eventually serious pathologic consequences ensue: hyperglycemia, keto-acidosis, diabetic coma, cardiovascular morbidity and mortality (through atherosclerosis and microvascular disease) , eye dysfunction leading to blindness, kidney disorders leading to forced dialysis, various neuropathies with ultimate destruction of nerve fibers and the ill-

consequences derived from such destruction, and difficult to treat leg ulcers which sometimes lead to amputations, gangrene, and eventually death.

During my twenty years at the FDA as a Medical Officer, I reviewed all the anti-diabetic drugs and recommended approval of all of them, save two. I was also instrumental in introducing into the US highly purified and recombinant DNA insulins. All available anti-diabetic drugs afford symptomatic treatment but no cure. Under these conditions, and since all drugs cause sometimes serious to lethal side-effects, it stands to reason that a reasonable drug manufacturer should do its best to prevent the advent of drug-caused, or drug-associated, diabetes and to warn prescribers of all known risks associated with the use of a drug.

3. Obligations of pharmaceutical manufacturers

The federal statutes, and the regulations that derive from them, define, in general terms, the mandate of the Food and Drug Administration (FDA) and the obligations of manufacturers pursuant to those regulations, as to how a new drug should be tested, the criteria that have to be met before a drug can be approved by the FDA, and the post-marketing follow-up activities that are mandated to ensure the drug's continued safety. Since each new drug is an unknown quantity at first, it follows that it should be tested and monitored over time as it is used more extensively. The manufacturers must take the initiative and act prudently to ensure the safety of new drugs introduced to the market. When a drug is introduced in the market, a reasonable and prudent pharmaceutical company must provide prescribers the information needed to decide whether and how to treat an individual patient with the new drug. Failing to inform the prescribers of the

risks of a drug, or minimizing and misrepresenting the facts to them, is the most egregious failure of a drug company.

4. The weight gain issue

4.1. Weight gain observed during animal studies

Internal Lilly documents refer to studies performed with clozapine indicating that the results raised the possibility that OL might cause weight gain and hyperglycemia by increasing insulin resistance (See, X4176[1]). In studies with OL, overeating was observed in animals (See, X927). Thus, Lilly was put on notice that the same adverse effects could be anticipated in humans and should be looked for during clinical studies.

4.2. Weight gain observed during clinical studies

According to Lilly's own studies, treatment-emergent weight gain was shown to be important and significant, i.e., all treatment emergent weight gain-related adverse events, in the overall integrated data, showed a 12-fold increase of adverse events in the OL-treated group, compared to placebo, with a highly statistically significant increase, compared to an active comparator control, with a $p<0.01$ versus placebo and haloperidol (See, X3680, pp. 125, 127, 134, 464, 472).

In time, the European regulatory agency (EMEA) (See, 3680, pp. 464, 472, Lilly's own academic advisors (See, X5850) the Veteran's Hospital Administration (See, X3184), and the American Diabetes Association (ADA) (See, X2368) endorsed the reality that OL had an increased risk of significant weight gain and diabetes. Although Lilly ignored the opinions expressed by consulting physicians to the company in 2000 that OL probably increased the risk of weight gain and diabetes (See, X6998), later

[1] References to "X____" refer to particular Zyprexa MDL Plaintiffs' Exhibit Numbers. Attached hereto as Exhibit A is a listing of the Plaintiffs' Exhibits I have reviewed. Exhibit A also lists the Lilly Bates Numbers corresponding to the Plaintiffs' Exhibit numbers.

published medical literature finally was able to observe what Lilly had known for a decade. (Lieberman JA et al., N Engl J Med 2005, 353(12):1209-13).

Lilly clearly recognized potential dangers of OL that physicians were not warned about in the product labeling (See, e.g., X3680, p. 19; X4176; X1451). Indeed, one of its scientists wrote, "It would be ludicrous to state that a patient gaining as much as 80 kg (176 lbs.) is not at long-term increased cardiac risk, especially if during that weight gain the patient developed an increase in fasting glucose and lipid levels (See, X6128). Other Lilly employees warned management in 2000 that its outside consultants were very concerned about the risk of diabetes with the use of OL, had urged the company to "come clean" on the issue of diabetes and recommended that the company turn over all the data to an independent outside board. See, X1451; X1449).

Despite all the evidence demonstrating an increased risk of both weight gain and diabetes in OL users, Lilly minimized and misrepresented the cogent facts and their potential consequences to prescribing physicians (See, X6128; X3680, p.52; X1110; X1926), trying, or example, to hide behind the spurious "class effect" theory (See, X927; X1110, and X995).

5. The diabetogenic issue

5.1. Diabetogenic effects observed during clinical studies

I was surprised to see that Lilly used in its clinical studies random blood glucose measurements, instead of the more accurate, better accepted, and unambiguous tests: Fasting blood sugar and HbA1c (See, X991; 2001, X4801, X5565;, X1440].

It should have used either fasting blood glucose measurements, or HbA1c values, or both.

During the Phase II studies (See, X3680, pp. 73-4;) and the pivotal placebo-controlled studies beyond the acute phase (See, X1349), it was clear that OL-treated patients showed 2.5% excess frequency of hyperglycemia, showed 8 cases of "serious glycemia-related adverse events," against zero for haloperidol and treatment emergent glycemia-related toxicities showed a 5–fold increased in the incidence of all OL glucose-related abnormalities. A later analysis in early 2000 showed a 3.5-fold increase in the incidence of treatment emergent hyperglycemia (See, X990). In one phase of a large pre-marketing study, urinary glucose was detected in 14 patients on OL but only 2 patients on haloperidol, a "typical antipsychotic" used as a comparator (See, X1602). In later clinical studies and during the Alzheimer's prevention indication studies, despite the wide variations in the compared groups, but when the proper controls were utilized, the higher incidence of serious diabetogenic event could be seen in the OL group (See, X3680, p. 165)

During later meetings in the presence of Lilly scientists outside consultants to Lilly made similar observations to the company that agreed with these initial observations (See, X2547). Several studies published in respectable and refereed journal also concurred that OL increased the risk of diabetes and appeared to do so more than typical antipsychotics or other atypical antipsychotics. (Ramankutty G, Acta Psychiatr Scand 2002, 105(3): 2356-6; Meyer JM, J Clin Psychiatry 2002, 63(5):425-33; Serniak MJ et al., J Clin Psychiatry 2002, 159:561-6; and Lieberman JA et al., N Engl J Med 2005, 353(12):1209-13)

5.2. Direct and indirect failure to warn

Lilly continually minimized and misrepresented facts and failed to provide prescribers with the proper information about the risks of OL (See, X3680, X988, X1110, X1111). It used a number of devices to bend the data its way (See, X3680, p. 51; X927, X1452) and continued to use the improper random blood glucose measurements in its clinical studies. Lilly's questionable handling of data is carefully described by all three referees of one of Lilly's rejected manuscript. (See, X1440).

It appears that Lilly trained its sales representatives to mislead prescribing physicaians about the risks of OL. (See, for example, X3211; X1926). Another example of Lilly's misleading of physicians includes the admission in an unpublished manuscript that OL users had significantly higher glucose elevations during treatment (See, X3567), while claiming in a Dear Doctor letter distributed to physicians by the sales force that OL's toxic effect was no different than that of most other "atypical antipsychotics (See, X3278). In fact, however, Lilly's internal documents show that OL is roughly 4 times worse than its pharmacological congeners, save for clozapine. All these activities led to a failure to inform prescribers about the importance and actual magnitude of OL's diabetogenic effect.

6. Lilly's Overpromotion of OL

Lilly compounded the danger of failing to adequately warn prescribers about the risks of OL by over-promoting the drug. For example, internally Lilly marketing personnel bragged that they had been promoting OL to prescribers for depression since 1998 despite the fact that the drug was not indicated for depression (See, X9807 and X9808). Further, in 2000 Lilly launched a marketing program for OL which targeted primary care physicians (PCPs) (See, X5846). Internally, Lilly acknowledged that OL's

approved indications for schizophrenia and bipolar disorder were not typically treated by PCPs and that there was not a specific indication for Lilly sales reps to promote to these physicians (See, X8479). Nevertheless, Lilly sent its sales reps out to promote OL to PCPs as "the safe, proven solution in mood, thought, and behavioral disorders" and noted internally that this position was "intentionally broad and vague, providing latitude to frame the discussion around symptoms and behaviors rather than specific indications" (See, X8479).

7. Conclusions

On the basis of an objective analysis of the best available evidence, I am ready to offer the following opinions to a reasonable degree of medical certainty:

1. OL can cause diabetes and its sequelae or be a substantial contributing factor in the development of diabetes in some individuals;
2. OL increases the risk of diabetes and its sequelae more than other atypical antipsychotics (other than clozapine) and thus the risk of diabetes with OL is not "comparable" with other atypical antipsychotic drugs as claimed by Lilly;
3. Internal Lilly documents demonstrate the company had credible scientific evidence in its possession since at least 1995 that the use of OL was correlated with both weight gain and hyperglycemia;
4. Internal Lilly documents demonstrate the company had credible scientific evidence in its possession that weight gain and diabetes were inter-related and would thus act concurrently to increase the frequency of diabetes, its complications, and cardiovascular disease (which happens to be the number one cause of death in diabetics);

5. Lilly's clinical studies were flawed by the use of imperfect methodologies, in particular the use of random blood glucose tests as opposed to the use of other more reliable methods of testing for hyperglycemia;

6. Internal Lilly documents demonstrate that the company delayed communicating essential data to regulatory agencies and resisted their requests to change the OL label;

7. Internal Lilly documents demonstrate that the company did not act as a reasonably prudent manufacturer in that did not take the initiative of voluntarily adding to the label information needed by prescribers and indeed ignored internal and external expert advice to warn physicians about the risks of diabetes;

8. Internal Lilly documents demonstrate that the company trained its representatives to mislead prescribers about the risks and benefits of OL;

9. Lilly failed to adequately warn physicians of critically important information regarding the risks of OL that were reflected in its own internal documents and in published medical literature; and

10. Lilly compounded the danger of failing to adequately warn prescribing doctors about the risks of OL by over-promoting the drug.

Respectfully submitted,

John L. Guerriguian, M.D.

January 30, 2007

Exhibit A to Report of Dr. John Gueriguian

EXH_NUMBER	BEGBATES
Zyprexa MDL Plaintiffs' Exhibit No.00195	ZY 4001 56.000
Zyprexa MDL Plaintiffs' Exhibit No.00320	ZY 4051 1633.000
Zyprexa MDL Plaintiffs' Exhibit No.00439	ZY 4091 10.000
Zyprexa MDL Plaintiffs' Exhibit No.00775	ZY 972 3.000
Zyprexa MDL Plaintiffs' Exhibit No.00778	ZY 994 158.000
Zyprexa MDL Plaintiffs' Exhibit No.00925	ZY 2196 1547.000
Zyprexa MDL Plaintiffs' Exhibit No.00927	ZY 2196 1668.000
Zyprexa MDL Plaintiffs' Exhibit No.00929	ZY 2197 44.000
Zyprexa MDL Plaintiffs' Exhibit No.00988	ZY 8032 313.000
Zyprexa MDL Plaintiffs' Exhibit No.00990	ZY 8032 1544.000
Zyprexa MDL Plaintiffs' Exhibit No.00995	ZY 8451 486.000
Zyprexa MDL Plaintiffs' Exhibit No.01074	ZY 7119 696.000
Zyprexa MDL Plaintiffs' Exhibit No.01077	ZY 7119 921.000
Zyprexa MDL Plaintiffs' Exhibit No.01110	ZY 7152 867.000
Zyprexa MDL Plaintiffs' Exhibit No.01111	ZY 7152 874.000
Zyprexa MDL Plaintiffs' Exhibit No.01169	ZYP 478 414.000
Zyprexa MDL Plaintiffs' Exhibit No.01345	ZY 403 182.000
Zyprexa MDL Plaintiffs' Exhibit No.01349	ZY 403 332.000
Zyprexa MDL Plaintiffs' Exhibit No.01440	ZY 2216 315.000
Zyprexa MDL Plaintiffs' Exhibit No.01449	ZY 2224 231.000
Zyprexa MDL Plaintiffs' Exhibit No.01451	ZY 2224 236.000
Zyprexa MDL Plaintiffs' Exhibit No.01452	ZY 2224 239.000
Zyprexa MDL Plaintiffs' Exhibit No.01453	ZY 2224 247.000
Zyprexa MDL Plaintiffs' Exhibit No.01456	ZY 2226 584.000
Zyprexa MDL Plaintiffs' Exhibit No.01586	ZY 147 3.000
Zyprexa MDL Plaintiffs' Exhibit No.01602	ZY 1234 36.000
Zyprexa MDL Plaintiffs' Exhibit No.01603	ZY 1234 115.000
Zyprexa MDL Plaintiffs' Exhibit No.01604	ZY 1234 320.000
Zyprexa MDL Plaintiffs' Exhibit No.01605	ZY 1234 871.000
Zyprexa MDL Plaintiffs' Exhibit No.01926	ZY200061996

EXH_NUMBER	BEGBATES
Zyprexa MDL Plaintiffs' Exhibit No.01962	ZY200098771
Zyprexa MDL Plaintiffs' Exhibit No.02197	ZY200367530
Zyprexa MDL Plaintiffs' Exhibit No.02368	ZY200381764
Zyprexa MDL Plaintiffs' Exhibit No.02441	ZY200386618
Zyprexa MDL Plaintiffs' Exhibit No.02547	ZY200392604
Zyprexa MDL Plaintiffs' Exhibit No.03184	ZY200581125
Zyprexa MDL Plaintiffs' Exhibit No.03211	ZY200597928
Zyprexa MDL Plaintiffs' Exhibit No.03278	ZY200622359
Zyprexa MDL Plaintiffs' Exhibit No.03567	ZY200896444
Zyprexa MDL Plaintiffs' Exhibit No.03645	ZY200959390
Zyprexa MDL Plaintiffs' Exhibit No.03680	ZY201021821
Zyprexa MDL Plaintiffs' Exhibit No.03909	ZY 8965 179.000
Zyprexa MDL Plaintiffs' Exhibit No.04176	ZY 2821 1184.000
Zyprexa MDL Plaintiffs' Exhibit No.04436	ZY201236621
Zyprexa MDL Plaintiffs' Exhibit No.04784	ZY201304173
Zyprexa MDL Plaintiffs' Exhibit No.04801	ZY201310108
Zyprexa MDL Plaintiffs' Exhibit No.04805	ZY201310979
Zyprexa MDL Plaintiffs' Exhibit No.04815	ZY201311406
Zyprexa MDL Plaintiffs' Exhibit No.04858	ZY201312281
Zyprexa MDL Plaintiffs' Exhibit No.04864	ZY201314863
Zyprexa MDL Plaintiffs' Exhibit No.04871	ZY201321744
Zyprexa MDL Plaintiffs' Exhibit No.05318	ZY201791493
Zyprexa MDL Plaintiffs' Exhibit No.05565	ZY201883634
Zyprexa MDL Plaintiffs' Exhibit No.05648	ZY201895820
Zyprexa MDL Plaintiffs' Exhibit No.05846	ZY 7300 423.000
Zyprexa MDL Plaintiffs' Exhibit No.05850	ZY 8091 355.000
Zyprexa MDL Plaintiffs' Exhibit No.06128	ZY200286391
Zyprexa MDL Plaintiffs' Exhibit No.06413	ZY200528823
Zyprexa MDL Plaintiffs' Exhibit No.06998	ZY 2224 230.000
Zyprexa MDL Plaintiffs' Exhibit No.06999	ZY 2224 245.000

Exhibit A to Report of Dr. John Guerigulan

EXH_NUMBER	BEGBATES
Zyprexa MDL Plaintiffs' Exhibit No.07028	ZY 2222 632.000
Zyprexa MDL Plaintiffs' Exhibit No.07032	ZY 8596 814.000
Zyprexa MDL Plaintiffs' Exhibit No.07033	ZY 8596 815.000
Zyprexa MDL Plaintiffs' Exhibit No.07766	ZY201299541
Zyprexa MDL Plaintiffs' Exhibit No.07802	ZY201302222
Zyprexa MDL Plaintiffs' Exhibit No.07804	ZY201303751
Zyprexa MDL Plaintiffs' Exhibit No.07822	ZY201358723
Zyprexa MDL Plaintiffs' Exhibit No.09201	ZY202237975
Zyprexa MDL Plaintiffs' Exhibit No.08666	ZY201584949
Zyprexa MDL Plaintiffs' Exhibit No.08479	ZY201450600
Zyprexa MDL Plaintiffs' Exhibit No.09807	ZY201809731
Zyprexa MDL Plaintiffs' Exhibit No.09808	ZY201809732
Zyprexa MDL Plaintiffs' Exhibit No.09876	ZY202362607

EXHIBIT B

The published literature concerning the safety and efficacy of the drugs known as atypical antipsychotic medications which I have reviewed are:

1. Ramankutty G., Acta Psychiatr Scand 2002, 205(3): 2356-6
2. Meyer JM, Journal of Clinical Psychiatry 2002, 63(5): 425-33
3. Serniak MJ et al., Journal of Clinical Psychiatry 2002, 159:561-6
4. Lieberman JA et al., New England Journal of Medicine 2005, 353(12): 1209-13)

EXHIBIT C

I am being compensated for my time at the rate of $500.00 per hour. I have expended 61.74 hours in review and preparation of this report.

The specific documents I have reviewed in preparing the report are listed in Exhibit A.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA, Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	Case No. 3AN-06-5630 CI **ORDER**

THIS COURT, having considered Defendant Eli Lilly and Company's Motion to Limit the Testimony of Plaintiff's Expert Dr. John L. Gueriguian, and any response thereto,

IT IS HEREBY ORDERED that the Motion is GRANTED. The plaintiff may not introduce testimony or evidence from Dr. Gueriguian regarding (1) the adequacy of the Zyprexa labels or documents or events occurring after the date of his deposition; (2) the proper interpretation or application of federal regulations; or (3) whether Lilly acted as a "reasonably prudent" drug manufacturer.

DATED this ____ day of March, 2008.

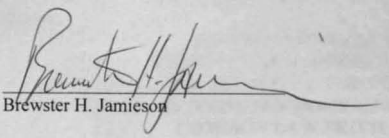
BY THE COURT:

_____

The Honorable Mark Rindner
Superior Court Judge

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document has been served via email upon counsel listed below, and by hand delivery and email upon Mary Beth Rivers, Room 532, Tower Two, Captain Cook Hotel.



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Date: March 6, 2008

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

MOTION TO EXCLUDE EVIDENCE REGARDING SPEECH PROTECTED BY THE *NOERR-PENNINGTON* DOCTRINE AND COMMON LAW PRIVILEGE

INTRODUCTION

Lilly expects that plaintiff will attempt to introduce evidence of efforts by Lilly and others to petition the State of Alaska to maintain open access to all psychiatric medications for Medicaid beneficiaries. This evidence reflects speech that is protected by the First Amendment and privileged under Alaska law and will inject peripheral issues into the trial and confuse the jury. The Court should bar plaintiff from introducing such evidence.

ARGUMENT

The First Amendment grants broad immunity from liability based on a defendant's efforts to influence governmental decision-making.[1] "Lobbying, like handbilling, is activity protected by the First Amendment. … [E]very person or group engaged ... in trying to persuade [governmental] action is exercising the First Amendment right of petition."[2]

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[1] *See Gunderson v. University of Alaska*, 902 P.2d 323, 326 (Alaska 1995); *Pepper v. Routh Crabtree, APC*, Case No. 3AN-07-8568 CI, 3d Jud. Dist. (Order Granting Motion to Dismiss, Jan. 11, 2008) (holding that defendant's filing of a lawsuit to collect a debt from plaintiff was protected by the First Amendment and therefore could not form the basis of a claim under the UTPCPA) (Rindner, J.).

[2] *Brown & Root, Inc. v. Louisiana State AFL-CIO*, 10 F.3d 316, 326 (5th Cir. 1994); *see also, e.g., Knology, Inc. v. Insight Communications Co.*, 393 F.3d 656, 658 (6th Cir. 2004) ("The *Noerr-Pennington* doctrine allows businesses to combine and lobby to influence the legislative, executive, or judicial branches of government or administrative agencies … because the First Amendment's right of petition protects such activities."); *Holzrichter v. County of Cook*, 595 N.E.2d 1237, 1242 (Ill. App. 1992) ("Certainly, legislative

(continued...)

"Under the *Noerr-Pennington* doctrine, those who petition all departments of government for redress are generally immune from liability."[3] "*Noerr-Pennington* protection is available regardless of the actor's motive," [4] and "includes direct communications with government officials, as well as incidental activities such as "talking to other citizens" or attending meetings,[5] "so long as [the incidental activities] are sufficiently related to petitioning activity."[6] Although the scope of *Noerr* immunity necessarily "varies with the context,"[7] a "claim of *Noerr* immunity cannot be dismissed on the ground that the conduct at issue involved no 'direct' petitioning of government officials, for *Noerr* itself immunized a form of 'indirect' petitioning," namely, "a publicity campaign directed at the general public on the ground that it was part of an effort to influence legislative and executive action."[8] Where a claim is not entirely barred, exclusion of evidence of the protected speech is appropriate.[9]

(continued...)

lobbying has long been recognized as a legitimate part of the governing process protected under the first amendment rights of citizens to assemble and petition the government.").

[3] *Empress LLC v. City & County of S.F.*, 419 F.3d 1052, 1056 (9th Cir. 2005).

[4] *McFarlin v. Gormley*, 2008 WL 410104, *10 (D. Or. 2008); *see also, e.g., City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991) ("That a private party's political motives are selfish is irrelevant."); *Empress LLC*, 419 F.3d at 1057 ("illegal purposes and motivations behind petitioning do not illegalize the petitioning conduct")..

[5] *McFarlin*, 2008 WL 410104 at *10 (citing additional case law).

[6] *Sosa v. DIRECTTV, Inc.*, 437 F.3d 923, 935 (9th Cir. 2006); *see also Pepper v. Routh Crabtree, APC*, Case No. 3AN-07-8568 CI, 3d Jud. Dist. (Order Granting Motion to Dismiss, Jan. 11, 2008) (noting limits on protections afforded to activities "incidental" to litigation) (Rindner, J.).

[7] *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988); *see also Pepper v. Routh Crabtree, APC*, Case No. 3AN-07-8568 CI, 3d Jud. Dist. (Order Granting Motion to Dismiss, Jan. 11, 2008).

[8] *Allied Tube & Conduit*, 486 U.S. at 503.

[9] *See Schwab v. Philip Morris USA, Inc.*, 449 F.Supp.2d 992 (E.D.N.Y. 2006) (noting that because the defendant's "alleged lobbying activities ... may implicate the First Amendment right to petition a government ... [t]he court will hear motions in limine with respect to specific items of evidence offered by plaintiffs on these matters.").

Additionally, independent of federal First Amendment protections, under Alaska law speech "is conditionally privileged if it concerns a matter of public interest,"[10] or "matters of public health and safety."[11] Liability cannot be imposed for such speech unless "the plaintiff proves that the speaker uttered untruths with actual malice."[12] This qualified privilege is not limited to defamation cases.[13]

Here, the plaintiff has recently elicited testimony in discovery regarding Lilly's participation in public policy discussions regarding access to psychiatric medications, and has indicated it will seek to introduce this evidence at trial. During the deposition of Joey Eski, an executive sales representative for Lilly in Alaska, plaintiff's counsel engaged in lengthy questioning about the efforts of Lilly and others to encourage the State to maintain open access to all psychiatric medications, including extensive questioning regarding efforts to influence the Legislature, the Governor, the Department of Human Services and other executive branch agencies on this issue. *See* Eski Deposion at 71-120, 357-61 (copy previously filed with court) and Exhibit A (Eski Deposition Exhibits 3-7, 25-26). Lilly's activities were part of a broader effort led and funded jointly by such well-regarded organizations as the State's own Alaska Mental Health Trust Authority Board, the Children's Mental Health Coordinator and the Alaska Psychiatric Association. *See* Exhibit A at 14- 15, 18-19, 23. The "stakeholders" included the Anchorage District Court's own Mental Health Court and the Anchorage Police Department. *Id.* These efforts to influence public policy, which focused on specific bills before the Legislature and specific policies under

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[10] *Olivit v. City and Borough of Juneau*, 171 P.3d 1137, 1143 (Alaska 2007).

[11] *Taranto v. North Slope Borough*, 992 P.2d 1111, 1115 (Alaska 1999).

[12] *Olivit*, 171 P.3d at 1143.

[13] *See State v. Carpenter*, 171 P.3d 41, 62-63 & n.75 (Alaska 2007) (applying privilege to statements regarding matters of public interest outside defamation context).

consideration by State agencies, fall squarely with the protections of the *Noerr-Pennington* doctrine, as well as the Alaska's common law conditional privilege for speech on matters of public interest.

In addition to the fact that this evidence reflects protected and privileged speech, it would inject confusing and prejudicial material regarding local political personalities into this case. For example, in the questioning surrounding Eski Exhibit 25, plaintiff's counsel made much of a reference on page 4 of the exhibit to an attempted meeting with the wife of "Senator Stevens." *See* Eski Dep. at 357-60 & Exhibit A at 19. Contrary to counsel's implication, the Senator Stevens referred to in Eski Exhibit 25 is the well-respected Gary Stevens of Kodiak; his wife is a well-respected leader in the Native community. The State's attempt to discredit the efforts of Lilly and others to ensure open access to psychiatric medications for those on Medicaid, by implying connections with "Senator Stevens" or other local political figures, confuses the issues, is misleading to the jury, and creates a danger of unfair prejudice.

For these reasons, the Court should bar plaintiff from introducing evidence that Lilly participated in efforts to petition any branch or agency of the State government regarding access to psychiatric medicines.

DATED: March 6, 2008.

Respectfully submitted,

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

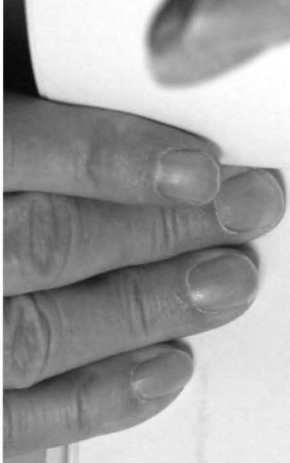
LANE POWELL LLC

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

Attorneys for Defendant

EXHIBIT A

(Eski Dep. Exhibits 3-7, 25-26)



Eski Dep. Exhibit 3

To:	docatfish2002@yahoo.com; mentalh@alaska.nte; mlangdon@provak.org; rnassar@gci.com; worthmore@gci.net; wsnow@peacehealth.org
CC:	CN=Jeffrey M Hattori/OU=AM/O=LLY@Lilly
Date:	04/29/2003 01:49:38 AM
From:	CN=Joey L Eski/OU=AM/O=LLY
Subject:	Physician Letters to Governor, Legislators and Commissioner
Attachments:	Alaska - PA Letter 1.doc; Alaska - PA Letter 2.doc; Alaska - PA Letter 3.doc; Alaska - PA Letter 4.doc

The following documents and addresses should be helpful in communicating your concern over the pending state prior autorization issue.
Thanks for your Support,

Joey Eski,
Eli Lilly & Co.

Alaska - PA Letter 1.doc Alaska - PA Letter 2.doc Alaska - PA Letter 3.doc Alaska - PA Letter 4.doc

Honorable Frank Murkowski
Governor, State of Alaska
P.O. Box 110001
Juneau, AK 99811-0001

fax: 465-3532
Dear Governor Murkowski...

Joel Gilbertson, Commissioner
Department of Health and Social Services
P.O. Box 110601
Juneau, AK 99811-0601

fax: 465-3068
Dear Commissioner Gilbertson...

Representative John Harris, Co-Chair
House Finance Committee
Capitol, Room 507
Juneau, AK 99801-1182

fax: 465-3799
Dear Representative Harris...

Representative Bill Williams, Co-chair
House Finance Committee
Capitol, Room 515
Juneau, AK 99801-1182

fax: 465-3793
Dear Representative Williams...

Senator Lyda Green, co-chair
Senate Finance Committee
Capitol, Room 516
Juneau, AK 99801-1182

fax: 465-3805
Dear Senator Green...

Senator Gary Wilken, co-chair
Senate Finance Committee
Capitol, Room 518
Juneau, AK 99801-1182

fax: 465-4714
Dear Senator Wilken...

Eski Dep. Exhibit 4

ALASKA STATE ACTION TEAM (ASAT) MEETING MINUTES

Monday, March 8, 2004 11:00am – 12:00pm Pacific
Teleconference Call

ATTENDEES

Nate Miles, MPA, Lilly
Kevin Walters, PHDAE, Lilly
Joey Eski, Neuro Institutional Sales, Lilly
Marit van Dort, Contract Advocacy Coordinator
Jeffrey Hattori, Public Affairs Liaison, Lilly
Frank Dorr, DM Institutional, Lilly
Sam Kito, Contract Lobbyist
Barbara Smith, PR Firm, Harris and Smith

ASAT MEETING MINUTES

Objectives:

1. Full MH Medication Carve-Out

Legislative/Administrative Update

MH medication carve-out language is crafted and prepared to be "dropped", if necessary, via Alaska Psychiatric Assoc (supported by the AK Recovery and Choice Coalition) through Rep. Peggy Wilson and supported by Lesil McGuire. Commissioner Gilbertson has mentioned he would protect MH meds administratively rather than legislatively, however, Anti-Depressants are on the agenda for the May 21, '04 P&T Committee and Gilbertson has made public comments that seem to contradict his earlier commitments to protect MH meds including protecting only anti-psychotics and for only this legislative session (versus 1 year). Need to identify interventions to partner with Commissioner Gilbertson…Kevin is working on CNS program.

Action Steps:

- Jeffrey follow-up on MH carve-out language with Psych Assoc and work with Sam to ensure correct language and follow-up with legislators.
- Kevin following up with HSS on CNS implementation.
- Kevin to ensure coverage of P&T members by sales.
- Kevin/Jeffrey work to have a special meeting on MH meds by P&T members…bring in speakers/experts.
- Kevin/Joey/Jeffrey work to have speakers/advocates at P&T meeting to defend MH meds. Joey identified a Larry Ershivski(?) as a potential speaker and will identify someone from the "Bush". Also, will see how we can better work with Lex von Hafften.

PHDAE Update

Kevin reported discussions continue with Commissioner Gilbertson's staff: Bob Labbe and Bill Hogan on CNS intervention. redacted Kevin working with Bob Johnson and Michelle Hansen on Diabetes medication issue. No issues around ADA report.

Action Steps:

- Kevin to follow-up on next steps with CNS and report to ASAT.
- Kevin to work with Nate and Jeffrey on CNS intervention.
- Kevin following up with Dr. Campana and First Health to determine clarity on process for "bidding" with Diabetes meds to be on PDL and will report back to ASAT.

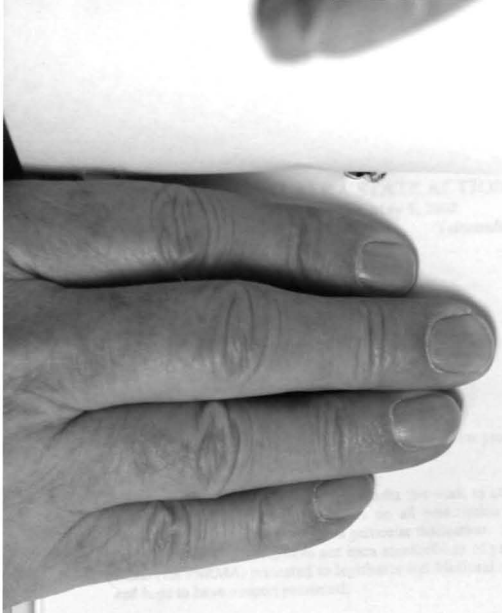
Advocacy Update

Coalition developing that will fight for MH carve-out, led by Psych Assoc, NAMI and others. Bi-weekly conference calls are being held. Preparing letters to legislators for continued push on MH carve out. Jeffrey also reported that the impacts to cuts in CAMA services are having devastating impact on consumers…advocacy groups will seek health outcomes data.

Action Items:

- Jeffrey will work with coalition on MH carve-out based on clarification of Gilbertson's intent to protect MH meds and implementation of CNS.

MEETING SCHEDULE
Next Meeting: Monday, March 29, 2004 11:00am – 12:00pm Pacific 10:00am- 11:00am Alaska
Dial-In Number: 1-877-455-8688 *Participant Code: 539384*



Eski Dep. Exhibit 5

ALASKA STATE ACTION TEAM (ASAT) MEETING

Monday, May 5, 2003 11:00am – 12:00pm (Pacific)
Teleconference Call

ATTENDEES

Jeffrey Hattori, Allied Development Specialist, Lilly
Frank Dorr, DM Neuro, Lilly
Bill Thomas, Contract Lobbyist Associate
Kevin Walters, PHDAE, Lilly
Nelda Stewart, Contract Lobbyist Aide (Sam Kito)
Amy Daugherty, Contract Advocacy Coordinator

ASAT UPDATES

Overarching Goals
Protect all Lilly Products, in particular Zyprexa, and new products.

Legislative Environment
Jeffrey reported that Nate will be in Alaska this week to attempt to secure a MH medication exemption. The legislature is moving forward to implement a PA on all prescription medications administratively and may create minimums and maximums number of scripts for a particular medication. PhRMA is attempting to add amendments to the bill with Chair Max Williams, however, have not been successful as of yet. The bill currently is in the House Finance Committee. Don Muse (via PhRMA) presented to legislators and Medicaid on 4/8 and 4/10 to develop alternative strategies for cost savings and hope to have a report presented.

Nate will also try and support efforts at state hospital on "informed consent" issue. Frank and Mary Beth Clements brought this up.

PHDAE Update
Kevin continues to work the Departments and will support efforts via letter writing with Alaska Pysch. Assoc. and CMHCs. Kevin I working with Dr. Campana on cost savings programs and supported arranging meeting with Del Paggio (who is a key advocate for open access).

Advocacy Update
Through the efforts of Frank Dorr, Jon Hett and Joey Eski...nine (9) physicians were secured via Dr. Verner Stillner to support access to MH meds by writing letters or testifying. Dr. Stillner has secured and sent off 5 letters and Joey and Mary Beth are securing more. Jeffrey will work with Joey and Amy to get letters to Governor and co-chairs of the Finance Committee in the House and Senate along with the Commissioner of DHS. We must continue to get letters!!!

NAMI Alaska and MHA Alaska have been hit hard by the budget crisis and will no longer be funded after June 30, 2003. National NAMI is not able to come up to Alaska to help with this issue and the PA due to major crises in other states. Amy is working to get letters.

Amy reported that the MH Commissioner has verbalized that MH medications will not be affected by the PA. However, Amy will try and work with Sam Kito to try and get this in writing. In addition, the MH Board and Trust along with providers are being very careful on how they approach this issue and may not "weigh-in" until the last minute.

Bill Thomas will work with "SEARL"? (Native Community) Executive Director to elicit their support.

Joey Eski had provided a great list of potential advocates including Dr. Verner Stillner, Bartlett Memorial; Pat Murphy, Clinical Director, JAMHI; Jeff Jesse, MH Trust Authority Board; Kate Webster/Richard Rainey, MH Board; Bill Hogan, HHS MH Director; Bob Levy, HHS Deputy Commissioner; Jill Gilbertson, Behavioral Mental Health.

2003 Legislative Battle Plan
Exempt MH medications from any PA. Next steps include:

- Nate will work with Sam Kito this week to secure legislative support.
- Amy will continue to get letters from advocacy organizations and follow-up with MH Commissioner on getting something in writing of his support of protecting MH medications.
- Jeffrey, Joey, Mary Beth, and, Kevin will continue to get letters from "Thought Leaders" and send out ASAP.
- Kevin to develop programs on VOA, differentiation for his customers…Jeffrey will support.
- SALES…please secure letters from physicians who will defend MH and are willing to write letters to media and legislators.

MEETING SCHEDULE
Next Teleconference Call is scheduled for:

Monday, May 19, 2003 11:00am – 12:00pm (Pacific)
Call-In Number: 1-877-455-8688 Participant Code: 539384

Bi-weekly meetings will be scheduled during the legislative session and Nate will provide periodic updates on VMX.

ALASKA STATE ACTION TEAM CONTACT INFORMATION

Nate Miles, Manager Public Affairs, Lilly
425-803-2617/phone redacted nate_miles@lilly.com

Jeffrey Hattori, Allied Development Specialist, Lilly
253-638-7104/phone redacted hattorijm@lilly.com

Kevin Walters, PHDAE, Lilly
253-858-8534/phone walters_kevin_r@lilly.com

Joe Busby, Manager, PHDAE, Lilly joebusby@lilly.com

Brian Stoneking, District Manager, Lilly
redacted 425-803-2685/fax stoneking_brian_d@lilly.com

Jonathon Hett, District Manager, Neuroscience Business, Lilly
425-803-2605/phone hett_jonathon_e@lilly.com

Frank Dorr, District Manager, Neuroscience Institutional, Lilly
425-803-2605/phone dorr_frank_h@lilly.com

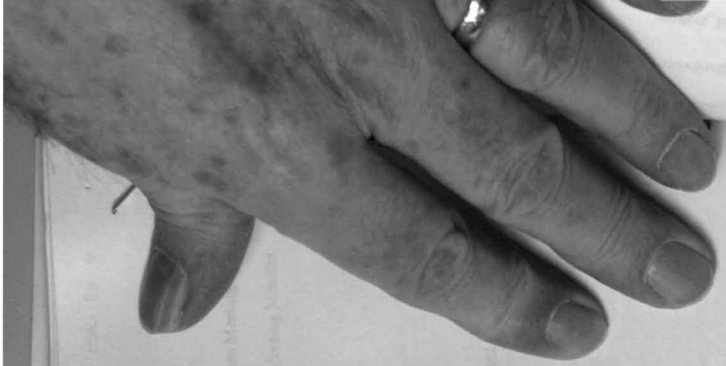
Lisa Lund Fitzer
949-305-2782/phone fitzer_lisa_lund@lilly.com

Trina Clark, Neuroscience Outcomes Liaison, Lilly (8-462-0485)
415-292-6725/phone redacted clark_trina@lilly.com

Amy Daugherty, Advocacy Consultant
907-463-2568/phone amydaugherty@gci.net

Sam Kito, Contract Lobbyist
907-463-5486/phone kitoinc@gci.net

Barbara Harris, PR Firm, Harris and Smith
206-343-0250/phone barbara@harrisandsmith.com



Eski Dep. Exhibit 6

ESKI EX. 6

To: CN=Jeffrey M Hattori/OU=AM/O=LLY@Lilly
Date: 05/08/2003 10:54:31 PM
From: CN=Joey L Eski/OU=AM/O=LLY
Subject: Re: URGENT!!! NEED LETTERS NOW!!! PLEASE READ: Alaska State Action Team Meeting 5/19/03 11:00am Pacific
Attachments: Alaska - PA Letter 1.doc; Alaska - PA Letter 2.doc; Alaska - PA Letter 3.doc; ASAT - Meeting Minutes 05-05-03.doc; PA - Bullet Points.doc

Jeffery,

All these people and more sent letters in directly - I did not request copies - but will try to get them - Joey

Jeffrey M Hattori
05/08/2003 02:18 PM

To: Jonathon E Hett/AM/LLY@Lilly
cc: Joey L Eski/AM/LLY@Lilly, Nathaniel R Miles/AM/LLY@Lilly, Schelly D Cramer/AM/LLY@Lilly
Subject: Re: URGENT!!! NEED LETTERS NOW!!! PLEASE READ: Alaska State Action Team Meeting 5/19/03 11:00am Pacific

Thanks everyone for your help on this...I have five letters from Dr. Stillner and other docs from Bartlett. I know Joey was working on some others...however, here are some others, if you have contact with, who had signed up from the APA meeting:

Mary Langdon	550-2300
Wynelle Snow	228-7660
Mark Samson	529-0061
Carrie Rader	550-2300
David Holladay	745-7080
David Samson	
Wandall Winn	
Ramzi Nassar	
Mari Jeanne Moore	

Thanks again!!!
Jeffrey

Jonathon E Hett

05/08/2003 02:59 PM

To: Schelly D Cramer/AM/LLY@Lilly, Joey L Eski/AM/LLY
cc: Jeffrey M Hattori/AM/LLY@Lilly, Nathaniel R Miles/AM/LLY@Lilly
Subject: URGENT!!! NEED LETTERS NOW!!! PLEASE READ: Alaska State Action Team Meeting 5/19/03 11:00am Pacific

Joey and Schelly,

Please provide me with an update on how this need is being implemented via vmx. Could you also copy Nate and Jeffrey on the vmx.

Thank you in advance for your efforts,

JH
---- Forwarded by Jonathon E Hett/AM/LLY on 05/08/2003 02:55 PM ----

Jeffrey M Hattori

05/08/2003 12:09 PM

To: amydaugherty@gci.net, Jorge Boldrini/AM/LLY@Lilly, Scott J Brown/AM/LLY@Lilly, C Joe Busby/AM/LLY@Lilly, clark_trina@lilly.com, Mary Beth Clements/AM/LLY@Lilly, clouthier_kristen@lilly.com, Frank H Dorr/AM/LLY@Lilly, Joey L Eski/AM/LLY@Lilly, Lisa Lund Fitzer/AM/LLY@Lilly, Michele Hansen/AM/LLY@Lilly, Jonathon E Hett/AM/LLY@Lilly, Robert C Johnson/AM/LLY@Lilly, kitoinc@gci.net, J Jerry Krizbacker/AM/LLY@Lilly, Sean K Murphy/AM/LLY@Lilly, nate_miles@lilly.com, Michael L Overfelt/AM/LLY@Lilly, John R Schultz/AM/LLY@Lilly, Brian D Stoneking/AM/LLY@Lilly, walters_kevin_r@Lilly.com, Kevin Noel Welsh/AM/LLY@Lilly
cc:
Subject: URGENT!!! NEED LETTERS NOW!!! PLEASE READ: Alaska State Action Team Meeting 5/19/03 11:00am Pacific

THE TIME IS NOW TO FULLY ENGAGE OUR BATTLE PLAN TO GET A MH CARVEOUT. PLEASE IDENTIFY ALL ADVOCATES INCLUDING PHYSICIANS TO ENGAGE IN THIS BATTLE.

I HAVE ATTACHED SAMPLE LETTERS BELOW, PLEASE SECURE LETTERS ON LETTERHEAD AND HAVE SENT TO THOSE

ADDRESSED. ALSO, FAX COPY OF LETTERS TO SAM KITO'S OFFICE @ 907-463-3275. NATE IS IN AK RIGHT NOW AND NEEDS THE LETTERS

LEGISLATIVE SESSION IS ENDING VERY SOON AND ACTING QUICKLY....THANKS FOR YOUR HELP!

I have attached the meeting minutes from 5/5/03 and the Physician "Truth Squad" strategy. The next ASAT teleconference call is scheduled for:

WHEN: **Monday, May 19, 2003 @ 11:00am - 12:00pm (Pacific)** **10:00am Alaska**

CALL-IN #: **1-877-455-8688**
PARTICIPANT CODE: **539384**

The draft agenda will include:

Prior Authorization Regulation
Legislative "Battle Plan" Implementation
Updates and strategies (legislative, PR, advocacy, physicians)
Next Steps and Meetings

If there are other individuals who should be on this call, please forward this e-mail. Please e-mail me if you will participate in the meeting or not AND to add any agenda items. Thank you.

Jeffrey Hattori, Ally Specialist
State Government Affairs - PNW Region
Eli Lilly and Company
redacted

ASAT - Meeting Minutes 05-05-03.c Alaska - PA Letter 1.do Alaska - PA Letter 2.do Alaska - PA Letter 3.do PA - Bullet Points.doc

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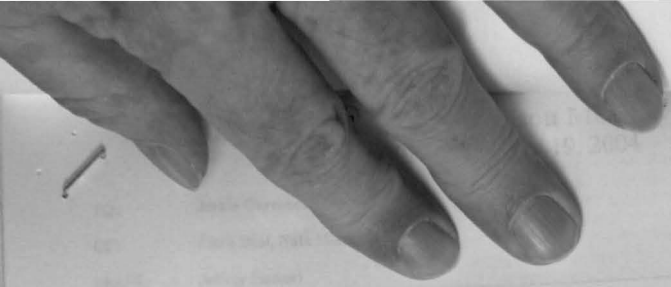


Eski Dep. Exhibit 7

Hattori Public Affairs Liaison Monthly Report

April 20, 2004 – May 19, 2004

TO: Jackie Giovanoni

CC: Chris Beal, Nate Miles

FROM: Jeffrey Hattori

KRA 1 – Pricing, Reimbursement, and Access
1) Mobilize advocates in response to access threats across Lilly's product portfolio including new products.
2) Broaden and deepen advocacy support through the engagement of:
   - Coalitions
   - Professional groups
   - Criminal justice organizations and officials
   - Communities of color
3) Effective and compliant utilization of PR firm.

KRA 2 – Brand
1) Promote the Lilly Brand through programs such as Lilly Answers and external engagement.
2) Support individual brands through disease education materials and programs – special emphasis on new mental health products.
3) Outreach and engagement of diverse communities.
4) Effective and compliant utilization of PR firm.

KRA 3 – Alignment of Corporate Employees
1) Provide support to State Action Team (SAT) objectives.
2) Interact with sales team regarding advocacy.
3) Provide advocacy support for federal and state policy initiatives.

KRA 4 – Corporate Affairs Training and Development
1) Take appropriate coursework according the agreed upon development plan via MPA and Supervisor.
2) Special projects.

KRA 5 – Compliance
1) Comply with all compliance requirements in daily work.
2) Participate in all compliance-training programs.

STATE ACTIVITIES: (narrative or bullets)

Washington (Session Completed)
WSAT "Battle Plan" developed for 2004 legislative session to protect DAW and secure FULL MH medication carve-out. OUTCOME: DAW still in place but did not secure MH carve-out, however, was able to secure additional legislative support to protect MH medications AND able to restore prescriptive authority of atypicals for health care professionals. Currently, working on SAT strategy with MPA and PHDAE in preparation for September P&T meeting that will review atypicals and anti-depressants. P&T meeting originally scheduled for June, however, postponed to allow for CEBP to present its findings. Worked with MPA on Rep. Alexander's MH Medication Forum with legislators, state budget staff and advocates. Successful meeting that exposed significant "holes" in state's depth of understanding and methodology to restrict access. Following up with advocates (WaPIC and NAMI).

- WaPIC continues to address MH medication access and is preparing to engage state Medicaid and P&T committee in September. Participated in Rep. Alexander's MH Medication Forum and will follow-up for further efforts. Hosted a presentation by Trina Clark, Outcomes Liaison, on value of atypicals and unintended consequences (health/fiscal) by restricting access…attended by NAMI WA. Planning is underway for 2nd annual statewide conference in Q3. WaPIC presented to state Medical Association on CJ/MH issues including need for "open access". Attended with WaPIC Executive Director presentation by Dr. Scot Purdon on schizophrenia/cognitive abilities/value of atypicals on 4/20.
- NAMI WA – Working with State President and VP on next steps to increase advocacy and educational efforts including supporting efforts to address state MH systemic, policy and budget issues. Developing plan to coalesce all MH advocacy organizations to work exclusively with legislators and budget analysts and create 1-2 meetings with legislators to address common MH legislative issues/agendas including access to medications.

- Continue to meet with key advocacy organizations/individuals including:

  Mental Health and Health Care Disparities Coalition of Communities of Color/PNW National Black Chamber of Commerce – participated in 4/30 meeting to continue work on SB 8419 that would create a bi-partisan taskforce to address health disparities with communities of color. Coalition will be a primary player in the development of recommendations. Supported and participated in PAP/Health Care Fair in Seattle on May 20. Served as luncheon speaker and had LillyAnswers display. Supporting summer MH forum with Dr. Rahn Bailey, tentatively scheduled for July 13/14 and will address cultural competency and access. Coalition preparing for September P&T meeting.

  ARNPs United – met with Legislative Chair to discuss strategy and issues including P&T meeting. They are very concerned and mentioned they would be at P&T meeting to testify.

  WA AAFP – developing relationship with Executive Director, Carla Pratt (meeting on June 7)…brokered by Patty Conroy, PAL.

  PNW JACL – discussed with Regional Director (in Seattle) and Governor (in Anchorage) and key Seattle Chapter Board members including President-Elect incorporating health (mental health) disparity issues as part of advocacy efforts.

  Denise Louie Early Childhood Education Center – discussed follow-up to children's MH issues community forum.

  City of Seattle, Division on Youth and Family Services – met with Director (former state legislator) to discuss state MH issues with emphasis on communities of color.

  Attended "Asian Pacific Islander Elected Officials" event with MPA on 5/4; attended Neighborhood House Fundraising Breakfast on 4/29 on behalf of Lilly.

  Held series of meetings with communities of color organizations and individuals to increase advocacy efforts (including supporting a Asian Pacific Islander Community Summit of 10,000 on advocacy…I am serving as a panelist on legislative advocacy activities) and education on mental health/health care.

- Implementing with PR Firm 6 month work plan that will redirect efforts towards more PR efforts for Lilly and general MH/prescription drug issues including supporting media efforts with product launches, issues including hyperglycemia/diabetes, importation, utilization/dissemination of "Library" materials, preparation to discuss new Medicare bill implications, promote LillyAnswers, and other efforts.

Oregon (Next Session in January '05)

Participated in Mental Health Matters (MHM) meeting on 4/28/04. MHM sent letters to Gov's Task Force on MH to protect MH services and RX benefit for OHP Plus and Standard populations. MHM developing strategy to incorporate their recommendations on MH services and access to medications to present on May 27 at Gov's Task Force on MH. In addition, most MHM members are on state's CNS Stakeholders group and are advocating against an algorithm that promotes "cheapest first" being introduced by Office of Mental Health/Addiction Services.

- NAMI Oregon – Working with new Executive Director, Angela Kimball, on reorganizing state organization. Continue to facilitate an overall strategic/marketing plan to increase NAMI OR "brand", membership and operations to support education/advocacy efforts.
- Participated in OR PIC Executive Committee meeting on 5/6/03l. Marion County (Salem) Sheriff Raul Ramirez, Local Public Safety Coordinating Council Chair, Multnomah County (Portland) Commissioner Lisa Naito, and Clackamas County Mental Health Court Judge Robert Sealander, are OR PIC State Co-Chairs. Interim Executive Director Jeff Davis who is former Marion County MH Director and advocate for open access. Currently a co-chair to develop short and long term goals for OrPIC and have developed and presented mission, objectives, and principles for short/long term goals. Recommendations have been accepted to present to Steering Committee.
- Working with OSAT and PR Firm to implement statewide PAP/Health Care Fair in Portland in May 2004. Goal is to have 100 attend including Governor, legislators, state departments, media, advocacy groups, seniors and others participate.
- Continue to meet with key advocacy organizations including:

  African American Health Coalition (AAHC) – planning a "depression" forum for African American women in Q3 '04. Dr. Marilyn Martin to speak and supported by Senator Avel Gordly and Margaret Carter.

  SMG Foundation – sponsoring a major Latino MH and Family Health Fair and Forum on 5/21 and 22 that will include PCPs and key legislative and state staff. Notion is to discuss and promote solutions (including access to meds) to treat depression and discuss public policy issues that support more

access and utili[illegible]n of Latino's in the MH system. Also, di[illegible]ng the creation of a communities of color coalition on MH...working with Executive Director and OHSU's Multicultural Health Dept.
Coalition for Responsible Treatment – Brokered meeting with OACMHA to discuss partnership at state and federal levels. Supporting planning efforts for May 27 conference on senior mental health issues.
MHA Oregon- met with President to discuss strategy and CEBP.
Oregon Advocacy Center (part of MHM and ORPIC) - met with Executive Director to discuss developing strategies to ensure patient protections. Concept revolves around incorporating aspects of "Environmental Impact Studies" that would require a further analysis of measuring health outcomes and fiscal impacts (unintended consequences) of any legislation or administrative rule that would cut access to MH medications and health services.
CADO - met with consultant, Elizabeth Byers (former Executive Director of MHA Oregon) on efforts to support "wellness" (nutrition and exercise) for individuals with mental illness.
Cascadia Behavioral Health – met with coordinator, Jackie Strong, of African American community/Criminal Justice/Mental Health effort to discuss solutions/strategies.

Hawaii (Session Completed) (Visited April 21-23)
HSAT "Battle Plan" developed for 2004 legislative session to secure FULL MH medication carve-out.
OUTCOME: Secured via lead efforts by MPA and Contract Lobbyist a "carve-in" of MH medications in HI "RX Plus" program. Budget proviso protecting MH meds in Medicaid FFS in place through June '05. Currently, working on SAT strategy to educate key legislators, providers, advocates, and, bureaucrats on clinical/fiscal value of "open access". Planning a MH Medication Forum with legislators, state budget staff and advocates.

- Met with and continuing efforts working with Mental Health Collaborative/"Five Families" that include MHA in Hawai'i, NAMI Hawaii, NAMI Oahu, Hawaii Families as Allies (children's mental health), and, United Self-Help (MH consumer group). Serving as "at-large" member of collaborative to support development of legislative priorities and organizational structure. Members held series of meetings/communications with key legislators to protect MH medications. Scheduling a presentation by United Self Help to Majority Caucus in June on MH and need for open access. Overall strategy is to develop an "empowerment" program to educate and mobilize consumers, family members and other key stakeholders to be more active in the political process including presentations to candidates on MH issues, candidates forums, voter registration and GOTV, and, community MH forums. Briefed members on implications of Multi State Purchasing Pool...two members are writing letters of concern to appropriate entities/individuals.
- Met with HI Clinical Research Center's Director and Coordinator to discuss community forums on MH meds. Supportive of "open access".
- Continue working with "Five Families" to engage criminal justice system on MH issues including access to medications. Next steps include a statewide conference on CJ/MH issues in Q3 '04.
- Continue supporting PHDAE on implementing a CNS type intervention. Meetings being scheduled for 2nd week of June to present CNS to state DOH and Medicaid offices and advocates. In addition, supporting PHDAE and Contract Advocacy Coordinator on P&T processes...First Health recently contracted to implement PDL.

Alaska (Session Completed) (Visited May 12-15)
ASAT "Battle Plan" developed for 2004 legislative session to secure FULL MH medication carve-out.
OUTCOME: Full MH Medication Carve-Out Legislation, proposed by AK Psychiatric Association, was removed in House Rules. "Medically Necessary" (Dispense as Written) provision also did not get of the Senate. Currently, implementing SAT strategy with MPA and PHDAE in preparation for the September P&T Meeting that will review anti-depressants and ADHD medications. Alaska appears to have contracted with CEBP and has postponed the P&T meeting, originally scheduled for May to allow for CEBP to present its review of Anti-Depressants. Planning a MH Medication Forum with legislators, state budget staff and advocates prior to P&T.

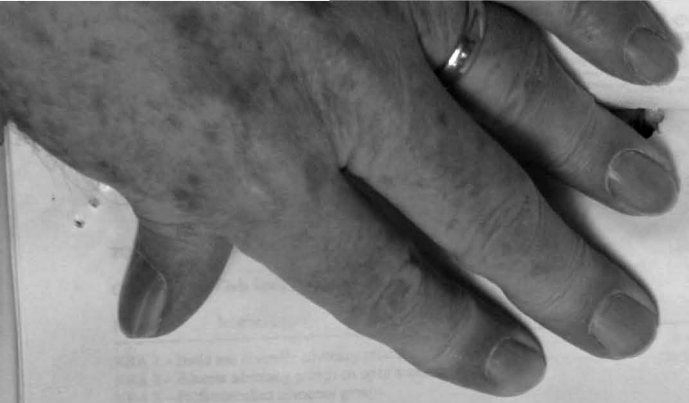
- Participated in three "Recovery and Choice" coalition meetings (4/23/04, 4/30/04, 5/7/04) led by NAMI AK and AK Psychiatric Association. Other members include AK MH Board, Provider's Association, and Criminal Justice to fight for open access to MH medications, MH funding, CJ efforts, parity, and, children's MH. Coalition members worked in coordination to testify, call and/or write legislators on MH funding and access to MH meds. Coalition is now preparing for September P&T meeting. Received and unsolicited request from coalition to have clinical/cost data on anti-depressants and ADHD meds presented by Outcomes Liaison...currently scheduling

August. Briefed the Coalition on CEBP and implications of Multi State Purchasing Pool. Coalition members concluded they would send letters of concern to appropriate entities/individuals. Met with Legislative Chair, AK Psych Assoc to further develop coalition.

- Attended and participated in NAMI AK State Conference and First Annual "WALK". Met with President, Board Members, Legislative Coordinator, and, Executive Director to continue development of a more education, funding and advocacy strategy. Access to MH meds was key topical/discussion item. Supported Kathy Conkrite (Walter Conkrite's daughter) as keynote speaker on depression (supported utilization of anti-depressants...good speaker).
- Met with key members of criminal justice system including AK MH Board Executive Director, Anchorage Police CIT Director and Anchorage MH Court to discuss replicating "Partners in Crisis". Strong potential...will continue to support efforts.
- Met with AK Disability Law Center to discuss joining coalition and developing strategies to ensure patient protections. Concept revolves around incorporating aspects of "Environmental Impact Studies" that would require a further analysis of measuring health outcomes and fiscal impacts (unintended consequences) of any legislation or administrative rule that would cut access to MH medications and health services.
- Developing relationship with AK AAFP's Executive Director and Legislative Chair. Held phone conversations...brokered by Patty Conroy, PAL.
- Continuing efforts to support PHDAE to coordinate efforts with AK Pysch Assoc.'s Leg. Chair to support implementation of CNS with Department of Health Social Services (HSS). Also working with PHDAE and MPA to support the creation of an advisory committee for HSS on MH medications (specifically for Atypicals) to support an administrative protection.
- Working with PR Firm to implement PR efforts for Lilly and general MH/prescription drug issues including supporting media efforts with product launches, issues including hyperglycemia/diabetes, importation, utilization/dissemination of "Library" materials, preparation to discuss new Medicare bill implications, promote LillyAnswers, and other efforts.

Other

- Participated in and/or co-led WA, OR, AK, and, HI State Action Team meetings.
- Participating in Lilly MH Summit/Advocacy Conference Planning Group meetings...supporting agenda development.
- Participating in Lilly strategy efforts to rebuff "Center for Evidence Based Policy"...supporting PAL efforts.
- Participating in Multicultural Advisory Board Development with Cymbalta Brand including Asian Pacific Islander representation. Developing relationship and objectives with Courtney Lang to engage Asian/Pacific Islander, African American, Latino, and, Native American National Mental Health Organizations.
- Hosted Patty Conroy, PAL, and Stephen Loaiza who met with Peter Lukevich, Executive Director, and Judge Mark Chow, State Co-Chair, to discuss potential development of a "Partners in Crisis" in Pennsylvania.
- Met with NAMI Regional Director to discuss "state of the states" (WA, OR, HI, AK).
- Met with new OR/AK DM, Carsten Brunn, to update on SAT efforts in each state and value of Lilly PAC.
- Met with new WA/OR DOC AE, Dane Roberts, to discuss strategies.
- Participated in SGA Multi-State Purchasing Pool Conference Call.
- Participated in SGA Compliance and LGO Conference Call.
- Participating in PAL conference calls.
- Made two PAC Presentation to North Seattle Neuro and Portland Neuro...secured new members and few who upgraded.



Eski Dep. Exhibit 25

Hattori Public Affairs Liaison Monthly Report

August 20, 2003 – September 19, 2003

TO: Jackie Giovanoni

CC: Chris Beal, Nate Miles

FROM: Jeffrey Hattori

KRA 1 – Build and diversify advocacy relationships
KRA 2 – Educate advocacy groups on open access
KRA 3 – Professionalize advocacy groups
KRA 4 – Mobilize advocacy groups
KRA 5 – Provide support to state action team

STATE ACTIVITIES: (narrative or bullets)

Washington (Legislative Session Complete)
Secured "Dispense as Written" (DAW) provision and partial MH medication carve-out ("Continuity of Care") for anti-psychotics and anti-depressants. WSAT "Battle Plan" developed for 2004 legislative session to protect DAW and secure FULL MH medication carve-out.

- WaPIC planning has occurred for statewide conference in early November, development of regional PICs, strengthening membership base and legislative strategies, roll-out WaPIC video, schedule statewide media tour, and, working with communities of color. Steering Committee meeting is scheduled for September 24 to discuss conference, membership, and legislative agenda including access to MH meds. WaPIC will hire former Contract Lobbyist of NAMI WA who will also coordinate with NAMI WA's new Advocacy Coordinator. Peter Lukevich, WaPIC ED, King County Sheriff Dave Reichert, King County MH Court Judge Mark Chow presented at the NAMI WA statewide conference on 9/12 on their efforts and received several standing ovations. Working with Parity Coalition on "aligning" on issues including access to MH meds.
- NAMI WA – supported their statewide conference on 9/12 and 13 in Bellevue. WaPIC and Steven Loaiza, ED, NAMI Oregon presented on issues including access to meds. Secured via MPA, King County Exec. Ron Sims (who is running for Governor) to speak as well. Over 600 were in attendance and Lilly was the primary sponsor. Continued support and development of increasing advocacy infrastructure/efforts at the affiliate level that will include participating in a statewide media tour. Meeting with Board Chair of Advocacy and new Advocacy Coordinator the week of 9/22 to discuss legislative agenda. Working with NAMI President, VP and ED to develop a new statewide marketing campaign to assist with "branding" and to deliver key messages…have engaged PR Firm to assist. Working with Whatcom and Pierce Affiliates to develop a statewide consumer network and programs to support advocacy across the state…strategies include "In Our Own Voice" that will target policy makers, e-mail database and newsletters.
- Continue working with District Managers, Sales Reps, PHDAE, and, PR Firm to develop/engage a Physicians "Truth" Squad to support access to medications and to serve on P&T Committee. Current efforts are to build additional physician advocates across the state.
- Continue to meet with key advocacy organizations/individuals including:

  Mental Health and Health Care Disparities Coalition of Communities of Color/PNW National Black Chamber of Commerce – facilitated Steering Committee meeting on August 20 to implement goals, priorities, and infrastructure to advocate on MH issues for communities of color. Cultural Competency, Criminalization and Access to Services and Treatment are the priorities. A preliminary report has been developed and delivered to the Governor and key legislators to announce the group's efforts. In addition, a database is just about completed for mass communication to support advocacy effort and development of a coalition and e-mail newsletter distribution list. Planning "mini-forums" throughout 2003 to prepare advocacy in 2004. Dr. Rahn Bailey spoke at the Health Care and Mental Health Disparities forum on September 5th. Dr. Bailey delivered key messages on open access and cultural competency. Media efforts including TV and print are being secured. Presentations to

Governor, King County Board of Health, and King County MH Advisory Board is scheduled for October. A grant from King County is forthcoming to the African American Community Health Network to support outreach to communities of color on MH issues.

American College of Nurse Practitioners and WA ARNPs United – Met with Marketing/Development person of ACNP and ED of ARNP to discuss partnerships and alignment on key legislative issues. Initial projects will include sponsoring a forum for all ARNPs on ADHD (children and adults) and on Strattera, announcing launches of Lilly meds and studies on current meds in their newsletter and website, and sponsoring a "summit" meeting with leadership from the Medical, Psychiatric, Physician's Assistants, Family Practitioners, and others on identifying key legislative areas of agreement including access to MH meds for '04.

Women's Center at University of Washington – met with ED to discuss the development of a program/campaign to support women's health and advocacy. Will target communities of color. Will tie in with Mimi Reid's efforts on Osteoporosis.

Therapeutic Health Services Clubhouse – met with Clubhouse who will work with me to enhance their current advocacy efforts in '04 and develop "train the trainer" efforts for other clubhouses. MH Forum with key legislators is scheduled for November '04…assisting with agenda.

NABVETS – discussed programs and advocacy efforts for '04 session with Commander of WA St. Will work closely with the MH COC group and help engage other veteran groups.

Snohomish County Executive – assisted with the WaPIC lobbyist on a forum (8/25) with a candidate running for Exec who is currently a state Senator with communities of color. Senator has been helpful on our issues.

Sponsored and participated in Minority Executive Director's Coalition Dinner on 9/19 and SeaMar Health Centers Golf Tournament on 8/25. These are key potential advocates with communities of color.

Oregon (Legislative Session Complete)

Advocates successful in protecting all MH medications from being prior authorized, however, Office of Mental Health and Substance Abuse are looking to do TMAP, pill splitting and other strategies that could impact access. Advocates are fully engaged in battling to protect MH medications, in particular, anti-depressants.

Revenue package has passed both Houses…however, will be voted on in February '04. Continue working with PHDAE, PR Firm and Contract Lobbyist to support "Mental Health Matters" (MHM) Campaign to ensure passage. Other "wins" include mitigating cuts to MH funding, restoring services for "standard" population and some for "medically needy", and, defeating and "anti-parity" bill for small businesses. In addition, providing support for CNS program.

- NAMI Oregon – facilitated a meeting on 9/11 to develop a strategic/marketing plan to increase NAMI OR "brand", membership and funding to support advocacy efforts. Have negaged PR Firm to assist in this area. Goal is to "touch" at least 1 out of 4 Oregonians to be aware of NAMI and to act (including voter registration and GOTV) on issues and legislators that support MH. Working with ED and Public Policy Staff to develop a B2G intervention that will support continued coalition development, advocacy training, engaging the criminal justice system (proposal funded by Chris Beal for OPIC development), and creating an e-mail newsletter.
- Older Adult Consumer Mental Health Association (OACMHA)/Coalition for Responsible Treatment – Partnership being developed with OACMHA (national consumer MH organization) in which a forum and focus group will be held in October to identify specific senior MH issues in Oregon. Funding has been secured via Chuck Gurierro and state advocacy budget.
- CRT - Planning two forums including legislative and Health Care Disparities in the context of MH. Key partners include African American Health Coalition, Native American Rehabilitation Association, Hispanic Services Roundtable, and, Asian Health and Service Center. Forum will occur in October.
- Working with District Managers, Sales Reps, PHDAE, and PR Firm to develop a Physicians "Truth" Squad to support access to medications. Sales reps and PHDAE have identified 7 physicians supported by the PR firm to write letters to media and legislators, op-eds, testimony, etc.
- Continue to meet with key advocacy organizations including:

  MHA of Oregon – met with President to discuss strategic plan and further consumer advocacy.

  OHP/OMAP Directors Meeting – attended meeting on 9/8 that discussed how to "control" costs of MH meds. Brought NAMI Assistant Director with me to attend.

Hawaii (Legislative Session Complete)
A budget proviso was placed in bill which MH medications were funded and protected from any type of restrictions. Advocates preparing to ensure that a FULL MH carve-out is secured in '04 session.

- Continued efforts working with MPA, Contract Advocacy Coordinator on advocacy strategy including the development of a Mental Health Collaborative/"Five Families" that include MHA in Hawai'i, NAMI Hawaii, NAMI Oahu, Hawaii Families as Allies (children's mental health), and, United Self-Help (MH consumer group). Serving as "at-large" member of collaborative to support development of legislative priorities and organizational structure. Current plans call for Contract Advocacy Coordinator (who will invite key legislators, department staff and other organizations) to support implementing monthly forums on key MH issues including access, criminal justice, service provision, funding, and, parity in preparation for the '04 session.
- Continued efforts with Hawaii Psychiatric Medical Association, Hawaii Psychiatric Nurse's Association (met with past President on programs) and Hawaii (National) Medical Association. Also, developing relationships with new organizations including Safe Haven (Psych/ED supports open access) and Hale Ipu Kukui Alaka'i who work with seniors and disabled.
- Working with NAMI Hawaii to engage criminal justice system on MH issues including access to medications. Working with Lt. Governor's Office, State Corrections. Attorney General's Office, and, Public Defenders with NAMI HI and Contract Advocacy Coordinator to begin work on CJ/MH effort. Contract Advocacy Coordinator will pursue relationship with "Five Families" to participate in AG Office led MH Task Force, support MH court, CIT efforts, and, access to services and treatments. PHDAE will secure funding for start-up efforts. Will bring King County MH Court Judge Mark Chow out to provide technical assistance on creating a MH court on 11/3 & 4 and meet with key CJ stakeholders on the value of developing a PIC.
- Continue working with PHDAE, Outcomes Liaison, Contract Advocacy Coordinator, and, Sales Representatives to develop and implement programs for department and advocacy organizations on VOA, unintended consequences of PAs and PDLs, cost effective strategies w/o limiting access throughout 2003. Supporting efforts of PHDAE on State Psychiatric Hospital's efforts to implement TMAP implementation and discuss Disease State Management programs. Another program will involve Atypicals and Diabetes to address the Zyprexa/Diabetes issue. In addition, will work with Contract Advocacy Coordinator to develop and implement media and advocacy trainings in preparation for next legislative session.
- Working with District Managers to develop a Physicians "Truth" Squad to support access to medications. Sales reps will identify physicians who will be supported by the PR firm on letters, op-eds, testimony, etc. Goal is to have five secured. Have secured 4.

Alaska (Legislative Session Complete) Visited AK on 8/26-28
A number of provisions/amendments have been placed in the PDL bill, which will effectively stall implementation. Working with advocates to ensure that a "Dispense as Written" (DAW) and FULL MH carve-out is secured in '04 session.

- Working with NAMI Alaska President and Children's MH Coordinator to develop a more effective advocacy strategy and engagement of criminal justice system to ensure access to MH meds and funding. Providing a two grants to support "In Our Own Voice" type consumer program that includes a family member, consumer, and police officer who will target presentations to legislators, policy makers, law enforcement, and, community in five key target areas: Anchorage, Juneau, Ketchikan, Fairbanks, and, Valdez. In partnership with PHDAE, have developed relationship with AK Mental Health Trust Authority Board who will co-fund at $19,000.00.
- Working with AK Psychiatric Association President to develop legislative/advocacy training in October will be supported by Contract Advocacy Coordinator. Working with PHDAE to coordinate efforts Leg. Committee Chair to discuss advocacy strategies on "open access" while considering potential interventions like CNS. In addition supporting an ad-hoc committee that has been developed, led by Leg. Comm. Chair, to serve as an advisory group to Governor and Health and Social Services on MH medication issues. (working with PHDAE and MPA on this). Helped create a "White Paper" on access to MH meds that will be presented to Governor and Commissioner of Health and Social Services.
- Continued work to develop an AK Partners in Crisis Network, at a minimum…met with MH Court Judge, Anchorage Police, NAMI – Anchorage to develop initial list of stakeholders to invite for a presentation on PIC in mid-October. Discussed "Lobby Day" planning. PHDAE will support via funding. Met with Director of State Corrections to discuss how Lilly could be helpful with reducing recidivism in jails.

- Met with NAMI Juneau and Polaris House (consumer clubhouse)... will develop an advocacy strategy for '04.
- Working with Contract Lobbyist and Advocacy Coordinator to engage Native Communities including the Alaska Federation of Natives and mental health counselors. Met with CEO of Alaska Native Health Center in Anchorage to discuss issues around co-occurring disorders and how limiting access to MH meds would negatively impact the disproportionate number of Natives who suffer. Will need to follow-up through contract lobbyist. Scheduled meeting with Rita Stevens (Kodiak and wife of Sen. Stevens) and Harriett Cutshall (Main Office – Anchorage).
- Working with WA PR Firm to develop media campaign.
- Engaged advocates to continue efforts on supporting open access to MH meds (HSS conference call scheduled for 9/19) also continue to testify on a potential administrative rule that the Department of Health and Social Services is considering eliminating in-patient hospitalization and nursing home services from the "Chronic and Acute Medical Assistance" (CAMA) program. This will affect mentally ill, offenders in corrections, and native communities. Also, will limit number of prescriptions (3 a month) that would be filled.
- Met with Jerry Jenkins who is with the Providers Coalition (CMHCs) to discuss coalition development and legislative advocacy. They promote "choice" for providers and consumers, which will form the basis for advocating for access to MH meds.
- Worked with District Managers and PR Firm to develop a Physicians "Truth" Squad to support access to medications. Sales reps identified 20+ physicians who wrote letters and called legislators during the session. Will work to develop more of a relationship with Medical Association.
- Met with various staff of key legislators to reinforce support of access to MH meds.
- Working with PHDAE, Outcomes Liaison, Contract Advocacy Coordinator, and, Sales Representatives to develop and implement programs for department and advocacy organizations on VOA, unintended consequences of PAs and PDLs, cost effective strategies w/o limiting access throughout 2003.

Other

- Coordinated and participated in WA, OR, AK, and, HI State Action Team meetings.
- Attended Lilly MH Advocacy Conference in Chicago and assisted with securing speakers for the Cultural Competency Mental Health Panel discussion at the Fall National Advocacy Conference. Secured Janet SooHoo (Asian Pacific Islander) and Jeff King (Native American). Outcomes from conference includes attempting to secure Joel Roberts to provide media training at the WaPIC conference and a regional training for WA, OR, HI, and, AK. Working with Chris Beal for funding. Will be scheduled in November (probably 11/4 & 5). In addition, a monthly conference call will be scheduled for attendees at the Advocacy Conference from all of my states to discuss best practices on advocacy including PIC development and state legislative issues.
- Assisting NAMI Regional Director on Q3 Medicaid/Advocacy Conferences and Q4 conference on engaging the criminal justice system..

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Hattori Public Affairs Liaison Monthly Report

September 20, 2003 – October 19, 2003

TO: Jackie Giovanoni

CC: Chris Beal, Nate Miles

FROM: Jeffrey Hattori

KRA 1 – Build and diversify advocacy relationships
KRA 2 – Educate advocacy groups on open access
KRA 3 – Professionalize advocacy groups
KRA 4 – Mobilize advocacy groups
KRA 5 – Provide support to state action team

STATE ACTIVITIES: (narrative or bullets)

Washington ('03 Legislative Session Complete – '04 Session starts January 2004)
Secured "Dispense as Written" (DAW) provision and partial MH medication carve-out ("Continuity of Care") for anti-psychotics and anti-depressants. WSAT "Battle Plan" developed for 2004 legislative session to protect DAW and secure FULL MH medication carve-out.

- WaPIC planning has occurred for statewide conference on 11/3-5/03. Content/outcomes will include development of regional PICs, strengthening membership base, legislative strategies, roll-out WaPIC video, schedule statewide media tour, and, working with communities of color. Participated in Steering Committee meeting on 9/24 to discuss conference, membership, and legislative agenda including access to MH meds. WaPIC has hired former Contract Lobbyist of NAMI WA who will also coordinate with NAMI WA's new Advocacy Coordinator. Scheduling a media training for early December 2003 for key "go-to" advocates, roughly 25-30, from WA, OR, AK, and, HI. Training will provided by Joel Roberts and Harris and Smith (WA PR firm) and includes message development and delivery to legislators, print, and radio. Working with Parity Coalition on "aligning" on issues including access to MH meds.
- NAMI WA – Continued support and development of increasing advocacy infrastructure/efforts at the affiliate level that will include participating in a statewide media tour. Providing funding to assist via B2G funds. Met with Board Chair of Advocacy and new Advocacy Coordinator to discuss legislative agenda for '04 including MH carve out. Working with NAMI President, VP and ED to develop a new statewide marketing campaign to assist with NAMI "branding" and to deliver key messages…have engaged WA PR Firm to assist. Working with Whatcom, Pierce, and Walla Walla affiliates to develop a statewide consumer network and programs to support advocacy across the state…strategies include "In Our Own Voice" that will target policy makers, e-mail database and newsletters.
- Continue working with District Managers, Sales Reps, PHDAE, and, PR Firm to develop/engage a Physicians "Truth" Squad to support access to medications and to serve on P&T Committee. Current efforts are to build additional physician advocates across the state.
- Continue to meet with key advocacy organizations/individuals including:

  Mental Health and Health Care Disparities Coalition of Communities of Color/PNW National Black Chamber of Commerce – Cultural Competency, Criminalization and Access to Services and Treatment are the priorities. A preliminary report has been developed and delivered to the Governor and key legislators to announce the group's efforts. This effort has spurred a key African American Senator to push for an ad-hoc task force to be created via the Democratic Caucus. In addition, a database is just about completed for mass communication to support advocacy effort and development of a coalition and e-mail newsletter distribution list. Planning "mini-forums" throughout 2003 to prepare advocacy in 2004. Next meeting is scheduled for 10/22/03. Presentations to Governor, King County Board of Health, and King County MH Advisory Board are scheduled for October/November. A grant from King County is forthcoming to the African American Community Health Network to support outreach to communities of color on MH issues. A

Legislative/Mental Health Reception is being scheduled in mid-February '04 in conjunction with African American Lobby Day to further advocacy efforts.

American College of Nurse Practitioners and WA ARNPs United – Met with Marketing/Development person of ACNP and ED of ARNP to discuss partnerships and alignment on key legislative issues. Initial projects will include sponsoring a forum for all ARNPs on ADHD (children and adults) and on Strattera, announcing launches of Lilly meds and studies on current meds in their newsletter and website, and sponsoring a "summit" meeting with leadership from the Medical, Psychiatric, Physician's Assistants, Family Practitioners, and others on identifying key legislative areas of agreement including access to MH meds for '04. The summit is planned for early December '03. Secured Marketing/Development Coordinator of ACNP to attend Lilly "Open Access" Conference in Phoenix – 10/17-19/03 who will use to develop agenda item on "open access" at their national conference.

Therapeutic Health Services Clubhouse – met with Clubhouse who will work with me to enhance their current advocacy efforts in '04 and develop "train the trainer" efforts for other clubhouses. MH Forum with key legislators is scheduled for November 21, 2004...assisting with agenda.

International District Housing Alliance – developing pilot project with MH Court Judge Mark Chow, HUD Region X, and, King County Housing Authority to provide housing support for individuals to be referred.

NABVETS – discussed programs and advocacy efforts for '04 session with Commander of WA St. Will work closely with the MH COC group and help engage other veteran groups.

Sponsored and participated in WA St. Latino Healthcare Conference in Yakima on 925-26/03. Met with state and national Latino organizations that support access. Sponsored and spoke at the "Getting Involved with Government" forum in Snohomish County on 10/03/04 to support advocacy efforts of people of color. Sponsored and spoke at NW Asian Weekly Dinner which honored key physicians of color on 10/11/03...Lilly was a primary sponsor.

Oregon ('03 Legislative Session Complete – next session in January '05)

Advocates successful in protecting all MH medications from being prior authorized, however, Office of Mental Health and Substance Abuse are looking to do TMAP, pill splitting and other strategies that could impact access. Advocates are fully engaged in battling to protect MH medications, in particular, anti-depressants.

Revenue package has passed both Houses...however, will be voted on in February '04. Continue working with PHDAE, PR Firm and Contract Lobbyist to support "Mental Health Matters" (MHM) Campaign to ensure passage. Other "wins" include mitigating cuts to MH funding, restoring services for "standard" population and some for "medically needy", and, defeating and "anti-parity" bill for small businesses. In addition, providing support for CNS program.

Governor has called for the development of a MH Taskforce to provide recommendations on a more effective and cost effective system. Working with MPA, Contract Lobbyist, PHDAE, and "MHM" to ensure that we have key legislators, advocates and providers (12 members out of 21) to ensure that we have the right messages and votes.

- NAMI Oregon – facilitating a strategic/marketing plan to increase NAMI OR "brand", membership and funding to support advocacy efforts. Have engaged PR Firm to assist in this area. Goal is to "touch" at least 1 out of 4 Oregonians to be aware of NAMI and to act (including voter registration and GOTV) on issues and legislators that support MH. Working with ED and Public Policy Staff to develop a B2G intervention that will support continued coalition development, advocacy training, engaging the criminal justice system (proposal funded by Chris Beal for OPIC development), and creating an e-mail newsletter. Meeting with key criminal justice leaders including Oregon Sheriffs Assoc and Local Public Safety Coordinating Council Chair and Staff week of 10/20/03. Supporting efforts to further the "Latino Outreach" program of NAMI.
- Older Adult Consumer Mental Health Association (OACMHA)/Coalition for Responsible Treatment – Partnership being developed with OACMHA (national consumer MH organization) in which a forum and focus group will be held in November to identify specific senior MH issues in Oregon. Funding has been secured via Chuck Gurierro and state advocacy budget.
- CRT - Planning two forums including legislative and Health Care Disparities in the context of MH. Key partners include African American Health Coalition, Native American Rehabilitation Association, Hispanic Services Roundtable, and, Asian Health and Service Center. Forums will occur in November.

- Working with District Managers, Sales Reps, PHDAE, and PR Firm to develop a Physicians "Truth" Squad to support access to medications. Sales reps and PHDAE have identified 7 physicians supported by the PR firm to write letters to media and legislators, op-eds, testimony, etc.
- Continue to meet with key advocacy organizations including:

  African American Health Coalition – planning a "depression" forum for African American women in 12/03. Will seek Dr. Marilyn Martin to speak. Funded and participated in their Wellness Village on 10/18/03.

  Native American Rehabilitative Association – providing funding through PHDAE on research of NA MH needs and issues.

  SMG Foundation – funding a major Latino MH and Women's health fair and forum in 5/04 that will include PCPs and key legislative and state staff. Notion is to discuss and promote solutions (including access to meds) to treat depression and discuss public policy issues that support more access and utilization of Latino's in the MH system.

  International Traditional Childbearing Association – sponsored and attended the Annual Conference on 10/18/03. Funding was used to engage a speaker, President of African American MH Professionals of WA, to discuss MH and depression for women including post-partum.

  Oregon Commission for Women – sponsored and attended annual dinner on 10/4/03. Working with ED to reestablish efforts on women's health.

  Cascadia Behavioral Health – met with major provider in Multnomah County to discuss and partner on Communities of Color and Partners in Crisis. Working with PHDAE.

Hawaii ('03 Legislative Session Complete – '04 Session begins January '04) Visiting HI 11/5-7/03

A budget proviso was placed in bill which MH medications were funded and protected from any type of restrictions. Advocates preparing to ensure that a FULL MH carve-out is secured in '04 session.

- Continued efforts working with MPA, Contract Advocacy Coordinator on advocacy strategy including the development of a Mental Health Collaborative/"Five Families" that include MHA in Hawai'i, NAMI Hawaii, NAMI Oahu, Hawaii Families as Allies (children's mental health), and, United Self-Help (MH consumer group). Serving as "at-large" member of collaborative to support development of legislative priorities and organizational structure. Current plans call for Contract Advocacy Coordinator (who will invite key legislators, department staff and other organizations) to support implementing monthly forums on key MH issues including access, criminal justice, service provision, funding, and, parity in preparation for the '04 session. President of NAMI HI has a very serious illness and may not be able to maintain efforts…working with Advocacy Coordinator and MHA in Hawaii ED to mitigate.
- Continued efforts with Hawaii Psychiatric Medical Association, Hawaii Psychiatric Nurse's Association (met with past President on programs) and Hawaii (National) Medical Association. Also, developing relationships with new organizations including Safe Haven (Psych/ED supports open access) and Hale Ipu Kukui Alaka'i who work with seniors and disabled.
- Working with DMs and Sales to identify key thought leader in HI who can speak on access, MH, physician issues for national conference of Medical Association in December '04. Working with Don Foy, PAL.
- Working with NAMI Hawaii to engage criminal justice system on MH issues including access to medications. Working with Lt. Governor's Office, State Corrections. Attorney General's Office, and, Public Defenders with NAMI HI and Contract Advocacy Coordinator to begin work on CJ/MH effort. Contract Advocacy Coordinator will pursue relationship with "Five Families" to participate in AG Office led MH Task Force, support MH court, CIT efforts, and, access to services and treatments. PHDAE will secure funding for start-up efforts. Will bring King County MH Court Judge Mark Chow out to provide technical assistance on creating a MH court on 11/3 & 4 and meet with key CJ stakeholders on the value of developing a PIC.
- Continue working with PHDAE, Outcomes Liaison, Contract Advocacy Coordinator, and, Sales Representatives to develop and implement programs for department and advocacy organizations on VOA, unintended consequences of PAs and PDLs, cost effective strategies w/o limiting access throughout 2003. Supporting efforts of PHDAE on State Psychiatric Hospital's efforts to implement TMAP implementation and discuss Disease State Management programs. Another program will involve Atypicals and Diabetes to address the Zyprexa/Diabetes issue. In addition, will work with Contract Advocacy Coordinator to develop and implement media and advocacy trainings in preparation for next legislative session.

- Working with District Managers to develop a Physicians "Truth" Squad to support access to medications. Sales reps will identify physicians who will be supported by the PR firm on letters, op-eds, testimony, etc. Goal is to have five secured. Have secured 4.

Alaska ('03 Legislative Session Complete – '04 Session begins January '04) Visiting AK on 11/12-14/03
A number of provisions/amendments have been placed in the PDL bill, which will effectively stall implementation. Working with advocates to ensure that a "Dispense as Written" (DAW) and FULL MH carve-out is secured in '04 session.

- Working with NAMI Alaska President and Children's MH Coordinator to develop a more effective advocacy strategy and engagement of criminal justice system to ensure access to MH meds and funding. Providing a two grants to support "In Our Own Voice" type consumer program that includes a family member, consumer, and police officer who will target presentations to legislators, policy makers, law enforcement, and, community in five key target areas: Anchorage, Juneau, Ketchikan, Fairbanks, and, Valdez. In partnership with PHDAE, have developed relationship with AK Mental Health Trust Authority Board who will co-fund at $19,000.00.
- Working with AK Psychiatric Association President to develop legislative/advocacy training in November will be supported by Contract Advocacy Coordinator. Working with PHDAE to coordinate efforts Leg. Committee Chair to discuss advocacy strategies on "open access" while considering potential interventions like CNS. In addition supporting an ad-hoc committee that has been developed, led by Leg. Comm. Chair, to serve as an advisory group to Governor and Health and Social Services on MH medication issues. (working with PHDAE and MPA on this). Helped create a "White Paper" on access to MH meds that will be presented to Governor and Commissioner of Health and Social Services.
- Scheduled media/advocacy training for 11/13 in Anchorage and 11/14 in Juneau for key advocates including NAMI, AK Psych Assoc, Criminal Justice, Providers, and, consumers. Invited NAMI OR ED Stephen Loaiza to attend and support advocacy, coalition development including Partners in Crisis, and CNS implementation.
- Working with PHDAE on efforts to introduce CNS as a co-solution to MH carve out. Scheduled meetings in Anchorage and Juneau for 11/13 & 14 in conjunction with media/advocacy training with key advocates, state staff and legislators. CNS' Sandy Forquer will present.
- Continued work to develop an AK Partners in Crisis Network, at a minimum…met with MH Court Judge, Anchorage Police, NAMI – Anchorage to develop initial list of stakeholders to invite for a presentation on PIC in mid-October. Discussed "Lobby Day" planning. PHDAE will support via funding. Met with Director of State Corrections to discuss how Lilly could be helpful with reducing recidivism in jails. Meeting set up with Juneau Police.
- Supporting NAMI Juneau and Polaris House (consumer clubhouse)…advocacy strategy for '04. Provided funding to support their "Family to Family" program.
- Working with Contract Lobbyist and Advocacy Coordinator to engage Native Communities including the Alaska Federation of Natives and mental health counselors.
- Engaged advocates to continue efforts on supporting open access to MH meds (HSS conference calls scheduled for 9/19) also continue to testify on a potential administrative rule that the Department of Health and Social Services is considering eliminating in-patient hospitalization and nursing home services from the "Chronic and Acute Medical Assistance" (CAMA) program. This will affect mentally ill, offenders in corrections, and native communities. Also, will limit number of prescriptions (3 a month) that would be filled.
- Continue efforts with Jerry Jenkins who is with the Providers Coalition (CMHCs) to discuss coalition development and legislative advocacy. They promote "choice" for providers and consumers, which will form the basis for advocating for access to MH meds.
- Worked with District Managers and PR Firm to develop a Physicians "Truth" Squad to support access to medications. Sales reps identified 20+ physicians who wrote letters and called legislators during the session. Will work to develop more of a relationship with Medical Association.

Other

- Coordinated and participated in WA, OR, AK, and, HI State Action Team meetings.
- Attended Lilly SGA/PR Firm meeting in Indy 11/15-16/03
- Made PAC presentations to Sigma, Delta and Portland Retail Neuroscience teams.
- Assisting NAMI Reg. Dir. on Q3 Medicaid/Advocacy Conf. and Q4 Conf. on engaging the criminal justice.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

ORDER

THIS COURT, having considered Defendant Eli Lilly and Company's Motion to Exclude Evidence Regarding Speech Protected by the *Noerr-Pennington* Doctrine and Common Law Privilege, and any response thereto,

IT IS HEREBY ORDERED that the Motion is GRANTED. The plaintiff is precluded from introducing evidence that Lilly participated in efforts to petition any branch or agency of the State government regarding access to psychiatric medicines for Medicaid beneficiaries.

DATED this ____ day of March, 2008.

BY THE COURT:

The Honorable Mark Rindner
Superior Court Judge

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document has been served via email upon counsel listed below, and by hand delivery and email upon Mary Beth Rivers, Room 532, Tower Two, Captain Cook Hotel.

Brewster H. Jamieson

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Date: March 6, 2008

Dis

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[2] S.

[3] Ord.

FILED IN OPEN COURT
Date: 3-6-08
Clerk: MM

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

MOTION TO EXCLUDE CERTAIN TESTIMONY AND PRESENTATION MATERIAL OF FREDERICK BRANCATI, M.D.

1. Yesterday morning, the State of Alaska ("the State") provided Eli Lilly and Company ("Lilly") with the presentation material that it would use during its direct examination of epidemiology expert, Dr. Frederick Brancati. Nearly half of this presentation material relates to the phase-two issue of damages and is irrelevant to phase one of trial under the Court's Bifurcation Order and Alaska Rules of Evidence 401 and 402.[1] Moreover, regardless of relevancy, much of this material is unfairly prejudicial to Lilly under Alaska Rule of Evidence 403.[2] The presentation material, and the testimony that Dr. Brancati will offer related to this material, therefore, should be excluded.

2. On November 27, 2007, the Court Ordered that this trial be bifurcated into phases dealing with "liability only" and "issues of causation and damages."[3]

3. On November 14, 2007, the Court affirmed a ruling of the Discovery Master that denied Lilly discovery of individual patient records, which would

[1] *See* Slides attached as Exh. A.

[2] *See* Slides attached as Exh. B.

[3] Orders re: Motions for Bifurcation and for Six Month Extension of Deadlines 1, Nov. 27, 2007.

have yielded evidence as to whether any Alaska patients, in fact, suffered *damage* as a result of Lilly's alleged conduct. On February 12, 2008, Lilly filed a motion, requesting that the Court reconsider this ruling.[4] The State opposed,[5] and the Court denied, Lilly's motion, but the Court noted that Lilly could re-file its motion during phase two of trial.[6]

4. Although the State opposed discovery sought by Lilly, which would have produced information regarding damages, it now seeks to shoehorn testimony on damages into trial. The potential complications of diabetes—which are not, as the slides present, a certainty—have no bearing on whether Zyprexa's labeling adequately warned of the risks of *developing* diabetes. Likewise, discussions of the treatment of diabetes and the "public health burden" of diabetes are irrelevant to findings of fact regarding Zyprexa's label. Finally, the gruesome photographs that are included among Dr. Brancati's slides cannot assist the jury in reaching a conclusion about the adequacy of Zyprexa's labeling. This presentation material is purely related to phase-two issues, irrelevant to the first phase of trial under Alaska Rules of Evidence 401 and 402, and this material as well as Dr. Brancati's testimony related thereto should be inadmissible.

5. Regardless of the relevancy of Dr. Brancati's presentation material, several slides are unfairly prejudicial to Lilly.[7] Dr. Brancati includes two full-page photographs, one of a foot with several toes amputated, and the second of a foot with

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[4] Def.'s Mot. in Resp. to the Ct.'s On-Record Comments During the Jan. 29, 2008 Hearing, Feb. 12, 2008 (requesting reconsideration of the Court's Nov. 14, 2007, Order). Lilly's motion also would have yielded evidence relevant to liability.

[5] Pl.'s Opp. to Lilly's Mot. for Reconsideration and Resp. to Ct.'s Order, Feb. 21, 2008.

[6] Order, Feb. 22, 2008.

[7] Exh. B.

several large, open sores. The sole purpose of these slides is to shock and horrify the jury. Case law is clear that evidence of this nature is impermissible.[8]

6. Additionally, Dr. Brancati notes that he relies upon the 2007 Zyprexa label change to support his opinion. Dr. Brancati, however, did not supplement his expert report to add this additional basis, and Lilly was not afforded the opportunity to cross-examine Dr. Brancati as to this additional basis. Dr. Brancati, therefore, should be precluded from testifying about Zyprexa's 2007 label change, and this basis should be struck from his presentation material.[9]

7. Striking the slides referenced in Exhibits A through C from Dr. Brancati's presentation material would take minutes to accomplish and will not disrupt the State's case. As the State has done for the past two days, Lilly expects that it will employ a technology specialist during today's proceedings who can adjust Dr. Brancati's presentation appropriately to the Court's ruling.

8. For the foregoing reasons, Lilly requests that the Court enter an Order excluding the presentation material of Dr. Brancati referenced in Exhibits A through C, and preventing Dr. Brancati from testifying about any of this excluded material.

DATED this 6th day of March, 2008.

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[8] *See, e.g., Campbell v. Keystone Aerial Surveys, Inc.*, 138 F.3d 996, 1004 (5th Cir. 1998) (in wrongful death suit against aerial survey company, excluding photos of scene showing remains of victim, to prevent decision based on "visceral response"); *Shahid v. City of Detroit*, 889 F.2d 1543, 1545-46 (6th Cir. 1989) (in suit arising out of death of jail inmate, excluding photos of body); *Panko v. Food Fair Stores, Inc.*, 403 F.2d 62, 64 (3d Cir. 1968) (in suit against store arising out of slip-and-fall, excluding photos of plaintiff); *Hrabak v. Madison Gas & Elec. Co.*, 240 F.2d 472, 479 (7th Cir. 1957) (excluding photos of plaintiff taken when he was being treated for his injuries and showing his face distorted with pain).

[9] *See* Slide attached as Exh. C.

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By: _____
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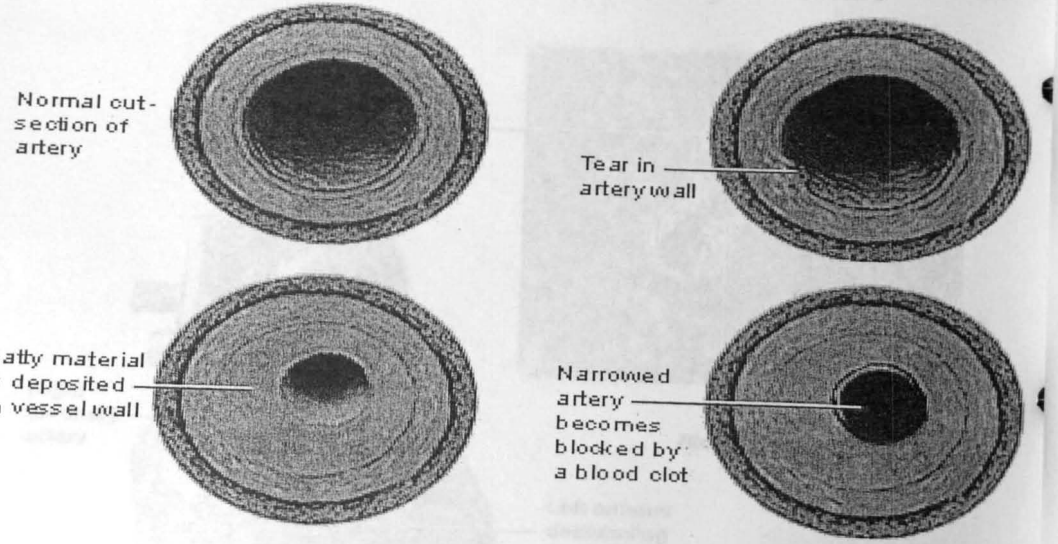
Exhibit A

Diabetes Leads to Long-Term Health Problems & Death by Damaging Blood Vessels

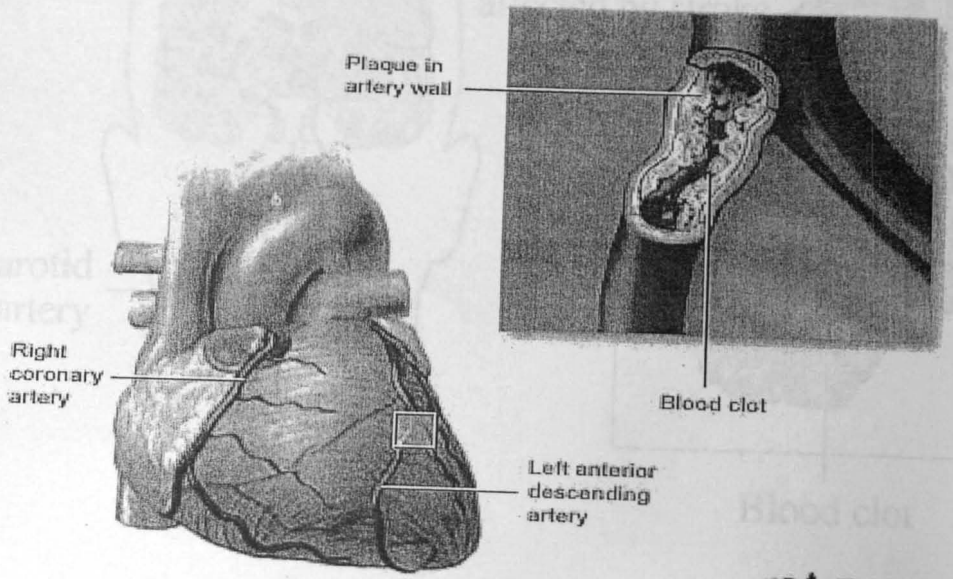
- Macrovascular Disease
  - Blockage of large arteries to heart, brain, and leg
  - Leads to heart attack, heart failure, stroke, and gangrene
- Microvascular Disease
  - Narrowing of small arterioles in retina, kidney, nerves
  - Leads to characteristic diabetic damage to these organs
    - Retinopathy → Blindness
    - Nephropathy → Kidney Failure / Dialysis
    - Neuropathy → Leg pain, Sensation loss, and gangrene

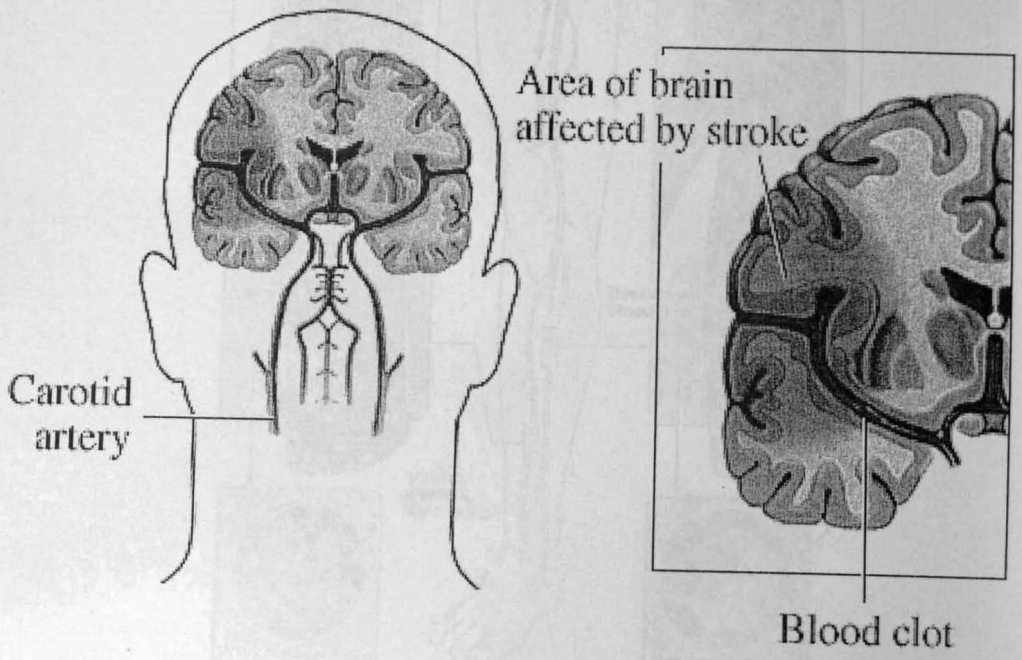
Atherosclerosis

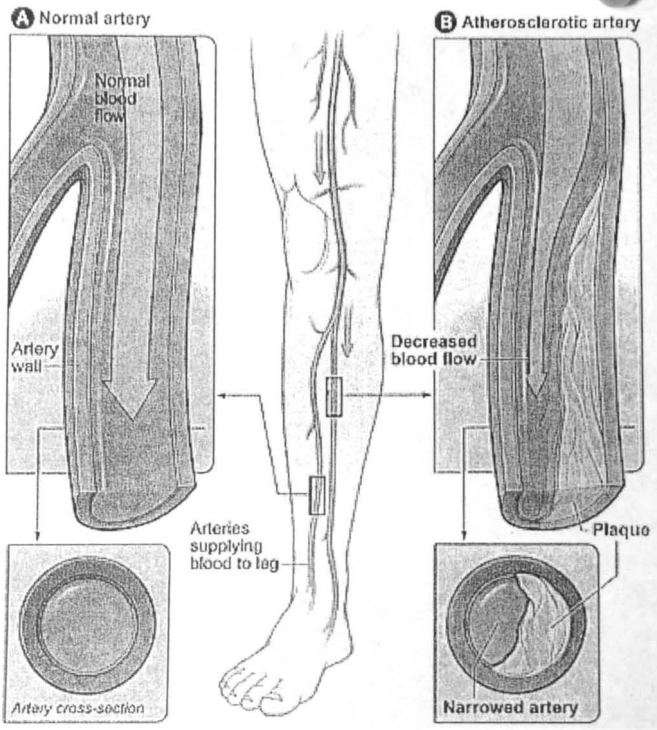


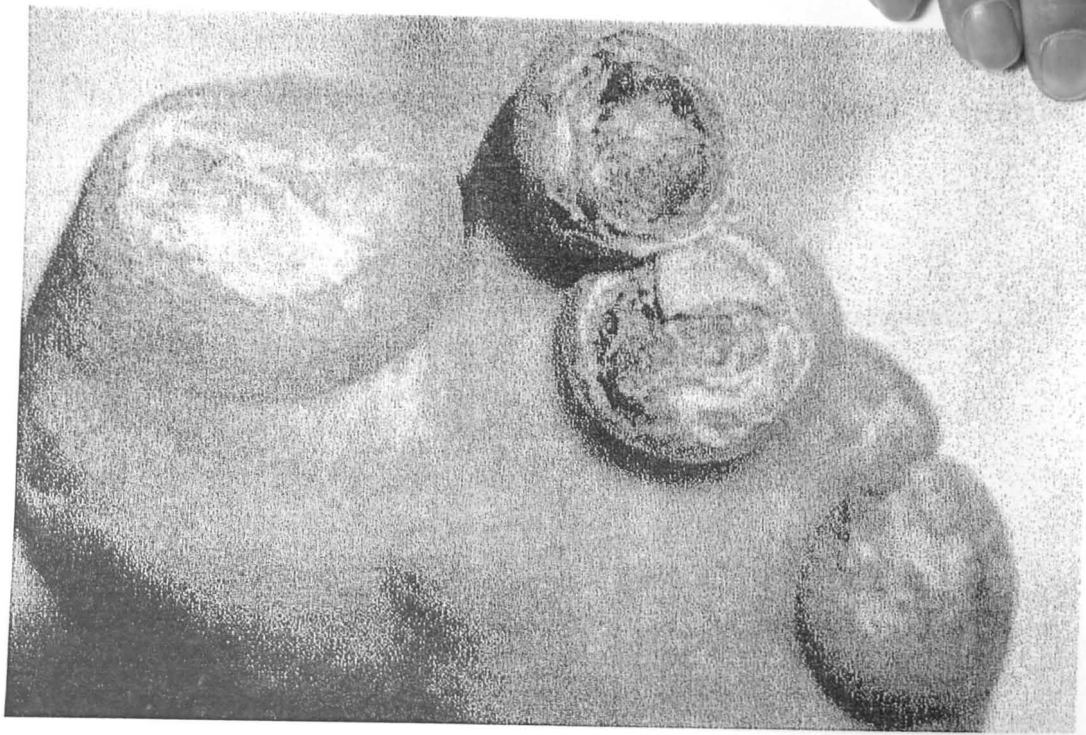
Atherosclerosis of Vessels Leading to the Heart

also Known As Coronary Artery Disease



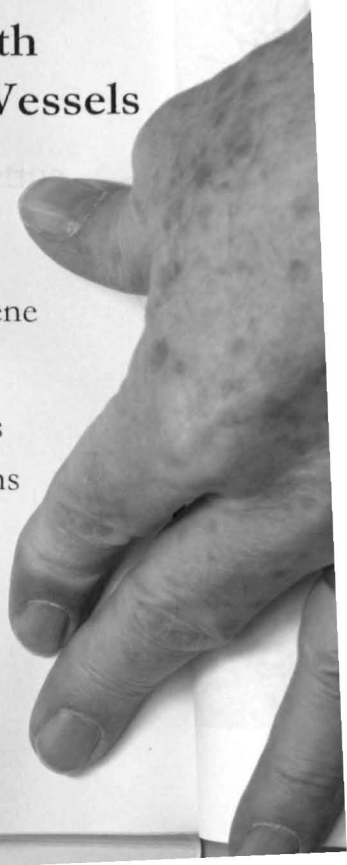

Area of brain
affected by stroke
Carotid
artery
Blood clot


A Normal artery
Normal blood flow
Artery wall
Artery cross-section
Arteries supplying blood to leg
B Atherosclerotic artery
Decreased blood flow
Plaque
Narrowed artery



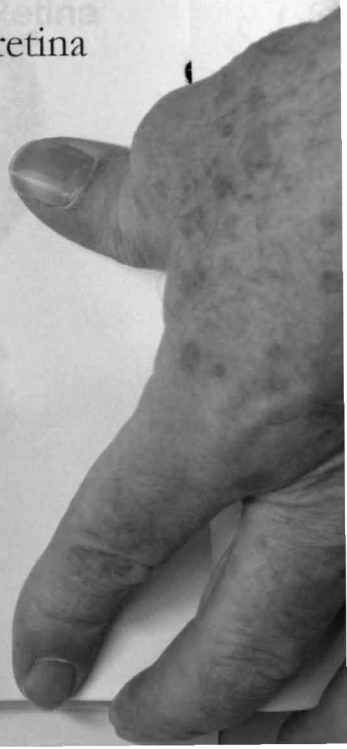
Diabetes Leads to Long-Term Health Problems & Death by Damaging Blood Vessels

- Macrovascular Disease
  - Blockage of large arteries to heart, brain, and leg
  - Leads to heart attack, heart failure, stroke, and gangrene
- Microvascular Disease
  - Narrowing of small arterioles in retina, kidney, nerves
  - Leads to characteristic diabetic damage to these organs
    - Retinopathy → Blindness
    - Nephropathy → Kidney Failure / Dialysis
    - Neuropathy → Leg pain, Sensation loss, and gangrene

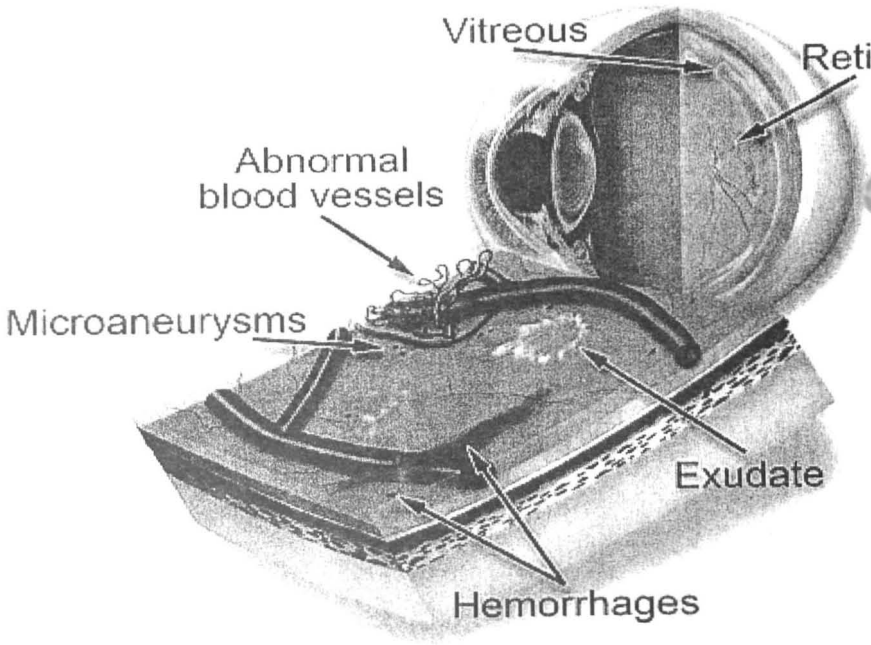


Diabetic Retinopathy

- Hyperglycemia damages small vessels in retina
- New, fragile vessels grow to compensate
- Interrupts vision in different ways
- Top cause of blindness in US adults
  - Leakage of fluid and proteins in retina
  - New vessels hemorrhage into retina
  - New vessels hemorrhage into vitreous
  - New vessels detach retina
- Diabetes also leads to glaucoma

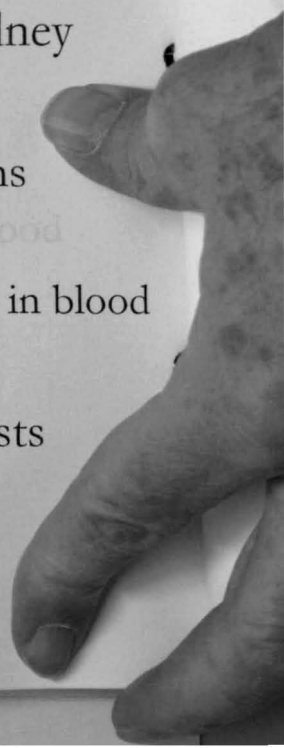


Diabetic Retinopathy



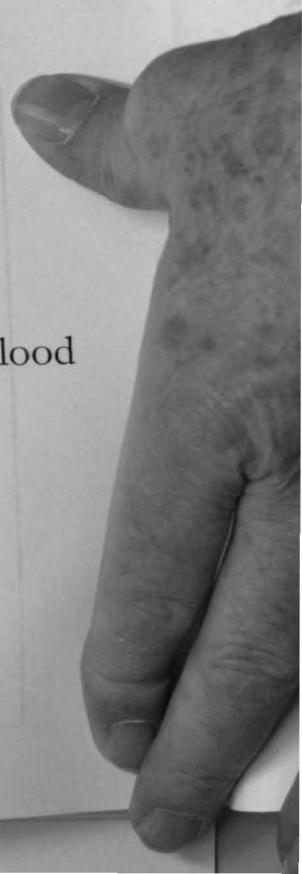
Diabetic Nephropathy I

- Damages the filtering function of the kidney
- Microscopic damage causes two problems
  - More leaky→ Blood loses vital proteins
  - Less filtering→ Waste products accumulate in blood
- Early damage shows in blood & urine tests

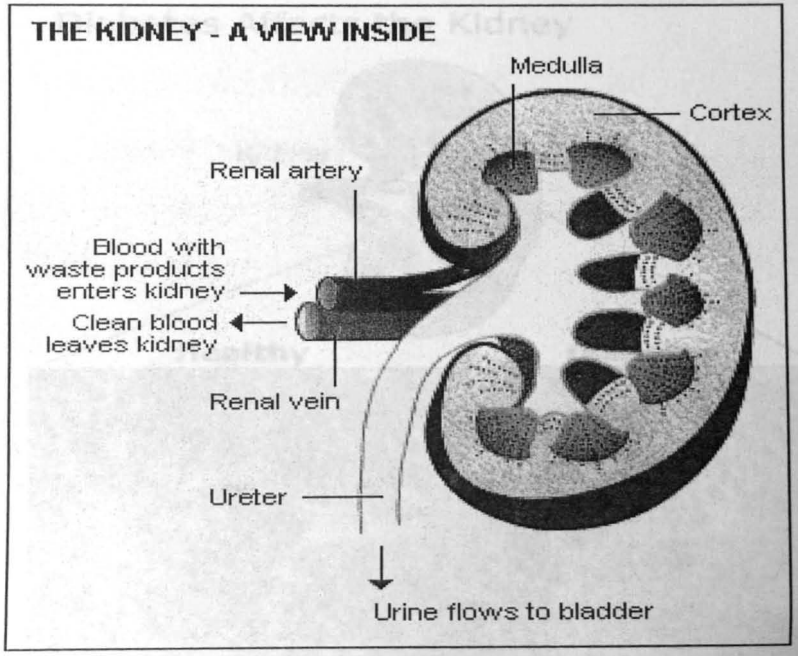


Diabetic Nephropathy II

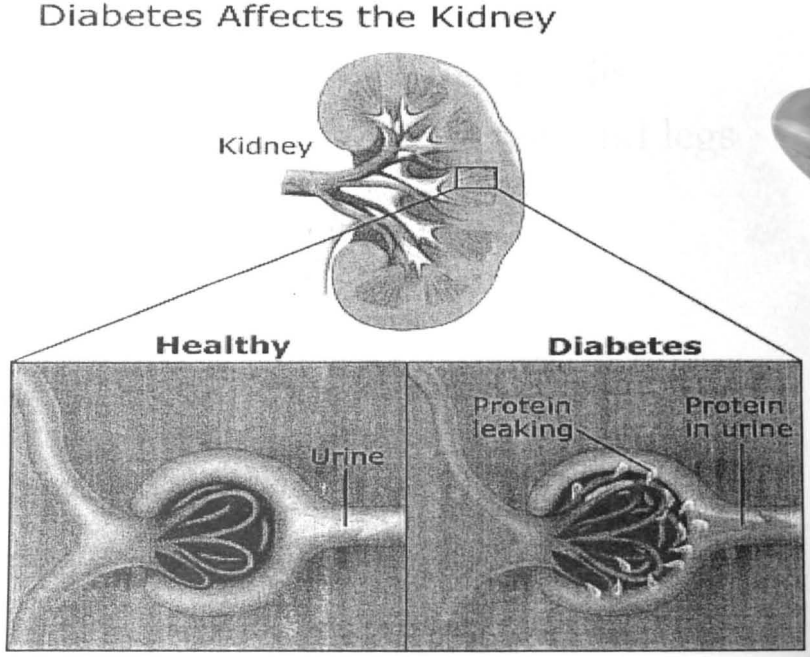
- Later problems are more serious
  - Fluid accumulation in legs, chest
  - Fatigue, Loss of Appetite
  - Accumulation of acids and other toxins in blood
- Leading cause of kidney failure / dialysis



Normal Kidney Function

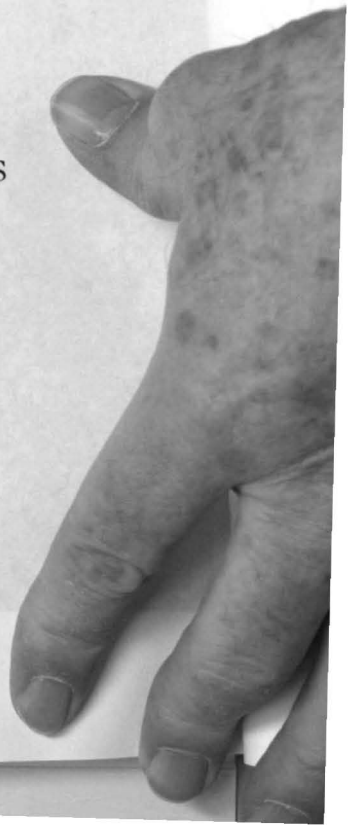


Diabetic Nephropathy



Diabetic Neuropathy

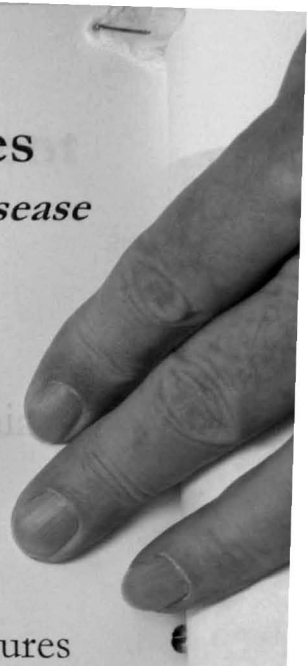
- Hyperglycemia damages nerve cells
- Most commonly affects the feet and legs
- Leads to several problems
  - Paraesthesia (chronic pain)
  - Numbness, Loss of Sensation
  - Increased Risk of Undetected Injury
  - Increased Risk of Infection
  - Gangrene
  - Amputation (toe, foot, or leg)



Treatment of Type 2 Diabetes

Proven to Reduce Risk of Microvascular Disease

- Lifestyle Change
  - Reduce calorie intake, More exercise
- Oral Diabetes Drugs
  - Sulfonylureas, Metformin, TZDs
- Injected Diabetes Drugs
  - Short or long-acting insulin, Insulin mixtures
- Glucose Self-Monitoring



Problems with Current Treatment for Type 2 Diabetes

- Most patients require multiple drugs
- Some drugs carry risk of hypoglycemia
- Self-monitoring is bothersome
- Some drugs are quite expensive
- Not proven to protect against macrovascular disease

Public Health Burden of Diabetes

- Morbidity
  - Complications, Hospitalizations
- Reduced Quality of Life
  - Symptoms and Lost Function
- Mortality
  - Excess Risk of Death
- Costs
  - Medical costs + Lost productivity

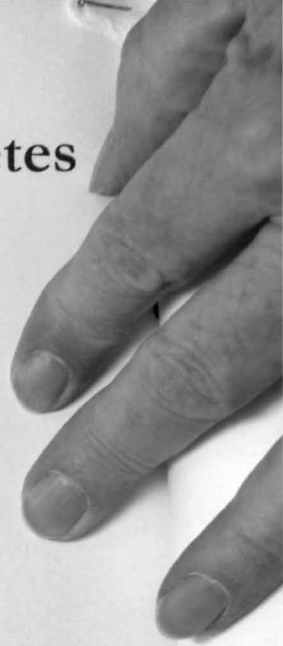
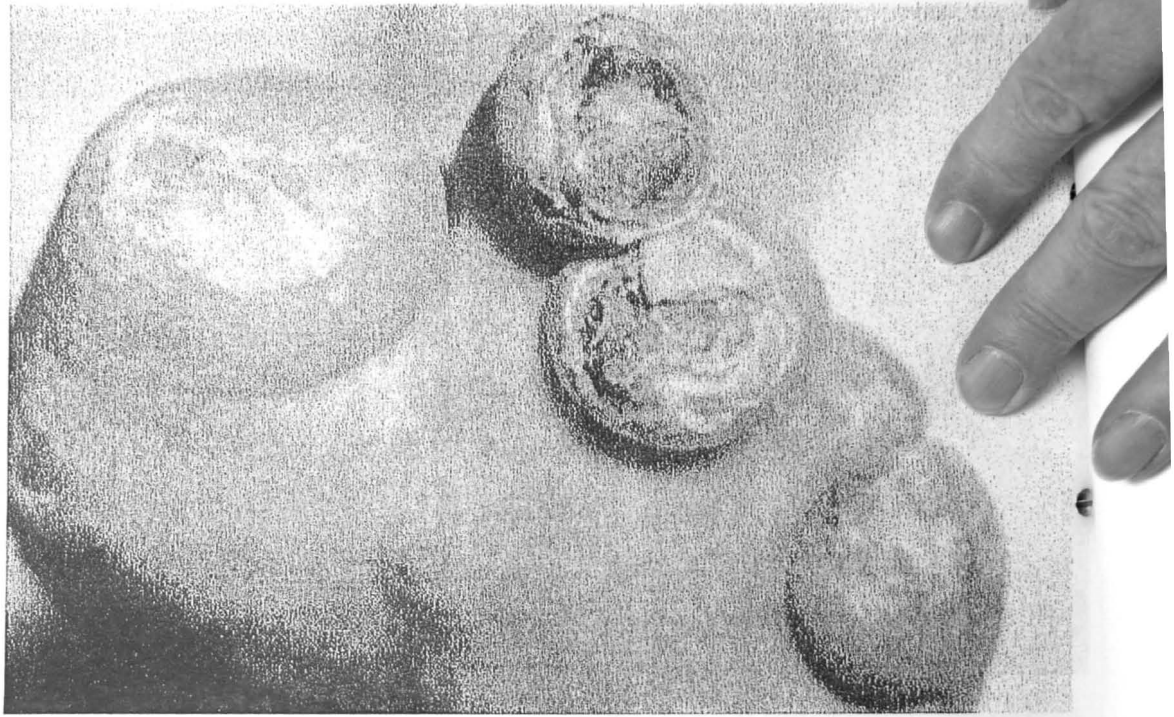


Exhibit B



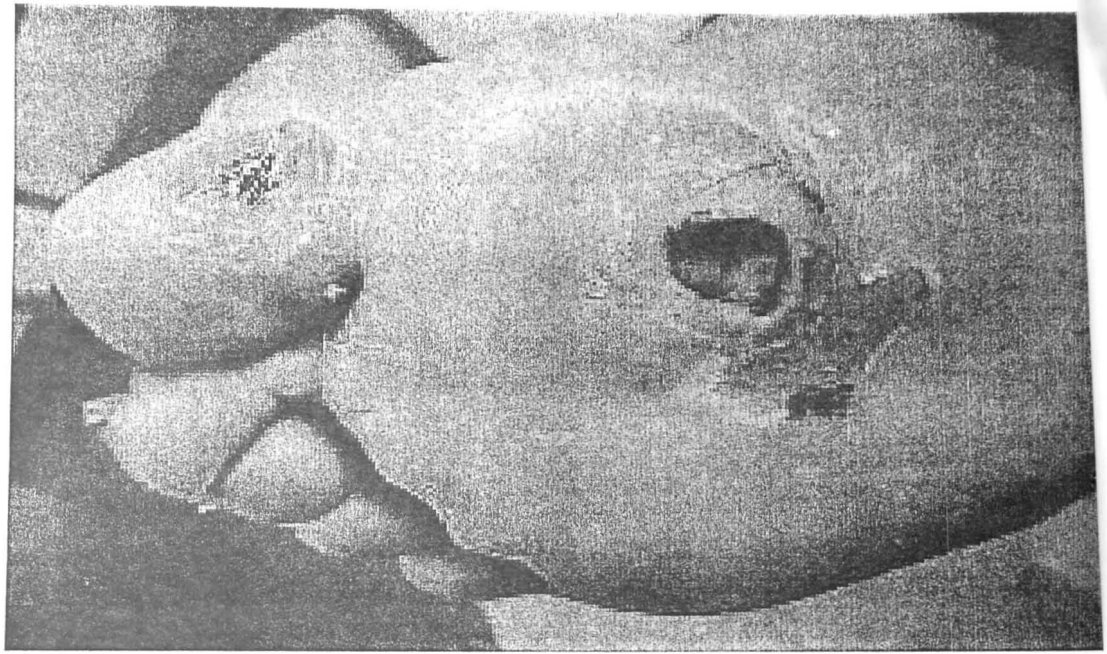
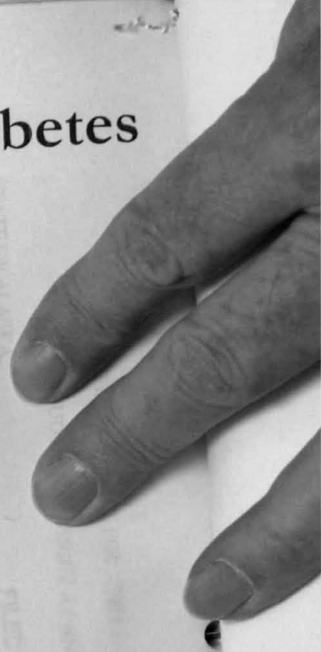


Exhibit C

Opinion Re Higher Risk of Diabetes with Zyprexa

Further supported by:

- 2003 Consensus Statement
- 2007 Zyprexa Label Change



Diabetes Care. 2004;27:596-601.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,	)	FILED IN OPEN COURT
	)	Date: 3-5-08
Plaintiff,	)	
	)	Clerk: MLD
v.	)	Case No. 3AN-06-05630 CI
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	
	)	

STATE OF ALASKA'S OPPOSITION TO ELI LILLY AND COMPANY'S MOTION TO PRECLUDE TESTIMONY OF JOEY ESKI FROM TRIAL PHASE ONE OR PROTECTIVE ORDER REGARDING HER TESTIMONY

After Eli Lilly and Company ("Lilly") identified Joey Eski as an Alaska-based sales representative during discovery in this case, the State of Alaska ("the State") noticed her deposition on November 21, 2007. While the deposition was originally scheduled for December 13, 2007, pursuant to Lilly's request, the deposition was re-noticed for February 28, 2008.[1] Lilly initially placed Ms. Eski on its witness list on January 7, 2008.[2] Lilly kept Ms. Eski on its Final Witness List dated February 22, 2008. The State engaged in discussions with Lilly in early February, making clear that not only was the State interested in deposing Ms. Eski, but also intended to call her live at trial to

[1] Exhibit A, Notices of Deposition dated November 21, 2007 and February 13, 2008.
[2] Exhibit B, Eli Lilly and Company's Supplement to Preliminary Witness List.

testify. [3] Indeed, Mr. Lehner represented to Plaintiff's counsel that Lilly would "work with" the State to make Ms. Eski available to testify live at trial upon 24-48 hours notice.

Throughout this litigation, Lilly has argued the State's evidence regarding Lilly's conduct was insufficient to prove its claims without some evidence that conduct complained of actually occurred in Alaska. However, Lilly now takes the position that such evidence is irrelevant to the State's claims and should be kept from an Alaska jury. Despite the previously scheduled and noticed deposition and the conversations between counsel regarding Ms. Eski's availability for trial, Lilly has on the eve of trial desperately attempted to make her unavailable. First, it unilaterally canceled her deposition the day before it was previously scheduled, requiring the intervention of this Court for rescheduling it. Then, Lilly informed the State for the first time that Ms. Eski would be unavailable for a large portion of the trial. Now, Lilly seeks not only to preclude Ms. Eski's live testimony, but also seeks to preclude testimony from the deposition it tried in vain to prevent. The Court should deny Lilly's request.

In *Pennsylvania Employees Ben. Trust v. Zeneca*, relied heavily upon by the Court in its recent summary judgment decision, the 3rd Circuit Court of Appeals correctly pointed out that under 21 C.F.R. 202.1(l)(2) ,material such as brochures, detailing pieces and other information for use by medical practitioners disseminated *by or on behalf of* the

[3] Exhibit C, Emails between counsel dated February 9 through 14, 2008.

manufacturer are considered labeling, not promotion or advertising.[4] The court went on, however, to cite 21 C.F.R. 202.1(l)(1) for the proposition that advertising included "physician-directed pitches by sales representatives."[5] The portion of the regulation cited does not actually state this, but instead only includes "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephonic communication systems."[6] Regardless, it is clear that court, and this Court, drew a clear distinction between promotion or advertising and *labeling*. The labeling claims still stand in this case – both as to common law negligence and with respect to alleged violations of Alaska's Unfair Trade Practices Act -- and they were the principal focus of Ms. Eski's deposition.

Ms. Eski's testimony contains relevant and admissible evidence that goes to the heart of the State's claims, i.e., that Lilly failed to properly warn of Zyprexa's risks and actively misrepresented Zyprexa's safety. In Lilly's opposition to the State's Motion to Preclude Testimony or Argument That Zyprexa's Labeling "Warned" of Diabetes, Hyperglycemia or Weight Gain, Lilly asserted that whether it had fulfilled its duty to warn "depends on all the information communicated by the manufacturer,... ."[7] As a

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[4] *Pennsylvania Employees Ben. Trust v. Zeneca*, 499 F.3d 239, 244 (3rd Cir. 2007).
[5] *Id.*, 245.
[6] 21 C.R.R. § 202.1(l)(1).
[7] Defendant Eli Lilly and Company's Opposition to Plaintiff's Motion to Preclude Testimony or Argument That Zyprexa's Labeling "Warned" of Diabetes, Hyperglycemia or Weight Gain, 1.

sales representative of Lilly, Ms. Eski is the literal face and voice of the company in Alaska. She has interacted with State officials and physicians in Alaska, both public and private.[8] Ms. Eski's testimony is directly relevant to whether or not Lilly satisfied its duty to warn of Zyprexa's risks, or whether it misrepresented those risks to physicians, and has nothing to do with whether or not Lilly promoted Zyprexa for off-label or non-indicated uses, the only claim this Court dismissed.

In her deposition, Ms. Eski testified that physicians need to know all available data or information about a product, and that she played an integral role in Lilly's communications in Alaska about Lilly products.[9] Lilly representatives in Alaska such as Ms. Eski delivered the "comparable rates" message to physicians in Alaska.[10] The message was delivered in part with the use of detail pieces or brochures which, under the Zeneca case and federal regulations, constitutes "labeling".[11] These are brochures the State has alleged were used in Alaska, and evidence and testimony from this deposition is relevant evidence of that fact.

Ms. Eski also testified regarding an issue raised by the State in a motion in limine, that is, the difference between a warning and an adverse reaction in the package insert of product label. Ms. Eski testified there was a significant difference between the two in

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[8] Exhibit D, Deposition of Joey L. Eski, February 29, 2008, at 10, 12-14 and 38-39.
[9] *Id.* at 187-89.
[10] *Id.* at 132-34, 138-41, 143-44, 146-48 and 150-56.
[11] *Id.* at 150-57; Exhibit E, exhibits 10 and 11 from Deposition of Joey L. Eski, February 29, 2008.

terms of severity and the rate of incidence of a particular side effect.[12] She further testified that warnings resulted in more focus and detail in communications with physicians on issues regarding side effects, and that warnings have a significant impact on such discussions.[13] Ms. Eski stated that a warning was an "alert" which would be proactively communicated to physicians, a "big difference" distinguishing it from an adverse reaction.[14]

Ms. Eski's testimony is also relevant to issues raised by Lilly in its defense, for example, its argument that the State has not restricted access to Zyprexa. Ms. Eski, in her role as a sales representative for Eli Lilly in Alaska, was involved in activities which sought to influence politicians and agency personnel in Alaska to maintain "open access" to mental health medications, including Zyprexa.[15] As a member of the "Alaska State Action Team," a team composed of Eli Lilly representatives, a contract lobbyist and a public relations firm, Ms. Eski personally participated in efforts such as securing letters from physicians, recruiting speakers, advocates and thought leaders, and assisting in lobbying efforts directed at politicians in Alaska to defeat efforts that could have resulted in the restriction of access to Zyprexa. One of these lobbying efforts involved legislation that, if it had passed, would have resulted in mental health medications being "carved

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[12] Exhibit D at 210-12.
[13] *Id.* at 225-27, 229.
[14] *Id.* at 272-73.
[15] *Id.*, at 67, 71-72, 75-78, 80-86, 88-92, 97-100, 103-07 and 112-18.

out" of consideration by Alaska Medicaid's Pharmacy and Therapeutics Committee. This committee can review drugs for, among other things, safety and efficacy.

These are but a few examples of the relevant issues upon which Ms. Eski testified in her deposition. Even a cursory review of Ms. Eski's deposition testimony reveals the absurdity of Lilly's position that not a single page or line from that testimony is relevant in this case. The State has foregone its insistence that Ms. Eski appear live at trial, and simply asks to present as evidence relevant portions of that testimony from her recent deposition. For these reasons, the Court should deny Lilly's motion to preclude her testimony.

DATED this 4th day of March, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

BY _____
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AK Bar No. 7510085

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FIBICH HAMPTON & LEEBRON
Kenneth T. Fibich
1401 McKinney, Suite 1800
Houston, Texas 77010
(713) 751-0025

Counsel for Plaintiff

Certificate of Service
I hereby certify that a true and correct copy of 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 _____
Date 3-5-08

EXHIBIT

A

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

NOTICE OF VIDEOTAPED DEPOSITION

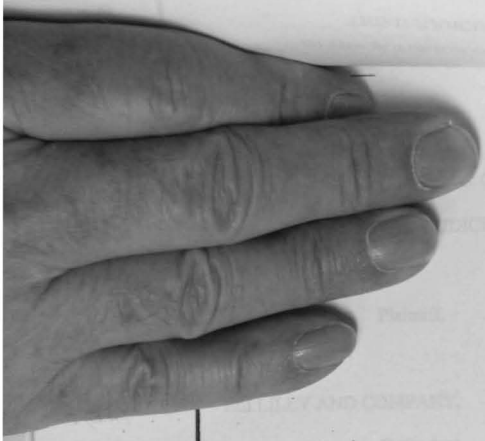
PLEASE TAKE NOTICE that pursuant to Rules 26, 30 and 30.1 of the Alaska Rules of Civil Procedure, Plaintiff State of Alaska will take the deposition upon oral examination of **JOEY ESKI** at 9:00 A.M. on Thursday, December 13, 2007, at the offices of Ice Miller, LLP, One American Square, Suite 3100,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

DATED this 21 day of November, 2007.

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



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

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

Certificate of Service
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Notice of Videotaped Deposition – Joey Eski
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Brewster H. Jamieson
Lane Powell LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648

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

By Peggy S Crowe
Date 11/26/07

FELDMAN ORLANSKY & SANDERS
500 L STREET
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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.	)	Case No. 3AN-06-5630 CIV
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	

RE-NOTICE OF VIDEOTAPED DEPOSITION

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

DATED this 13th day of February, 2008.

FELDMAN ORLANSKY & SANDERS
Counsel for Plaintiff

By _____
Eric T. Sanders
AK Bar No. 7510085

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& SANDERS
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Matthew L. Garretson
Joseph W. Steele
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H. Blair Hahn
Christiaan A. Marcum
David L. Suggs
Counsel for Plaintiff

Certificate of Service
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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 5/13/08

FELDMAN ORLANSKY & SANDERS
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99501
TEL: 907.272.3538
FAX: 907.274.0819

EXHIBIT

B

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 POW[illegible], LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

3. Tim Franson **Attorney-Client Privilege**
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 POW[illegible] LLC
301 West Northern Lights [illegible]levard, 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.

LANE POW[illegible] LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

DATED this 4th day of January, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
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Eric Rothschild, admitted *pro hac vice*
3000 Two Logan Square
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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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Anchorage, Alaska 99503-2648
Telephone 907.277.9511 Facsimile 907.276.2631

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 99501-3911

_____

092867.0038/162627.1

EXHIBIT

C

From: Lehner, George A. [lehnerg@pepperlaw.com]
Sent: Wednesday, February 13, 2008 9:34 AM
To: dsuggs@attglobal.net; Boise, Barry
Cc: Brenner, John F.
Subject: RE: Zyprexa AK - Deposition of Joey Eski
Dave - I will call you later today.

George A. Lehner
Pepper Hamilton LLP

600 14th Street N.W.
Washington D.C. 20005-2004
Tele: 202-220-1416
Fax: 202-220-1665
lehnerg@pepperlaw.com

From: David Suggs [mailto:dsuggs@attglobal.net]
Sent: Wednesday, February 13, 2008 10:19 AM
To: dsuggs@attglobal.net; Boise, Barry
Cc: Brenner, John F.; Lehner, George A.
Subject: RE: Zyprexa AK - Deposition of Joey Eski

Hellooooooooooo??

From: David Suggs [mailto:dsuggs@attglobal.net]
Sent: Tuesday, February 12, 2008 9:38 AM
To: 'Boise, Barry'
Cc: 'Brenner, John F.'; 'Lehner, George A.'
Subject: RE: Zyprexa AK - Deposition of Joey Eski

I didn't hear back from you yesterday on the question of whether Lilly will agree to make Ms. Eski available to testify live in the State's case-in-chief upon 24 or 48 hours notice, or whether you prefer that we subpoena her. Any word?

From: Boise, Barry [mailto:BOISEB@pepperlaw.com]
Sent: Saturday, February 09, 2008 4:48 PM
To: dsuggs@attglobal.net
Cc: Brenner, John F.; Lehner, George A.
Subject: Re: Zyprexa AK - Deposition of Joey Eski

Will get back to you on Monday on second question.
Barry H. Boise
Pepper Hamilton LLP
----------Attorneys at Law
215.981.4591

David Suggs

Richardson, Patrick, Westbrook & Brickman

27995 Boulder Circle

Shorewood, MN 55331

Telephone: 952-401-4377

E-Fax: 425-963-3467

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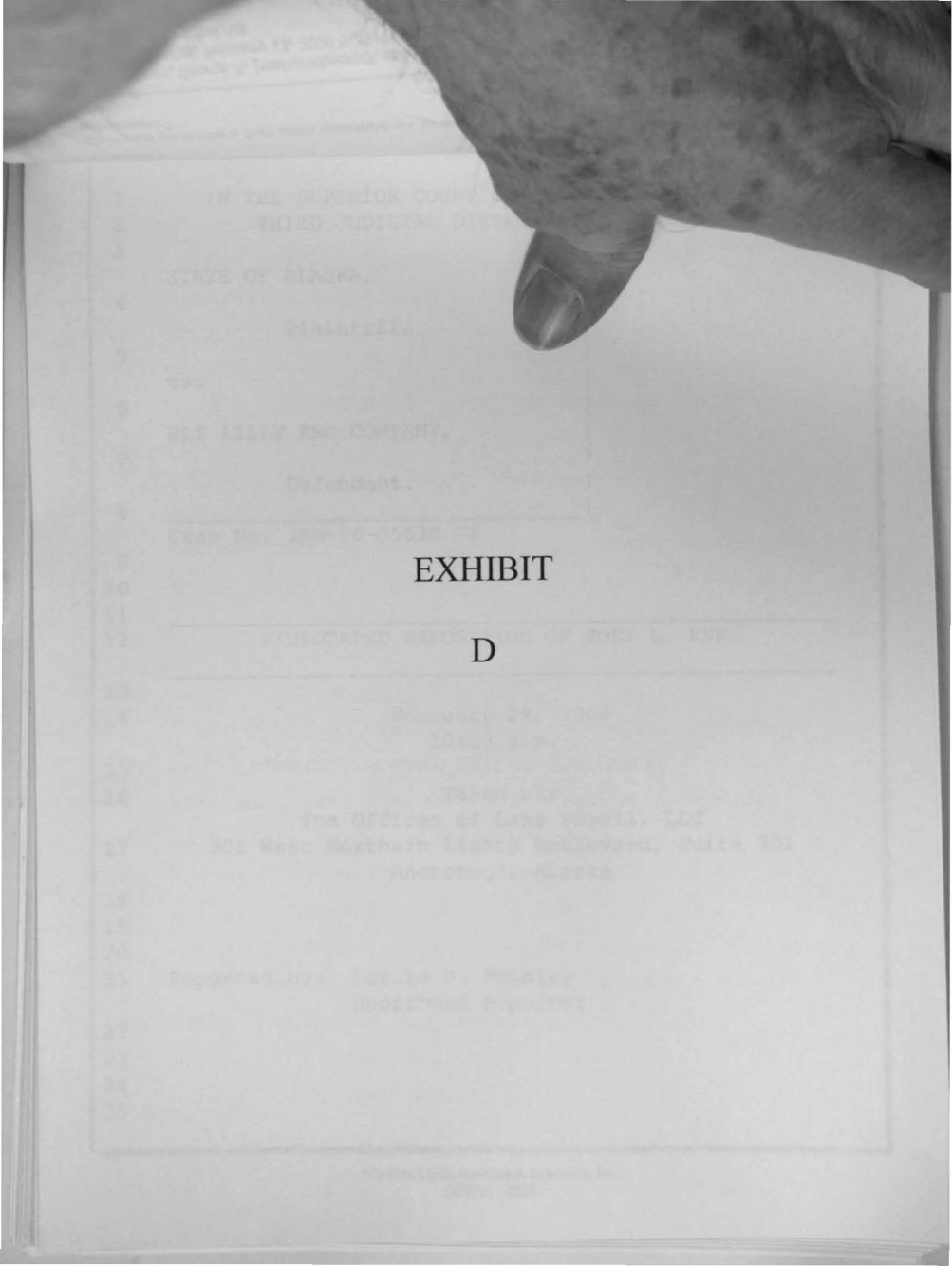
From: David Suggs [dsuggs@attglobal.net]
Sent: Thursday, February 14, 2008 8:56 AM
To: 'Lehner, George A.'
Subject: RE: Witnesses
George –

Can you give me a ball park estimate as to the week when you would expect to call the witnesses?

From: Lehner, George A. [mailto:lehnerg@pepperlaw.com]
Sent: Wednesday, February 13, 2008 6:26 PM
To: dsuggs@attglobal.net
Cc: Boise, Barry
Subject: Witnesses

We will work with you to produce Ms Eski at trial without need for a subpoena assuming you will reciprocate with those witnesses represented by the State. Those witnesses are:
Dr hopson (api), Campana (state pharm director), Karleen Jackson (current commissioner), Gilbertson (former commissioner) all represented by state at their deps.



EXHIBIT

D

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 JOEY L. ESKI

February 29, 2008
10:23 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

A I do.
Q In fact, you've had considerable experience in helping Eli Lilly engage in contacts with the State of Alaska; isn't that true?
A You'd need to define considerable for me, but I've had -- I've had some contact.
Q Yes. Tell the jury, please, the contact that you have either had personally or coordinated for Eli Lilly in the contacts for the State of Alaska, please.
A Do you mean with the State employees or -- I'm --
Q Of any sort.
A Of any sort. Okay. I've had minimal contact with the director of Medicaid, State Medicaid, Dave Campana, over the last ten-year span. You know, interactions as far as introducing myself so he has a contact with Lilly. That's my main interaction -- interactions with him. I've infrequently called on him before we had public health people that came up here and did that.
Q You frequently --
A Infrequently.

A Yes.
Q And they specifically had the responsibility on behalf of Eli Lilly to be in contact with the State Medicaid Department?
A Yes.
Q And their responsibilities in that regard were to do everything they could to assure that there were no restrictions placed on the prescription of Zyprexa here in Alaska, correct?
MR. BRENNER: Object to the form.
A That is not correct.
Q (BY MR. ALLEN) Okay. We'll cover that in some detail.
Let me go back to my question, which I briefly got off of, about your contacts with the State of Alaska.
A Sure.
Q You told us about your contact with Mr. Campana. Can you tell the jury the remaining contacts you've had with the State of Alaska or the representatives of the State of Alaska involving your duties at Eli Lilly?
A Do you consider the State hospital State employees? I mean --
Q Ma'am, I just can only -- really I can

only get your testimony and then we can determine later.

A Okay. My primary responsibility would have been for Alaska Psychiatric Institution, which is our State hospital for the entire State. And I would work with the medical director and all the physicians and the pharmacy in that facility. Other --

Q When you were working, and we're using your words, working with the director of that facility and the employees, who was paying you?

A Eli Lilly and Company.

Q Okay. And what kind of work did you do at the State hospital for Eli Lilly?

A At the State hospital with Eli Lilly, a lot of educational programs. We -- I would come in and present at medical staff meetings or I may bring a speaker in that they requested or someone that I have come into town that they're interested in hearing. Provide them with, you know, updated information on Zyprexa would be, you know, one of my primary goals. And, you know, really just respond to what their -- what their needs are in terms of what information they need from Lilly, what kind of resources they --

they could use.

Q And you did this on behalf of Eli Lilly and Zyprex --

A Of course.

Q Let me finish.

A Yeah. Sorry.

Q No need to apologize. We'll talk about that.

A Jumping ahead, I guess.

Q That's all right. It's going to be a while, so we can just take our time.

A Okay. Sure.

Q And you did those activities at the State hospital on behalf of Eli Lilly?

A Yes.

Q They included, as you said, providing information to the State employees and the doctors and personnel at that hospital about Zyprexa?

A Sure. Yeah.

Q And, of course, you could not ever provide information that would be outside the label, could you?

A No -- well, in -- in response to an unsolicited question. If somebody asks me a

changed a lot over the years. Can you please tell us?

A I can speak to how it's changed personally in my position.

Q Okay. And do you know how it's changed within the company?

A I have a basic idea, but not an overall. I don't have a real clear --

Q Well, I'd like you, first, to give us your basic idea of how the sales forces for Zyprexa have changed within the company.

A Originally when I started, the neuroscience division was responsible for all areas of mental health, so -- and I can only speak to Alaska, but here I was responsible for the entire State of Alaska for Zyprexa. And I was --

Q Beginning in -- let me interrupt you there. Beginning of September of '98?

A That's correct.

Q You were responsible for the entire state?

A Yes, but my responsibilities were mental health only. So I would be private practice psychiatry, community mental health psychiatry,

State facilities, like the State hospital, Native health, and military DoD accounts would have been my responsibility.

Q DoD accounts?

A Yes. So like Elmendorf, or like an Air Force Base or a VA Hospital would be a DoD account.

Q Okay.

A So basically the whole -- the whole region.

Q The whole shooting match.

A The whole shooting match, yes.

Q Okay. Go ahead.

A At some point -- the Lower 48 was all what we call a bi-ad for partners, whereas Alaska, because it's smaller in terms of the number of physicians had always been a un-ad. So at one point a partner was added, and I became a bi-ad just to match the Lower 48 setup.

Q Can we stop you there? When was that? Probably in 2000, wasn't it?

A I can't remember the exact date.

Q About the time of the primary care physician launch?

A No, it had nothing to do with primary

Q Do you remember the Alaska State Action Team?

A I do, uh-huh.

Q Okay. By the way, before we get into that, why don't I ask you: Besides being a sales representative or now executive sales representative, the other duties and responsibilities or teams you've been on here in Alaska.

A Sure.

Q Can you tell the jury what other teams you've been on for Eli Lilly here in Alaska?

A In Alaska specifically?

Q Or in -- well, you know what, ma'am, sometimes when people say it to me I feel like I'm getting tricked. So let me -- let me rephrase the question.

Can you tell the jury, please, what other teams you've been on for Eli Lilly?

A Sure, that I can remember. The Alaska State Action Team --

Q There's been a lot of teams.

A -- which you're referencing.

Q Hold on, ma'am. You said of which I can remember. That's leaves me under the impression

can give me? If you can't, just say you can't.
A Probably not.
Q I just wanted to clarify that for the record.
A Okay.
Q All right.
This Alaska State Action Team --
A Uh-huh.
Q -- what was its goal in regard to Zyprexa?
A The Alaska State Action Team isn't specific to Zyprexa.
Q Okay. Tell us what its goal is, please.
A Its goal is open access for mental health drugs, and they may -- they might work with other divisions, but I don't -- I'm not involved with that.
Q That's exactly what I thought it was. The -- well, tell the jury what open access is.
A Open access is a physician's choice to pick whatever medication they feel is appropriate for the patient that they're treating.
Q Now, you understand -- I'm sure you do -- that the Medicaid system picks up the bill for Medicaid patients here in Alaska, right?

A Sure.
Q And you understand that the State obviously has an interest in trying to do that as economically as possible; you understand that?
A I do.
Q And you understand that there have been proposals at times to restrict the sale and distribution of certain drugs in order to change the formulary; do you understand that?
A You know, I'm having trouble with the word restrict because --
Q Well, you use whatever word and explain to me -- tell me what you understand --
A The State of Alaska proposed a preferred drug list, which is not a restriction --
Q That's right.
A -- and so physicians, no matter mental health or what type of physician they are, they can always write on a prescription "medically necessary," if it's a preferred drug list.
Q Right. But a preferred drug list is different than open access, true?
A There are slight differences, yes. Yes, there are.
Q An open access formulary would allow the

ask Dave Campana or somebody about the mechanics of how the State of Alaska institutes their prior authorizations, but --

Q Well, you had a concern or your bosses had a concern about the State prior authorization pending State legislation, did they not?

A I don't remember.

(Exhibit 3 marked.)

Q Well, I'll help you remember maybe.

A Okay.

Q Exhibit 3.

A Sure.

Q There's an e-mail that you wrote in April of 2003. Do you see that?

A Uh-huh.

Q Is that yes?

A Yes, yeah.

Q I see it's to docatfish, mentalh and mlangdon and to rnassar and to worthmore and wsnow with a carbon copy to Mr. Hattori; is that correct?

A That is correct.

Q Who are the people that you're sending this e-mail to?

A The first one, I'm not sure who that is,

and I don't know who the second one is either. Mlangdon is Mary Langdon, rnassar is Ramzi Nassar. Worthmore, I believe, is Mari Jeanne Moore, but I'm not 100 percent positive. And wsnow is Wynelle Snow.

Q Where do these people work?

A The ones that I can identify are psychiatrists.

Q And you're carbon-copying your boss, so you're e-mailing --

A Jeffrey is not the boss. I'm sorry to interrupt you.

Q I'm sorry?

A Jeffrey Hattori, is that what you're saying?

Q I don't even remember.

A Ask the question again. I'm sorry.

MR. BRENNER: I think you said her boss and she was saying --

MR. ALLEN: I got that.

Q Let me see where I was.

A Okay. Sorry.

Q The people that you wrote the e-mail to are doctors?

A Yes. I don't know the -- who the first

two are.

Q And you're sending them letters that you prepared for them to sign, right?

A That is not correct.

Q Okay. Well, you're sending -- what are you sending them?

A I am sending them -- I did not prepare these documents, so the attachments are not mine. I'm sending them letters that they can look at as -- I think they were just like ideas of what to write.

Q What to write who?

A To their -- Frank Murkowski or Joel Gilbertson.

Q Right. Your e-mail and your carbon copy to Jeff Hattori -- who is Mr. Hattori?

A Jeffrey Hattori is one of the public health representatives, but he's actually -- his focus is advocacy.

Q Advocacy?

A Uh-huh.

Q And what does that mean? A public health representative with a focus on advocacy.

A He just works with the advocacy group, so NAMI Alaska, international NAMI --

Q NAMI, that's --
A -- Partners in Crisis.
Q Partners in Crisis, right.
A Right, but he doesn't work with providers and he doesn't --
Q And NAMI is the National Association of Mental Health?
A Uh-huh.
Q Ma'am?
A Yes.
Q And Partners in Crisis --
A National Alliance -- I'm sorry -- National Alliance for Mentally Ill.
Q Whatever. And the Partners in Crisis is what, ma'am?
A That is an educational program for police officers.
Q And by the way, these organizations are funded in part, both NAMI and Partners in Crisis, by Eli Lilly?
A I don't know the answer to that question.
Q You don't?
A I don't.
Q Have you ever heard that Eli Lilly gives

Q Let me see. And so I'm trying to think of a drug that Eli Lilly sold -- would Zyprexa be one of these drugs that treats these chronic mental illnesses?

A Sure, but -- yes.

Q Thank you. All right.

Now, you say in your e-mail -- why did you carbon copy Mr. Hattori?

A I can -- I don't know. I can only guess. It's a long time ago. I don't know.

Q Well, I mean, you had a business purpose. You wanted Mr. Hattori -- he had asked you to do this, hadn't he? This project.

A Most likely. I don't know.

Q Most likely. Here's what you say in your e-mail. By the way, you attach -- it says, Attachments: Alaska PA letter, PA letter, PA letter, PA letter. What does PA stand for? Prior authorization?

A I can guess, but I'm not a hundred percent sure.

Q Why don't you go ahead and do that for me, please.

A That's my best guess, but I don't -- I don't really know.

Q Prior authorization?
A Sure.
Q And it says: The following documents and addresses should be helpful in communicating your concern over the pending State prior authorization issue. Thanks for your support, Joey Eski. What is this concern about prior authorization?
A I don't remember. I do know that in a physician's office a prior authorization takes a significant amount of time and that if they have to go through a prior authorization for whatever medication it is, it's a big -- it's a big pull on their office. I mean, it's hard for their staff and it's hard on them.
Q And this is signed Joey Eski, Eli Lilly and Company, right?
A That's right.
Q Okay. And so you were preparing letters or drafts of letters --
A I didn't prepare these. I'm sorry.
Q Well, you do -- you remember you didn't prepare it?
A I didn't -- these are not my documents.
Q Well, where did they come from?

A I think Jeffrey Hattori, but I don't remember at this point. I don't know.

Q The attachments that you were sending on behalf of Eli Lilly and Company came from Eli Lilly and Company, right?

A I would assume so.

Q Yeah. And you assume it would come from Jeff Hattori?

A Probably.

Q And you're sending them to the doctors concerning this prior authorization issue, right?

A It looks that way, but I'm not sure.

Q Yes. And then you list four of the doctors besides the attached letters. You list some names that include the governor -- the then governor's name, Governor Murkowski, Joel Gilbertson at the Department of Health & Human Services.

A Uh-huh.

Q Representative John Harris of the Alaska legislature, Representative Bill Williams, Senator Lyda Green, Senator Gary Wilken; is that correct?

A That's correct.

Q You wanted -- so you were having these

doctors try to assist Eli Lilly in a lobbying campaign for Eli Lilly, right?

MR. BRENNER: Objection to the form.

A You know, we never asked them to do it for Lilly specifically. I mean, just open access in general, so --

Q (BY MR. ALLEN) You were -- you were --

A -- no prior authorization for anything. Nothing.

Q Nothing?

A For mental health drugs.

Q So you were trying to stop prior authorization for mental health drugs?

A Yes.

Q That would include Zyprexa?

A It includes Zyprexa.

Q Right. And do you remember being asked to find speakers and advocates to defend the mental health medications that Eli Lilly sold?

A Speakers and advocates. For this topic specifically? For open access or for --

Q For any topic.

A I don't know what you're asking me. Say it again, please.

(Exhibit 4 marked.)

Q Yes, ma'am. I'm going to hand you what I've marked as Exhibit 4. And by the way, I don't have time today to go over all of them, but there's many of these in the files with your name on it.

A Sure.

Q This is a -- at the top it says, Alaska State Action Team, ASAT, Meeting Minutes, March of 2004. Have you ever been to, first of all, an Alaska State Action Team Meeting?

A They're by phone.

Q Okay. Your attendance right there. It says Joey Eski, Neuro Institutional Sales, Eli Lilly, right?

A Right.

Q Tell me -- we see ASAT Meeting Minutes. Objectives: Full MH Medication Carve-out.

Do you see that? Want me to help you?

A Right here?

Q Well, no, ma'am. I think the objective is right up here.

A I'm sorry.

Q Do you see that?

A I do see that.
Q Tell us -- tell the jury what that means.
A A full mental health carve-out?
Q Yes, ma'am.
A Would be -- I believe my understanding of it is to have mental health drugs legislatively carved out by using a House Bill or Senate Bill instead of having it reviewed by the preferred drug list P&T committee.
Q Why would you want that done?
A I don't know. I mean, it's just two ways to do the same thing.
Q What thing are you trying to accomplish?
A Open access.
Q Okay. No restrictions on Zyprexa prescriptions, correct?
A No prescriptions on any mental health drugs.
Q Objection; nonresponsive. And I think you also misspoke.
A Oh, I did?
Q You were trying to get no restrictions on any mental health drugs, according to you, including but not limited to Zyprexa, correct?

A Right.
Q And you, in fact, were involved in a team that was looking to try to get legislation passed in this state on that matter, right?
A I was a participant in the team.
Q Yes. So we see now you have sent letters to doctors and gave them lists of elected representatives, right?
A Uh-huh.
Q Is that a yes?
A Yes.
Q And you were on a team that had as its goal specific legislation that would help protect access to drugs including Zyprexa, correct?
A Yes.
Q Do you think any of this activity involves the desire to make money by Eli Lilly?
A We are a business. It is a business.
Q But just so the record is clear, here in Alaska you can personally speak to the fact that there are activities, teams, meetings and persons with job responsibilities whose focus is on maintaining access to Lilly's drugs in particular and Zyprexa is one of those, right?
MR. BRENNER: Objection to the

Q Okay. Jeffrey Hattori, Lilly; is that correct?
A Yes.
Q Frank Dorr, Lilly; is that correct?
A Yes.
Q Now, you also had a lobbyist that you all hired to help you with this open access, correct?
A That's correct.
Q Do you know the lobbyist's name?
A I do.
Q Tell the lobbyist's name, please.
A Sam Kito.
Q Have you worked with him?
A I have not worked directly with Sam Kito.
Q You've been in meetings with him?
A On the phone, by phone.
Q What's the lobbyist -- what's his job? To lobby the legislature and the governmental offices?
A You know, I -- I don't really know exactly what his -- what we've engaged him for. You know, on calls it's usually -- he's usually the person that updates on what House Bill or

Senate Bills are out there. I mean, he's kind of -- he's kind of the --

Q The political guy?

A Yeah.

MR. BRENNER: Objection to the form.

A I don't know.

Q (BY MR. ALLEN) Right. And then we've got the PR firm. You all have a PR firm also, do you not?

A Yes, it is.

Q Ms. Barbara Smith and that firm is Harris and Smith, right?

A I'm not familiar with the firm.

Q Well, those are the people that attended the meeting, Lilly employees and contract people that Lilly hired on the Alaska State Action Team, right?

A Uh-huh.

Q Is that a yes?

A Yes.

Q And that was to try to help Lilly maintain open access for its drugs, including Zyprexa, right?

MR. BRENNER: Objection to the

form.

A That was -- it's more, it's bigger. It's to help maintain open access for everyone and Lilly's a piece of it.

Q (BY MR. ALLEN) Okay. I'm just looking for the other companies that attended this meeting. I don't see any.

MR. BRENNER: Strike that. There's no question.

MR. ALLEN: Oh, there's a question. Let me rephrase it into another way.

Q On this Alaska State Action Team did you have any non-Lilly personnel or non-Lilly hired personnel on this team?

A No.

Q Thank you. Now, under Action Steps there's five arrows, and I'm just going to read the fifth arrow. It says: Kevin slash Joey slash Jeffrey. I guess Joey is you, Mrs. Eski?

A I would assume that.

Q Work to have speakers and advocates at P&T meeting to defend MH meds. Can you explain P&T?

A Pharmacy and therapeutics.

Q And where would these meetings take

place?

Let me stop. Just for the record, that's not my cell phone. That's your lawyer's cell phone. So my question -- why don't we take a break and we'll come back. We're on what is P&T.

A Okay.

THE VIDEOGRAPHER: Going off the record at approximately 11:36 a.m.

One moment, please.

(Break.)

THE VIDEOGRAPHER: One moment, please.

We're on the record. The time is approximately 11:51 a.m.

Q (BY MR. ALLEN) Mrs. Eski, Scott Allen again. We took a break at my request. Again, if you need to take a break, you let me know and I'll take one at your request.

A Okay. Thank you.

Q We don't need to match evenly. If you have more than me, that's fine. All right?

A All right.

Q On Exhibit 4, the Alaska State Action Team Meeting Minutes of March of 2004, it

records, as we've discussed, that you are working with Kevin Walters, Public Health, and Jeffrey Hattori, public affairs liaison, to have speakers and advocates at P&T meetings to defend mental health medications.

Did I read that --

A Sure.

Q And tell -- did I read that right?

A Uh-huh.

Q Yes?

A Yes.

Q And P&T means what?

A Pharmacy and therapeutics.

Q And speakers and advocates, what kind of speakers and advocates were you trying to obtain and for what purpose?

A To the best of my recollection, it would have been for this -- we would welcome anyone in mental health that has very strong feelings about open access and open treatment for patients. So it could be a psychiatrist. It could be a clinician. It could be a nurse. Anybody who interacts with the patients.

Q Okay, but where were you going to have them speak and advocate?

Where is he a psychiatrist?
A He is currently at Langdon Clinic.
Q Ma'am?
A Langdon Clinic.
Q And where is that?
A 401 Dale Street.
Q All right.
A Is that what you're asking me? I don't -- in Anchorage.
Q Yes, ma'am. All right, ma'am.
Now, you also, as part of your job on this Alaska State Action Committee, would identify potential advocates, would you not?
A Define advocate, please.
Q Well, let me ask you the question, first. Did you define -- or help recruit advocates?
A I don't know what you mean by advocate. I'm sorry.
(Exhibit 5 marked.)
Q Yes, ma'am. I'm going to hand you what's marked as Exhibit No. 5. I have one for you and one for your counsel.
A Okay.
Q Alaska State Action Team Meeting

Minutes, teleconference call in May of 2003. I'll go down to Advocacy Update. Do you see that?

A I do.

Q And it says: Through the efforts of Frank Dorr, Jon Hett and Joey Eski. Who are Mr. Dorr and Mr. Hett?

A Frank Dorr is a district sales manager for Eli Lilly, and John Hett was a past district sales manager for Eli Lilly.

Q It says, through the efforts of those individuals, including you, nine physicians were secured via Dr. Verner Stillner to support mental health meds by writing letters or testifying. Dr. Stillner has secured and sent off five letters and Joey -- that's you -- and Mary Beth are securing more. Jeffrey will work with Joey and Amy to get the letters to the governor and co-chairs of the Finance Committee in the House and Senate, along with the commissioner of the Department of Human Services. We must continue to get letters, three exclamation points.

Did I read that correctly?

A You read it correctly.

Q Okay. What were you doing there in this

advocacy update? What was your job there?
A To discuss with physicians open access --
Q Well, ma'am --
A -- basically, and were they interested -- I mean, how strongly did they feel about open access that they would want to write a letter or attend a meeting.
Q Ma'am, it also indicates that you were involved in getting physicians to write letters and testify and to get letters to the governor and to the legislature and to the Department of Human Services, right?
A It looks that way.
Q What were you trying to get these letters and people -- who were they going to testify before, first of all? The legislature?
A I don't believe so. I don't really recall. I mean, I would guess P&T, but that's a guess.
Q P&T?
A Yeah.
Q The therapy committee, pharmaceutical and therapy committees?
A I don't know exactly what the date of

this is.

Q Well, it is -- it's May the 5th, 2003. It's right there at the top.

A Sure. And I don't know -- I can't remember the time frame of when the P&T began.

Q Okay. Well --

A So there was a time leading up to it that there was no P&T and that they were considering what kind of system to use.

Q Okay. Well, why were you involved in the efforts to get letters to the governor and the legislature and the regulatory departments in this state? What was your goal? What was your goal?

MR. BRENNER: Objection to the form.

A You asked me two questions. Why was I involved and --

Q Okay. Let's start with why were you involved?

A Because I was the -- I was a local person who had the contacts with the physicians.

Q And what was Lilly's goal in this process?

A Open access for all mental health

wouldn't have produced that list. Verner Stillner would probably be the extent of my contact. I've never met Pat Murphy, Jeff Jessee, any of the other people on this list.

Q Nevertheless, the -- this paragraph states that Joey Eski has provided a great list of potential advocates including, and it lists individuals from the Alaska Department of Health and Human Services, correct?

A It's correct, but I -- that's what it says, but I don't believe the document's correct --

Q Okay. Well, why don't we go --

A -- to be honest with you.

Q All right. I apologize for interrupting you. Are you finished?

A No. I'm just surprised that I got credit for something I didn't do.

Q Okay, ma'am. Let's go to the next page of this document, the Legislative Battle Plan. Did you all have a legislative battle plan there at the Alaska State Action Team?

A That's not my -- that's what I would consider it, but that's what they call it. And, I mean, my -- I mean, that's what it says.

Q That's what it says. Then, under it, three bullet points down it says -- you were involved in this battle plan. It says: Jeffrey, Joey, Mary Beth and Kevin will continue to get letters from, quote, thought leaders, closed quote, and send out ASAP.

Did I read that correctly?

MR. BRENNER: Objection to the form.

A You read it correctly.

Q (BY MR. ALLEN) ASAP means as soon as possible, right?

A Yes.

Q And you were involved in the process of trying to influence the Alaska State legislature, were you not?

MR. BRENNER: Objection to the form.

A I don't know how to answer your question. I'm sorry.

Q (BY MR. ALLEN) Well, ma'am, the document reflects that you were a part of the legislative battle plan, correct?

A It does kind of. I don't know what you're asking me. I'm sorry.

Q Well, I'm just asking a simple question now. The document reflects that you were part of the activities involved from -- excuse me. Let me rephrase it.

The document reflects you were a part of the -- Eli Lilly's legislative battle plan and you had activities and responsibilities regarding that, true?

MR. BRENNER: Objection to the form.

A I guess.

Q (BY MR. ALLEN) Thank you.

A I can't really answer that. I don't -- I'm sorry.

Q Well, the document -- the jury will have the document.

Ma'am, do you remember there was -- you were involved in urgent activity surrounding the Alaska State Action Committee in trying to get letters as soon as possible sent around concerning this mental health carve-out?

A Do I recall it?

Q Yes, ma'am.

A I do recall it.

Q Okay. Now, on this mental health

carve-out, I think I heard you earlier say -- and I'm paraphrasing. This is my co-attorney here. Mr. Marcum wrote this down for me and wanted me to explore it.

A Okay.

Q He said you said the full mental health carve-out. I have mental health drugs -- what's that word?

MR. MARCUM: Carved out.

Q (BY MR. ALLEN) Here's what you said about -- I asked you what the mental health carve-out was --

A Sure.

Q -- and we have you say -- and the record will reflect exactly what you said, but it says, to have mental health drugs carved out of review by the PTL (sic) committee.

Do you recall that?

MR. BRENNER: Objection to the form.

Q (BY MR. ALLEN) P&L -- let me rephrase it.

Do you recall giving an answer that the goal of this mental health carve-out was to have mental health drugs carved out of review by

the P&T committee?

Mr. Brenner has great humor in this, evidently. So we're going to get to it.

Let me see -- what was your goal in the mental health carve-out? Tell me again.

A To not have those drugs reviewed.

Q By whom?

A By State Medicaid P&T.

Q And the State Medicaid P&T would be the committees that would review the safety information concerning the drug, right?

MR. BRENNER: Objection to the form.

A You know, P&T looks at a number of things. Safety is just one of them.

Q (BY MR. ALLEN) Right. And you were trying to get mental health drugs, including Zyprexa, exempted from the review by the P&T, correct?

A Trying to get them exempted. We were trying to have open access to all meds, so that it wouldn't need to go through the review process.

Q Yeah. You were trying to have Lilly's drugs, mental health drugs, including Zyprexa,

exclamation points. All caps, Need letters now, three exclamation points. All caps, Please read, colon, Alaska State Action Team Meeting from Joey Eski.

Did I read that correctly?

A Sorry, I'm --

Q You see the -- it's right there. The subject. It says re: Urgent -- it's all capital letters. Urgent, need letters, please read, three exclamation points, Alaska State Action. Isn't it right there?

A Uh-huh.

Q Is that a yes?

A Yes.

Q And you wrote this e-mail, did you not? From Joey Eski?

A I replied to this e-mail, so that's not my subject title.

Q Okay. Ma'am, the one we're looking at, the very top of the exhibit --

A Yeah, but I wrote the -- I wrote the Jeffrey and then the next line.

Q Yes, ma'am. I'm not trying to trick you. Do you think I'm trying to trick you here?

A Absolutely not. I'm just --

Q Okay. It says to Jeffrey Hattori, May 8, 2003, from Joey Eski. And it says, Urgent, Need letters now, Please read, Alaska State Action Team Meeting. And then it has attachments again, which is Alaska PA letters, right?

A It looks like they're the same letters as the last e-mail.

Q And what's the PA stand for?

A I guess prior auth, but I don't recall.

Q Prior what?

A Prior authorization, but I don't recall.

Q And it says -- you write this. It says: Jeffrey, all these people and more sent letters in directly. I did not request copies, but will try to get them, Joey. And the letters were sent to where, ma'am?

A I don't recall, actually. I mean --

Q Well, we can look back here. As part of this battle plan, if you go back to the second page, this is an e-mail chain. Jeffrey Hattori sends you an e-mail on the same day, May 8th at just a little after noon. You see that? You see it?

A Yes.

Q Urgent, Need letters now, Please read.

And then you're listed as a recipient of the e-mail.

A I am.

Q And it says that -- and this is all caps and bolded, is it not? This e-mail?

A It is, yes.

Q Does that mean there's some emphasis on this? Would you agree?

A I didn't write it, but I would guess it was --

Q You received it?

A I received it, yes.

Q So the writer is trying to convey a message to the recipient, and so you would have been a recipient. Would you interpret all capitals, exclamation points and bold letters as being something that's pretty important?

MR. BRENNER: Objection to the form.

A I guess. I don't know. I didn't write it. I don't really --

Q (BY MR. ALLEN) Well, let's see what it says. Let's go back to that e-mail, second page. You there with me?

A I am.

Q The time is now to fully engage our battle plan to get a mental health carve-out. Please identify all advocates, including physicians, to engage in this battle. I have attached sample letters below. Please secure letters on letterhead and have sent to those addressed.

It's all caps. Also fax copies of letters to Sam Kito's office. That's the lobbyist, right?

A Yes.

Q Gives a number. Nate -- who's Nate?

A Miles.

Q What's his job -- public -- what is his job?

A I don't know what his title is.

Q Well, you told us earlier what his job is.

A He's -- I said he's part of the public health, but I don't know what his title is.

Q Says: Nate is in Alaska right now and needs the letters. Continuing, all caps and bolded, legislative session is ending very soon and acting quickly. Thanks for your help, exclamation point.

Did I read that correctly?

A Yes.

Q And when you got this, you responded within three hours to Jeffrey -- let me see where it was. You responded -- no, you actually responded -- your response came ten hours later and it says: All these people and more sent letters in directly. I did not request copies, but I will try to get them; is that correct?

A That is correct.

Q And right below that you're a recipient of an e-mail from Mr. Hattori at 2:00 in the afternoon that says: Thanks everyone for your help on this. I have five letters from Dr. Stillner and other docs from Bartlett. I know Joey was working on some others, however, here are some others. If you have contact with who signed up from the APA -- American Psychiatric meeting, correct?

A Yes.

Q Okay. So you were involved in the legislative battle plan to try to carve out mental health drugs from P&T review, were you not?

MR. BRENNER: Objection to the

form.

A Yes, I was part of the State Alaska Team.

Q (BY MR. ALLEN) Yes. Thank you. Now, you also worked -- do you remember working with a PR firm? Well, first of all, let me ask you: That last e-mail, Exhibit 6, seemed to indicate that you at least were instructed to call the lobbyist --

A Call?

Q -- Mr. Kito.

A Where?

Q Where? Let me see. Right here -- e-mail that you received at 12:09 p.m. Urgent, Need letters now, Please read, Alaska State Action Team Meeting. And then if you go to the second page, Also fax copies of letters to Sam Kito's office, right?

A I've never called Sam Kito's office. I mean, there's -- on the State Action Team I play a role. So that's not one of my roles.

Q Okay. Well, you were advised to send these letters that you were gathering in the legislative battle plan to the lobbyist, right?

A Was I specifically? Let me see. It

so it wasn't a big change. I mean, I've never --

Q (BY MR. ALLEN) Oh, you've always told doctors --

A No, I've never told them that -- sorry, go ahead.

Q Did you mean to state that you always told doctors that Zyprexa carried a greater risk other than Clozaril?

A No, but I've always told them we don't really know and that, you know, there's lots of risk factors, and weight gain is one of them and you want to look at that and -- you know, I just don't talk to my doctors that way. It's conversational. It's responsive to them, and I'm not going to -- I can't tell them how to practice medicine.

Q Well, don't -- objection; nonresponsive. Don't you remember giving doctors the comparable rates message in handouts? You remember that, don't you?

A Vaguely, yes.

Q Vaguely. Would writings help refresh your recollection? Would your writings help refresh your recollection, ma'am?

A Of course.

Q Of course
A Uh-huh.
Q Is that a yes?
A Yes.
Q Okay. Well, let me give you some writings of yours to refresh your recollection.
(Exhibit 8 marked.)
Q Did I mark that already? Well, good for me.
Ma'am, I'm going to hand you what I've marked as Exhibit No. 8.
A All right.
Q They're some copies of your call notes --
A Sure.
Q -- from the past years. And let me see if I can point you to some that may refresh your recollection. I put these in chronological order. I'll try to find you one.
Here we go. Go back to a meeting you had with Chuck Ellis in Juneau in October of 2001. It's October 17th.
A Are these numbered at all?
Q Ma'am, they're in chronological order, so if you can get back to October, 2001. October

17th to be exact.
A Okay.
Q This is a call note that you prepared, correct?
A It is.
Q It is?
A I believe so.
Q It's regarding Dr. Ellis. You know Dr. Ellis?
A I do.
Q And you said, Melvin and diabetes data. What is that, ma'am?
A It was a long time ago. I don't know. It's a shorthand. I -- I don't know.
Q Ma'am, I found the shorthand Melvin -- if you go to the prior note -- go to the prior note for the prior day.
A Right.
Q August 29th, 2001, when you were meeting with Dr. Nella Davis in Anchorage. You have Melvin written down, do you not?
A I do.
Q So if you go to the prior note, the date August 28th, 2001, you have Melvin, do you not?
A I do.

not?
A We used to a long time ago. We don't do that very much anymore.
Q Okay. Well, back to your note about this issue of what you tell doctors about diabetes. In October of 2001 your note says: Melvin and diabetes data -- skipping along -- brought late lunch in for him. Lead with diabetes info.
Did I read that correctly?
A You did.
Q So you're leading, you're going into the doctor's office to affirmatively discuss diabetes, right?
A You know, to make -- sure, to make them aware of our current data. I would use whatever was provided to me from corporate at that time.
Q Sure. And then you record what you provided and what you said.
A Uh-huh.
Q He did really -- he did really have an issue, but has heard there may be a problem from other reps. Agreed with comparable rates data.
Did I read that correctly?
A You did, but I think I had a typo.

Q Okay. Well, why don't you -- yes, ma'am. I'm focusing on agreed with comparable rates data. Do you see that?

A Uh-huh.

Q Is that a yes?

A Yes.

Q Did you, in fact, have comparable rates sell sheets or data sheets that you would provide to doctors?

A I remember the terminology, but I don't remember the -- the sheets.

Q Okay, ma'am. The reason I ask, ma'am, it's in more than one place in your call notes. Let's go to the next page. We were talking about the meeting of October 17th with Chuck Ellis in Juneau. I have one with Jean Boga in Anchorage in October of 2001, do I not?

A Yes.

Q That's your call note, isn't it?

A It is.

Q It says: Went through full diabetes info. That's you doing that, right?

A Uh-huh.

Q Is that a yes?

A Yes.

Q It says: She agrees that there are comparable rates across agents. Some push-back on weight gain relation.

Did I read that correctly?

A Yes.

Q If you go to the next note, October 24th, 2001, you're talking to Dr. Mark Erickson in Anchorage and it says: Action, lunch presentation, led with diabetes data.

Do you see that?

A Uh-huh.

Q Is that a yes?

A Yes.

Q It says, Reaction, group in general didn't believe there was a direct link between Zyprexa and diabetes, but thought there might be a secondary link with weight gain.

A Uh-huh.

Q Did I read that right?

A You did.

Q This is your note. Went through data in detail. Focused on weight gain chart and risk factors. All should have walked away thinking and saying comparable rates.

Did I read that correctly?

A Yes.
Q Let's go to the next page. Let's go two pages back, two pages back, ma'am. Your call note of November the 14th. You're in Fairbanks -- of November 14th, 2001. You're in Fairbanks with Dr. Duane Hopson. Do you see down towards the bottom of your call note it says: Showed him -- showed him diabetes data. He agreed that it made sense. There are comparable rates across agents. Discussed possibly setting up another afternoon meeting and presenting data.
Did I read that correctly?
A You did.
Q We need to change tapes.
THE VIDEOGRAPHER: Going off the record at approximately 12:37 p.m. This is the end of Tape No. 1 of today's deposition of Joey Eski, being taken on the 29th of February, 2008. Again, the time is approximately 12:37 p.m.
We're off the record.
(Break.)
THE VIDEOGRAPHER: One moment, please.
We're on the record. This is the beginning of Tape No. 2 in today's deposition of

Q If you find March 20th.
A I'm looking. Okay. She's a nurse practitioner, yes.
Q I'm sorry. She can prescribe medication?
A That's correct.
Q Okay. So you're talking to her because she can write prescriptions for Zyprexa, right?
A Yes.
Q Thank you, ma'am. It says: Action, Waffle Wednesday. Showed diabetes in mentally ill video.
Did I read that correctly?
A You did.
Q So this DVD or -- show diabetes video. Was that a DVD or is it a tape? I can't remember.
A I don't know. I mean, it could have been a VHS tape. I don't know.
Q But it had to be consistent with the labeling, correct?
A I don't know exactly the reference to which one is being used here.
Q Well, let's just read what you wrote. Really good take-aways from the audience. I

personally took four pages of notes. Follow-up to make sure each participant came away knowing that there are comparable rates of diabetes among patients taking atypical antipsychotics.

Did I read that correctly?

A Yes.

Q It says -- and I want to make sure: You followed up to make sure each participant came away knowing that there were comparable rates, correct?

A No, follow-up is like a note to myself.

Q Okay.

A So I'm looking at this and -- I mean, I'm guessing because it's been a long time. But if I'm showing a video and I'm taking notes on it, we had lots of at the time CME videos that were not specific to our product called psychLINKs and so --

Q So let's just read your words, though.

A Right.

Q It says you took four pages of notes and then you said, Follow up to make sure each participant came away knowing that there are comparable rates of diabetes among patients taking atypical antipsychotics, right?

Q Okay. Does it all bring it back to you that there for -- at least during the time period we've identified in these brief excerpts of notes, from 2001 through 2003, you were involved in the comparable rates message?

MR. BRENNER: Objection to the form.

A Around diabetes, yes.

Q (BY MR. ALLEN) Yes. Tell the jury what the comparable rates message was.

A I don't recall the specifics of the comparable rates message.

Q Just give us the best you can recall.

A You know, my message has always been, with diabetes we don't know. We don't know. And, you know, take precautions with patients that have risk factors, so we've done a lot of education on risk factors and education around what are recommended baselines. So to say that I gave a comparable rates message, I'd have to see what you're showing me. And that's not -- I write it as a shorthand to -- that I discussed diabetes. I don't know that I gave the -- I don't know if I gave exactly what you're calling the comparable rates message.

Q Objection; nonresponsive.

Ma'am, I'm talking about your notes.

A Right.

Q Your personal notes --

A Correct.

Q -- reflect that you were discussing the comparable rates message, right?

MR. BRENNER: Objection to the form.

A I refer to it as a comparable rates and I don't -- but I don't know if I'm specifically giving what you're -- I don't know if we're talking about the same exact message. I'm not sure.

Q (BY MR. ALLEN) Well, who trained you on the comparable rates message?

A I couldn't answer that. I don't know.

Q Eli Lilly, didn't they?

A Well, the company, yes.

Q Okay. You at least concede that Eli Lilly trained you as a sales representative for Zyprexa on the comparable rates message, right?

MR. BRENNER: Objection to the form.

A I remember receiving training around it. I don't remember the specifics of it or the details or who implemented it or what it said, to be honest with you. It's been a really long time.

Q (BY MR. ALLEN) It hasn't been that long, has it?

A It has.

Q Well, what about when the consensus statement came out? Do you recall that?

A I do, yeah.

Q The consensus statement indicated that Zyprexa and Clozaril were worse than the other second-generation antipsychotics concerning risk for diabetes and hyperglycemia, did they not?

MR. BRENNER: Objection to the form.

A You'd have to put it right in front of me. I don't remember the exact details of it.

Q (BY MR. ALLEN) Okay. Well, are you still giving the comparable rates message?

MR. BRENNER: Objection to the form.

A About what?

Q (BY MR. ALLEN) Hyperglycemia and/or

Q Let me rephrase the question.

Would you agree that you discussed the comparable rates message with doctors here in Alaska or nurse practitioners or other health care providers when you detailed Zyprexa?

MR. BRENNER: Objection to the form.

A Comparable rates of what?

Q (BY MR. ALLEN) You never heard the comparable rates message and what it was related to?

A Yes, but we have, you know, diabetes versus hyperglycemia. It's different. There's --

(Exhibit 10 marked.)

Q Well, ma'am, I'm going to hand you Exhibit 10. Maybe this will help clear up the confusion. You recognize this, don't you?

A I do recognize this, yes.

Q Doesn't it say comparable rates of diabetes and hyperglycemia among psychotropics?

A It does.

Q And isn't this something that you gave to doctors?

A I can't remember if we left it with

doctors or not.

Q Well, isn't this the type of information that you would leave -- you know, was it Mr. Noesges -- he's testified under oath this was given to doctors. Are you telling --

A I don't know if we could hand it out. I don't know is what I'm saying.

Q Does this not appear to you to be -- let me ask this question first: Does this document, Exhibit No. 10, refresh your recollection that you were out detailing doctors and health care providers with the comparable rates of diabetes and hyperglycemia among psychotropics? Does that refresh your recollection?

A You know, I remember using this, but I don't know that I actually ever gave this as a message. I've always told my providers we don't know about diabetes and it's so multi-factorial, diabetes is. And you can -- when I'm interacting with a physician, I don't -- I just give them the data that we have, but we've never told them either way whether Zyprexa causes or doesn't cause diabetes. It's never been a comfort level for me. I think they have to watch their patients. So I've never -- you know, I've never

given them this kind of -- I mean, I just have always told them we don't really know. I mean, this is what we know, but it's not much. Because that's what I believe.

Q You through with your answer?

A I guess.

Q Objection; nonresponsive.

Ma'am, on Exhibit No. 10 -- I'm trying to look for the company that drafted this. Can you identify it for me, please?

A May I ask you a question first? Sorry. Or do I ask you? What does it mean, objection; nonresponsive?

MR. BRENNER: Don't worry about that.

THE WITNESS: Okay.

MR. BRENNER: You can just answer his question.

THE WITNESS: Okay.

Q (BY MR. ALLEN) Let me rephrase my question. Very simple question. I'm trying to see who prepared Exhibit No. 10.

A Someone at Lilly.

Q They have Lilly -- this is a Lilly document, isn't it?

A It is, yes.
Q And let me read what Lilly said. It has a number up there, 1, doesn't it, the number 1. Do you see it?
A Uh-huh.
Q Is that a yes?
A Yes.
Q Comparable rates of diabetes and hyperglycemia among psychotropics. Patients treated with Zyprexa had rates of diabetes and hyperglycemia comparable to those in patients treated with Risperidone, haloperidol and divalproex sodium in clinical trials.
Did I read that correctly?
A Yes.
Q Are you still telling doctors that today?
MR. BRENNER: Objection to the form.
A In clinical trials? In the clinical trials that were used here? I mean, it's evolved. We have more data. Back then we didn't have as much data. So in clinical trials -- is that what you're asking me? Do I still tell them that in clinical trials we had -- I'm sorry,

you're going to have to define what you mean. Does it mean premarketing clinical trials? Postmarketing clinical trials?

Q Is that your answer to my question?

A Can you rephrase the question again? Sorry.

Q No, ma'am. Did you answer my question?

A I don't know if I answered your question. I need it to be rephrased -- asked again.

Q If Mr. Noesges and others have identified Exhibit 10 as a physician handout, are you disagreeing with them?

A No. I'm saying I can't remember.

Q Okay. You're not denying that this was given?

A No. No, I just don't know.

Q You just don't know?

A Yeah, I can't remember.

Q Let me see if I can get another one.

(Exhibit 11 marked.)

Q Let's see. Exhibit 11, maybe it will help you see if you can recall the message. Exhibit No. 11, you see that? Do you recognize this document, ma'am? By the way, it's poorly

stapled together. I need to -- it's upside down.

A I remember the concept. I don't know that I remember the document per se as it's presented here.

Q Uh-huh. Do you see on the third page of this document -- by the way, if individuals have testified this was another physician handout, are you contradicting them or what are you saying?

A I'm saying I have not seen it in this kind of a form. I don't know.

Q Okay. What kind of format have you seen it in?

A I just don't remember it looking like this. I mean --

Q What do you remember it looking like?

A I thought it was on a detail piece or something. I can remember. I remember it, but I don't remember where it was.

Q Okay. But you've already agreed that anything that was a detail piece or anything you left with doctors had to be within the label, right?

A Yes.

Q Okay. So if you look at the third page of this document: How do the medications you use

compare? Rates of diabetes were comparable for commonly-prescribed psychotropics during longer-term clinical trials.

Do you see that?

A Uh-huh.

Q Ma'am?

A I do see that, yes.

Q Okay. So we know, at least, that this comparable rates message that you were transmitting to doctors was within the label according to you; is that correct?

MR. BRENNER: Objection to the form.

A I don't know that I ever used this.

Q (BY MR. ALLEN) Okay. Then, put that Exhibit 11 aside. You said you just can't remember, right?

A About this document?

Q Yes, ma'am.

A Yeah. I mean, it just looks vaguely familiar. I don't remember.

Q So No. 10, which has a discussion of comparable rates, you recall, and No. 11 which discusses comparable rates you have a vague recollection of?

A I recall this one; this one I do not.
Q You recall 10?
A Yes.
Q And you do not recall 11?
A Not really, but --
Q But what? But what?
A I mean, there are periods of time when I'm on leave that I may not have received these documents because I was not in the field.
Q But we do know, because you've sworn to it under oath and it's a matter of company policy and we saw it in the company policy, that you would never detail outside the label, right?
A Never proactively detail outside of the label.
Q You don't do that?
A No.
Q Okay. You've already sworn to that and we saw the policy. Remember?
A Right.
Q Right?
A Yeah. Unless a doctor asks me an unsolicited question. I don't proactively talk to them about anything off-label.
Q So we know regarding safety information

Q No, ma'am.
A In general, are physicians worried about Zyprexa? Is that --
Q Ma'am, you're rephrasing -- have you ever undergone media training?
A No. No, am I doing something wrong?
Q Have you ever undergone any training like bridging or anything like that?
A No, I have no idea what you're talking about.
Q Has anybody trained you that when you answer a question, that you answer the question with another question? Have you ever undergone any training like that?
A No.
Q Okay. Then I'll go back to my original question. Doctors who you detailed on Zyprexa, they were interested in the risk of Zyprexa, were they not?
A They are interested in everything about Zyprexa, all of the available data. So if you're asking me specifically to this, they're interested in everything about the drug. They need to know everything to make their decision.
Q Why do they need to know everything?

A Because they need to look at their patient and look at the patient profile and look at the risk factors of a patient to decide what is going to work for them or what, you know, they think might be not an appropriate choice for them, so --

Q When did you first learn that doctors needed to know everything?

A About what?

Q About the product, using your term.

A That's my job, is to communicate as much as I can to give them the data to make the clinical decision. They -- ultimately they make the clinical decision based on the information that they have.

Q And the information that they have comes in part from you, does it not?

A It comes in part, but there are other sources as well.

Q Ma'am, I'm fully familiar with that answer. I've heard it a lot in my career.

But my question to you was: Part of the information and data comes from you, does it not?

A It does, yes. And I --

Q And you've testified, you swore to tell the truth today, right?
A Yes.
Q And you just got through telling us that the doctor needs to know everything in order to make that choice. Do you recall that?
A Everything that's available, yes, they should -- they should know.
Q Okay. And why do they need to know everything that's available?
MR. BRENNER: Objection; asked and answered.
A So that they can customize their decision to the patient.
Q (BY MR. ALLEN) It's in order to make an informed choice, correct?
A Yes.
Q Ma'am?
A Uh-huh, yes.
Q And why do you want them to make an informed choice?
A So that they have a better outcome for their patient.
Q Right. And if information is hidden from them and is not contained within the

what you focus on?

A That's what I focus on. Yes, and then my focus is, this is our information, these are the risk factors. This is how you implement it in your practice. Not this is what the label says. This is -- how does it impact your practice.

Q So when you get a new warning that says there's undesirable alterations in lipids, you start communicating that, correct?

A Right.

Q Okay. And you said if the company would give you material that says that, you begin to distribute it to your physicians?

A Yes.

Q And when you get a warning that says, Patients taking olanzapine should be monitored regularly for worsening of glucose control, you pass that warning along to your physicians?

A Yes.

Q And when you get a warning of weight gain and that the potential consequences of weight gain should be considered prior to starting olanzapine in the warning section, you pass that on to physicians?

A Yes.
Q And if it's not in the warning section concerning those statements as we just discussed, you don't pass it on, do you?
MR. BRENNER: Objection.
A That's not true.
Q (BY MR. ALLEN) Well, did you ever pass on to doctors prior to October of 2007 that undesirable alterations in lipids have been observed with olanzapine use?
A No.
Q Okay. And you don't even know what the word undesirable means.
A I'm not sure exactly what they're referencing here. I mean, if it's true as to what --
Q When you say what they're referencing --
A -- what the package insert's referencing as undesirable alterations.
Q That's Eli Lilly, right?
A It is.
Q Okay. All right. Now --
A I focus on the next paragraph, so --
Q You're focusing on what?
A No, I mean, I would just focus on the

details with my provider.
Q The details as contained in the warning?
A Right, but not that word, I guess, is what I'm trying to --
Q And what you're telling us is: Mr. Allen, I want you to clearly understand, I as a sales representative will focus on the details in the warning and I'll pass that along to the doctors?
A Yes.
Q And then that way the doctors can make a better informed choice?
A Uh-huh.
Q Is that yes?
A Yes.
Q And the patients can get better information?
A Yes.
Q And so the contents of the warning matter; isn't that what you're telling me?
A They do. I just was stumbling over the words --
Q Okay. That's fine.
A -- of what the words mean, so --
Q I understand. You're just trying to

A Sorry.
Q You raised a good point and I'll be glad to discuss that with you. But let me go back to my last question. So what's said in the warning does make a difference in what you hand out to the physicians?
A Yes, the warnings are important.
Q Thank you. And it makes a difference in what you hand out to the physicians?
MR. BRENNER: Objection; asked and answered.
A Do I still have to --
Q (BY MR. ALLEN) Ma'am?
A I mean, I hand out whatever the materials are at the current time. If it focuses on the warning, you focus on the warning. If it's -- you know, if it's efficacy, it's efficacy.
Q So you look to Eli Lilly to give you the best --
A Absolutely. Uh-huh.
Q Okay. Have you ever heard the word fair balance?
A Yes.
Q Can you tell the jury what that is?

A It wasn't a surprise to my providers, but it is in the warning section and we brought that to their attention.

Q (BY MR. ALLEN) Are you -- isn't the warning label -- I thought you said to me earlier, you said it's up to the FDA. Do you recall that?

A I do.

Q And so you've told me, I bet you, you follow what the FDA says, right?

A I try to.

Q So if the FDA says, go give a warning, you'll go give a warning?

A Absolutely.

Q So it's a big difference when something's in the warning section, right?

MR. BRENNER: Objection.

A It's a big difference in terms of -- that we go and proactively alert people, yes.

Q (BY MR. ALLEN) Yeah. You go alert people, right?

A Uh-huh.

Q Is that a yes?

A Yes.

Q So a warning is like an alert, is it

not?

MR. BRENNER: Objection.

A I guess. I don't know.

Q Okay.

MR. ALLEN: We'll change tapes, I think. Do you need to change tapes?

THE VIDEOGRAPHER: Yes, sir, I do.

Here ends Tape No. 2 in today's deposition of Joey Eski, being taken on February 29th, 2008. The time is approximately 3:57 p.m. We're off the record.

Stand by.

(Break.)

THE VIDEOGRAPHER: One moment, please.

We're on the record. The time is approximately 4:11 p.m. on February 29th, 2008. This is the beginning of Tape No. 3 in the deposition of Joey Eski.

Q (BY MR. ALLEN) Okay, Ms. Eski. We're back from our break.

A All right.

Q Do you know anything about the first-generation antipsychotics?

A Yes.

EXHIBIT

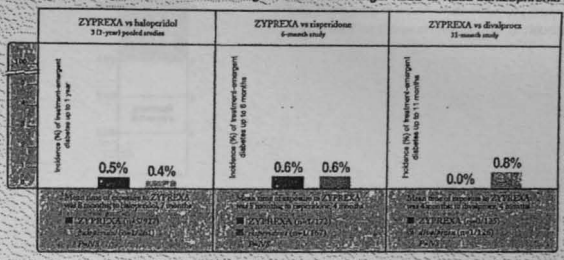
E

ZYPREXA Olanzapine

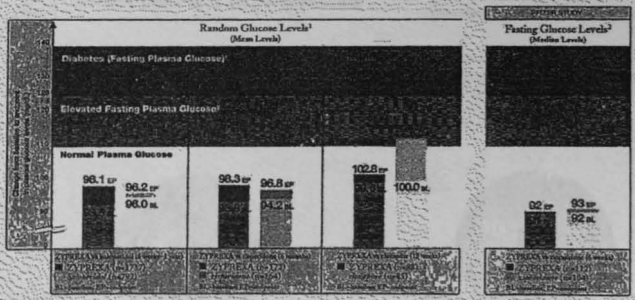
1 Comparable rates of diabetes and hyperglycemia among psychotropics

Patients treated with ZYPREXA had rates of diabetes and hyperglycemia comparable to th in patients treated with risperidone, haloperidol, and divalproex sodium in clinical trials*

Incidence of diagnosed treatment-emergent diabetes in longer head-to-head schizophrenia and bipolar mania trials*



Baseline to endpoint increase in average glucose level across comparative studies*



1. Allison DB, et al. Presented at: 2001 International Congress of Schizophrenia Research, Vancouver, British Columbia.
2. Glick ID, et al. Presented at: 2001 Annual Meeting of the American Psychiatric Association, New Orleans, Louisiana.

* Please see inside for study methodologies.

† Diabetes (Fasting Plasma Glucose) defined by ADA guidelines as ≥126 mg/dL (2 fasting blood draws).

‡ Elevated Fasting Plasma Glucose defined by ADA guidelines as ≥110 mg/dL (see reference 17).

EXHIBIT 4 Noesges 20-11-1

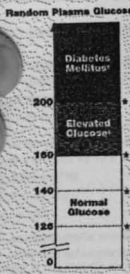
For safety information on haloperidol, risperidone, clozapine, divalproex, and ziprasidone, see the manufacturers' respective package inserts.

EXHIBIT 10 ESPI

Lilly

1 (cont'd)

Individual patient likelihood of random glucose elevations[1]

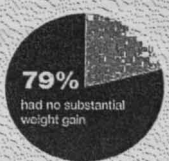


- In head-to-head data measuring random glucose, the likelihood of an individual patient exceeding any of the following thresholds was examined (126 mg/dL, 140 mg/dL, 160 mg/dL, or 200 mg/dL).*
- Individuals on ZYPREXA were not more likely to experience glucose elevations than those on haloperidol or risperidone at any threshold.[1§]

1. Allison DB, et al. Presented at: 2001 International Congress of Schizophrenia Research, Vancouver, British Columbia.
* Thresholds examined in this analysis.
† Diabetes (Random Plasma Glucose) defined by ADA guidelines as ≥200 mg/dL, confirmed with a subsequent fasting or oral plasma glucose test.
‡ Elevated (Random Plasma Glucose) outlined by ADA-supplied information as >160 mg/dL.
§ P values ranged from 0.11 to 0.93.

2 Weight gain and hyperglycemia*

Of patients treated with ZYPREXA, the majority (79%) of those who had an episode of hyperglycemia† did not experience substantial weight gain‡ in longer-term comparative studies.



Even among those patients with substantial weight gain,‡ over 96% had no glycemic abnormalities at all.†

* Analysis from Lilly-sponsored head-to-head schizophrenia treatment trials. Please see inside for study methodology.
† Hyperglycemia episodes and glycemic abnormalities defined as random glucose levels ≥160 mg/dL.
‡ Substantial weight gain defined as >10% increase in weight.

The Adverse Reactions section of the full Prescribing Information for ZYPREXA includes hyperglycemia (infrequent), glycosuria (infrequent), diabetes mellitus (infrequent), diabetic acidosis (rare), and ketoels (rare) as well as postintroduction reports of diabetic coma.

See accompanying safety profile and full Prescribing Information for ZYPREXA.

For safety information on haloperidol, risperidone, clozapine, divalproex, and ziprasidone, see the manufacturers' respective package inserts.

Additional prescribing considerations for ZYPREXA

The most common treatment-emergent adverse event associated with ZYPREXA in 6-week schizophrenia trials vs placebo was somnolence (26% vs 15%). Also observed (ZYPREXA vs placebo) were:

postural hypotension (5% vs 2%) | akathisia (5% vs 1%) | dizziness (11% vs 4%)
constipation (9% vs 3%) | personality disorder* (8% vs 4%) | weight gain (6% vs 1%)

The most common treatment-emergent adverse event associated with ZYPREXA in placebo-controlled bipolar mania trials was somnolence† (35% vs 13% for placebo). Also observed (ZYPREXA vs placebo) were:

dry mouth† (22% vs 7%) | dizziness† (18% vs 6%) | dyspepsia (11% vs 5%)
asthenia† (15% vs 6%) | constipation (11% vs 5%) | increased appetite (6% vs 3%)
tremor (6% vs 3%)

Transient, asymptomatic elevations of hepatic transaminase

In placebo-controlled schizophrenia studies, clinically significant ALT (SGPT) elevations (≥3 times the upper limit of the normal range) were observed in 2% (6/243) of patients exposed to ZYPREXA compared to none (0/115) of the placebo patients. None of these patients experienced jaundice. Periodic assessment of transaminases is recommended in patients with significant hepatic disease.

No baseline ECG required

No difference in clinically significant QTc prolongation with ZYPREXA compared to placebo in premarketing clinical trials.

Orthostatic hypotension

In premarketing trials of oral ZYPREXA, some patients may have experienced orthostatic hypotension associated with dizziness, tachycardia, and in some cases, syncope (15/2500, 0.6%).

Low potential for drug interactions

Important for patients changing to ZYPREXA from other antipsychotics and for those on multiple medications, such as diazepam, imipramine, lithium, warfarin, theophylline, and biperiden.

Coadministration of diazepam or ethanol with ZYPREXA may potentiate orthostatic hypotension.

Tardive dyskinesia—as with all antipsychotic medications, prescribing should be consistent with the need to minimize TD. If its signs and symptoms appear, discontinuation should be considered.

Seizures—occurred infrequently in premarketing clinical trials (22/2500, 0.9%). Confounding factors may have contributed to many of these occurrences. ZYPREXA should be used cautiously in patients with a history of seizures or with conditions that lower the seizure threshold.

* COSTART term for nonaggressive objectionable behavior.

† In bipolar mania trials, 4 adverse events occurred with statistically significantly higher incidence with ZYPREXA than with placebo—none of these resulted in discontinuation.

‡ In acute-phase, placebo-controlled schizophrenia trials (n=366), dizziness (11% vs 4%) and tachycardia (4% vs 1%) were reported; these events were not always associated with hypotension.

For safety information on haloperidol, risperidone, quetiapine, thioridazine, and clozapine, see the manufacturers' respective package inserts.

See accompanying full Prescribing Information for ZYPREXA.

References

1. Allison DB, et al. Presented at 2001 International Congress of Schizophrenia Research, Vancouver, British Columbia.
2. Glick ID, Romano SJ, Horne RL, et al. Insulin resistance in ZYPREXA- and ziprasidone-treated patients: results of a double-blind, controlled, 6-week trial. Presented at: 2001 Annual Meeting of the American Psychiatric Association, New Orleans, Louisiana.
3. Harris, MI. Diabetes in America: epidemiology and scope of the problem. *Diabetes Care*. 1998; Suppl 3:C11–14.
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Study methodology and limitations

ZYPREXA vs haloperidol, risperidone, clozapine, and divalproex

These results are from randomized clinical trials sponsored by Eli Lilly and Company comparing ZYPREXA vs haloperidol (3 studies, each with an acute double-blind phase of 6 weeks followed by a longer-term double-blind observation allowing total exposure up to 52 weeks); ZYPREXA vs risperidone (1 28-week double-blind study); ZYPREXA vs clozapine (1 18-week double-blind study), and ZYPREXA vs divalproex for acute mania (47-week study). Mean time of exposure to haloperidol was approximately 7 months; to risperidone, approximately 4 months; and to divalproex, approximately 4 months. Patients were 18 to 65 years of age, with a DSM-III-R or DSM-IV diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, or Bipolar I Disorder. Dosage ranges were 2.5 to 25 mg/day for ZYPREXA, 5 to 20 mg/day for haloperidol, 4 to 12 mg/day for risperidone, 200 to 600 mg/day for clozapine, and 500 to 2500 mg/day for divalproex.

The treatment-emergent diagnosis comparison also includes 33 subjects from 1 haloperidol-controlled study receiving ZYPREXA 1 mg/day.

Treatment-emergent diagnosis of diabetes: Diagnosis was based on the clinical discretion/judgment of the investigator. For this analysis, all randomized patients were considered. The ZYPREXA-haloperidol study includes only those patients enrolled in the longer-term trial (up to 52 weeks), ZYPREXA n=927, haloperidol n=261. The patients randomized in the risperidone trial were ZYPREXA n=172, risperidone n=167, and the patients randomized in the divalproex trial were ZYPREXA n=125 and divalproex n=123.

Mean and categorical analysis of plasma glucose: As blood samples were not necessarily fasting, results are considered random plasma glucose. Generally, 2 measurements were obtained prior to initiation of therapy and then with a frequency as specified by protocol. When 2 pretreatment measurements were available, their average was used as the baseline glucose value. All measurements up to and including the day following the last day of treatment were included in these analyses, to a maximum of 52 weeks in the haloperidol-ZYPREXA comparisons, 28 weeks in the risperidone-ZYPREXA comparison, and 18 weeks in the clozapine-ZYPREXA comparison. Patients with a known diagnosis of diabetes or taking antidiabetic medications at baseline were excluded from these analyses. The resulting samples were: haloperidol n=792 vs ZYPREXA n=1737 (from 3 pooled haloperidol-ZYPREXA trials), risperidone n=164 vs ZYPREXA n=172, and clozapine n=85 vs ZYPREXA n=88.

Mean change in glucose: The significance and magnitude of the differences in mean glucose values were assessed using a restricted maximum likelihood-based repeated measures analysis.[16] The following effects were included in the analysis: treatment, time, baseline BMI, mean baseline glucose, age, and study (for the haloperidol comparisons). A 2-tailed *P*-value of <0.05 was considered statistically significant.

Likelihood of exceeding glucose thresholds: An iteratively weighted restricted/residual pseudo likelihood (REPL)-based approach[16] was used to estimate the probability of an "event" of elevated *random* glucose values. Multiple thresholds were used to account for the lack of universally accepted criteria for what constitutes a clinically significant elevation in *random* glucose, in the absence of signs or symptoms of diabetes, with 126, 140, 160 and 200 mg/dL threshold values extrapolated from published suggestions.[17] Analysis with each of these thresholds was performed excluding those patients who had baseline glucose values above that threshold. An "event" was defined as occurrence of one of the following: (a) 2 consecutive glucose measurements at or above threshold, (b) last glucose measurement at or above threshold, or (c) initiation of glycemic medication or glycemic adverse event. Cox proportional hazards regression analyses were implemented to assess the relative hazard of experiencing a glucose measurement that reaches or exceeds the preestablished thresholds.

Limitations: While fasting glucose concentrations with confirmation of elevated values would be a preferable approach to defining potentially clinically significant glucose elevation,[17] these trials were not designed primarily to evaluate glycemic effects. Thus, fasting glucose levels were not determined. To date, fasting glucose results are not available from large randomized prospective comparative trials of ZYPREXA. Secondly, while treatment-emergent diagnosis of diabetes was a prospectively anticipated comparison, the other information reported (mean change in random plasma glucose, likelihood of exceeding a particular glucose threshold, and weight-gain hyperglycemia relationships) are post-hoc analyses of prospectively collected data. Thirdly, these trials are of moderate duration (maximum 1 year) and therefore may not inform about the long-term risks (or lack thereof) of the drugs studied herein. Fourthly, in the studies analyzed, power to detect differences in likelihood of crossing a lower glucose threshold (eg, 126 mg/dL) is greater than at a higher threshold (eg, 200 mg/dL) because of relative infrequency of events at the latter.

ZYPREXA vs ziprasidone

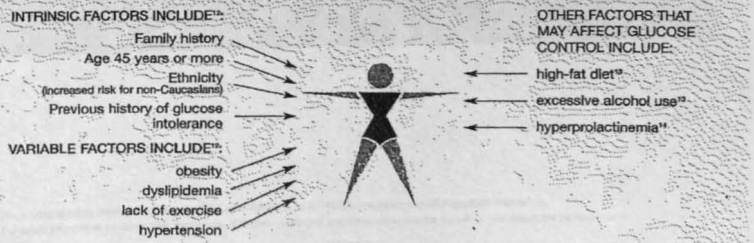
This 6-week, double-blind trial sponsored by Pfizer, Inc. compared ZYPREXA (n=133) to ziprasidone (n=136) for the treatment of schizophrenia or schizoaffective disorder. Dosage was titrated up to 15 mg/day for ZYPREXA and 80 mg BID for ziprasidone. Fasting plasma glucose was measured at baseline and endpoint. Median levels were reported. (Glick et al, American Psychiatric Association, Annual Meeting, 2001.)

3 Diabetes is commo...

Diabetes is common in the general adult population, and is more common in patients with psychiatric illness

- Approximately 7.8% of the general adult population had diabetes (one-third of which was undiagnosed) as reported in an epidemiologic study of prevalence in the US.[3]
- An additional 6.9% of the general population had fasting blood glucose levels above normal in the same study.[3]
- Prevalence of type 2 diabetes among patients with schizophrenia and bipolar disorder was as high as 2-4 times greater than in the general population in several other studies.[4-7]
- An association between antipsychotics and hyperglycemia has been reported since the 1950s.[8]
- Patients treated with certain mood stabilizers may have disrupted glucose control as compared with the general population.[9-11]

4 A number of factors affect risk for diabetes



Risk/Benefit Analysis

Psychotropic therapy in any individual patient (including those with hyperglycemia) should be evaluated in the context of that patient's overall response and toleration of therapy.

For additional safety profile and other prescribing considerations for ZYPREXA, see inside and full Prescribing Information.

For safety information on haloperidol, risperidone, clozapine, divalproex, and ziprasidone, see the manufacturers' respective package inserts.

ZYPREXA
Olanzapine

www.ZYPREXA.com

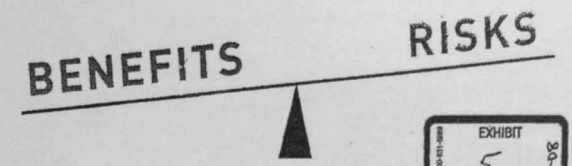
Lilly

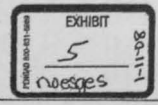
Diabetes and patients with mental illness

What do you consider when choosing medications?

What benefits do you associate with ZYPREXA® (olanzapine)?

What risks do you associate with it?





...etes is common.

- As many as 6.2% of American adults have diabetes.[1]
- One half of them may not know it.[1]
- 6.9% more have fasting blood glucose levels that are above normal.[1]

But your patients are at an even greater risk.

- People with serious mental illness are 2 to 4 times more likely to develop diabetes.[2-5]
- There have been reports linking antipsychotics and certain mood stabilizers with hyperglycemia since the 1950s.[4-9]

For additional safety profile and other important prescribing considerations for ZYPREXA, see insert and the full Prescribing Information.

The Adverse Reactions section of the full Prescribing Information for ZYPREXA includes hyperglycemia (infrequent), glycosuria (infrequent), diabetes mellitus (infrequent), diabetic acidosis (rare), and ketosis (rare) as well as postintroduction reports of diabetic coma.

Lilly

...rs That Matter.

Study methodology

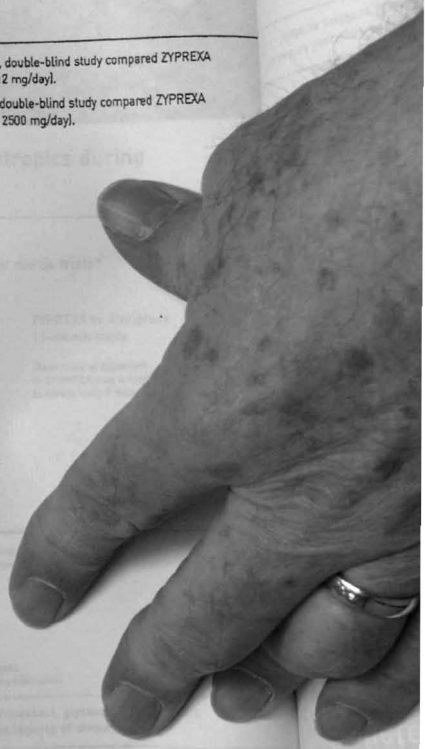
Studies included patients aged 18 to 65 years, with a diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, or acute bipolar mania. Diagnosis of treatment-emergent diabetes was based on the clinical discretion of the investigator. For this analysis, all randomized patients were considered.

ZYPREXA vs haloperidol: Three randomized, double-blind studies compared ZYPREXA (5 to 20 mg/day) with haloperidol (5 to 20 mg/day). After the initial 6-week phase, further double-blind observations were conducted following exposure for up to 52 weeks.

Comparisons also include a haloperidol-controlled study of 33 subjects receiving ZYPREXA (1 mg/day).

ZYPREXA vs risperidone: One 28-week, double-blind study compared ZYPREXA (5 to 20 mg/day) with risperidone (4 to 12 mg/day).

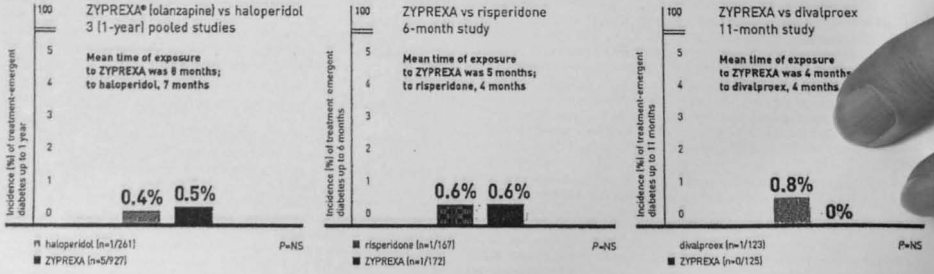
ZYPREXA vs divalproex: One 47-week, double-blind study compared ZYPREXA (5 to 20 mg/day) with divalproex (500 to 2500 mg/day).



How do the medications you use compare?

Rates of diabetes were comparable for commonly prescribed psychotropics during longer-term clinical trials.*

Incidence of diagnosed treatment-emergent diabetes in longer head-to-head schizophrenia and bipolar mania trials*



* These trials were not designed specifically to evaluate glycemic effects. Fasting glucose levels were not determined.

For safety information on haloperidol, risperidone, or divalproex, see the manufacturers' respective package inserts.
For additional safety profile and other important prescribing considerations for ZYPREXA, see inside and the full Prescribing Information.

The Adverse Reactions section of the full Prescribing Information for ZYPREXA includes hyperglycemia (infrequent), glycosuria (infrequent), diabetes mellitus (infrequent), diabetic acidosis (rare), and ketosis (rare) as well as postintroduction reports of diabetic coma.

Lilly
Answers That Matter.

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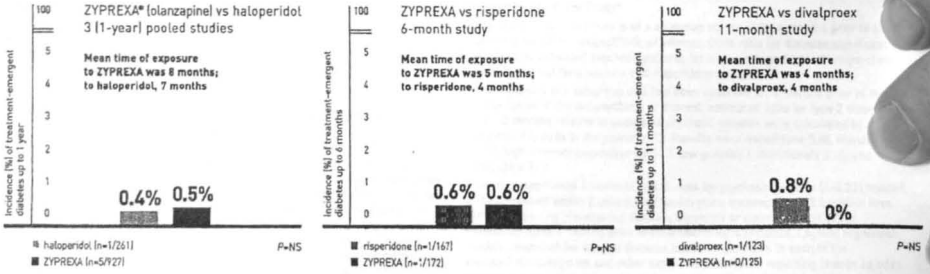

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Lilly
Answers That Matter.

Study methodologies

Lilly Advance PCS Study

- Incidence among all patients combined on typical antipsychotics was 1.6% (307/19,782)
- Hazard ratio was significantly elevated for all treatment groups vs control patients not receiving antipsychotic medications

A 3-year retrospective, pharmacoepidemiological study of an independent prescription claims database (Advance PCS) containing over 50 million members. Patients who had been prescribed a diabetes medication at any point during the 12-month period prior to enrollment or who had been prescribed an antipsychotic during the 6-month period prior to enrollment were excluded. Diabetes mellitus was identified by oral hypoglycemic or insulin prescription claims in both the study and control groups. Patients in the antipsychotic study group were prescribed a single typical or atypical antipsychotic during the 6 months of follow-up. Out of this database, 5.8 million patients receiving a prescription medication that was not an antipsychotic served as the reference group. Hazard ratio was determined by Cox proportional hazard regression controlling for age, gender, and accounting for time to event. Incidence of new antidiabetic prescription was haloperidol 133/8476, thioridazine 62/3133, clozapine 7/277, olanzapine 194/13,863, quetiapine 40/4196, and risperidone 400/20,633. Average duration of treatment with antipsychotic medications was: clozapine 137 days, olanzapine 89 days, quetiapine 89 days, risperidone 90 days, haloperidol 68 days, and thioridazine 76 days.

Janssen Quebec Medicare Study

- *P*-value for olanzapine vs risperidone hazard ratio was not reported by the investigators

A Janssen-sponsored analysis of patients identified from the Quebec Medicare database between January 1997 and December 1999. One cohort consisted of patients who had at least 1 prescription for olanzapine but not clozapine during that period (n=19,153) and the other of patients receiving risperidone but not olanzapine or clozapine (n=14,792). Patients with a diagnosis of diabetes or a prescription for insulin or an oral hypoglycemic agent before beginning antipsychotic therapy were excluded. New diabetes diagnoses after the first antipsychotic prescription were tabulated. Incidence of new diabetes were olanzapine 319/19,153 and risperidone 217/14,792. Cox proportional hazard ratio adjusting for age and gender was calculated and reported relative to risperidone group. Duration of treatment with antipsychotic medicines was not reported by the investigators.

Lilly IMS Study

- Odds ratio for olanzapine- and risperidone-treated patients was not significantly different vs patients receiving typical antipsychotic medication

A retrospective analysis of the IMS LifeLink™ claims database identified patients aged 18-65 initiated on antipsychotic medicine between October 1996 and December 1998. The study included only patients with no antipsychotic use for 6 months prior and no diagnosis of diabetes or receipt of any diabetic medication for 1 year prior to antipsychotic initiation. Observed diabetes incidences were typical antipsychotics 68/3208, olanzapine 32/1530, and risperidone 43/1598. Logistic regressions were used to estimate odds ratios (OR) of a diagnosis of diabetes or use of any diabetic medication in the 1-year post-initiation compared to patients on typical antipsychotics; controlling for age, gender, mental health comorbidities, and regional differences. This analysis tabulated all diabetes incidences during 1 year subsequent to antipsychotic prescription irrespective of duration of the treatment episode.

Sernyak Study

A 4-month retrospective analysis included 38,632 outpatients listed in the Veterans Health Administration database with schizophrenia who were treated with typical or atypical antipsychotics. Using the same database, patients with a diagnosis of diabetes were also identified and used to calculate the prevalence of diabetes mellitus among patients receiving prescriptions for antipsychotic agents. Of the total number of patients included in the study, 15,984 received typical neuroleptics and 22,648 received atypical neuroleptics; 1,207 received clozapine; 10,970 olanzapine; 955 quietapine; and 9,903 risperidone.

Janssen Health Plans Study*

- The analysis depicted here is of a subgroup observed for 4 months prior to the prescription of the antipsychotic of interest. Odds ratio for diabetes significantly elevated vs untreated psychotic patients for olanzapine and typical antipsychotic groups, but not for clozapine and risperidone groups.
- In an analysis of a subgroup that had been observed for 8 months prior to the prescription of the antipsychotic of interest, estimated odds for type 2 diabetes per 12 months relative to untreated psychotic patients were calculated by raising the monthly odds to the power of 12. Results were risperidone 0.88, olanzapine 3.10, high-potency conventionals 2.13, low-potency conventionals 3.46, and clozapine 7.44.

A Janssen-sponsored analysis of claims data for psychosis patients (n=4,331 treated, 3,041 untreated) within 2 unspecified health plans encompassing 2.5 million lives. Patients reporting pre-existing diabetes diagnosis or claim for antidiabetic medication up to 4 months prior to observation were excluded. Logistic regression models compared the odds of diabetes based on exposure to each of the antipsychotic categories and other explanatory variables, reporting results as odds ratio per month relative to untreated psychotic patients. Also reported were odds ratios of 1.05 high-potency typicals and 1.06 low-potency typicals. Characteristics reported for the group observed for 4 months prior to the antipsychotic treatment episode of interest were: Number of observed treatment episodes—clozapine 64, olanzapine 1,047, risperidone 1,368, high-potency typical antipsychotics 1,376, and low-potency typical antipsychotics 480. Average duration of antipsychotic treatment episodes were: clozapine 5.8 months, olanzapine 5.6 months, risperidone 6.4 months, high-potency typical antipsychotics 6.7 months, and low-potency typical antipsychotics 6.8 months. The investigators did not provide these details for the subset observed for 8 months prior to the antipsychotic treatment episode.

* Control group is psychotic patients not treated with antipsychotic medication.

Incidence and odds ratios of developing diabetes during treatment with antipsychotics.

Findings from 5 epidemiological studies show no consistent differences regardless of the agent studied.

	Lilly[12] Advance PCS Database	Janssen[11] Quebec Medicare Database	Lilly[13] IMS Database†	Sernyak[12] Veterans Database	Janssen[14] Health Plans Study
N	58,751	33,945	6,440	38,632	4,308
Control	0.8%‡	[illegible]	[illegible]	–	1.00‡
Clozapine	1.5%	[illegible]	[illegible]	1.25	1.08
Quetiapine	1.0%	[illegible]	[illegible]	1.31	–
Risperidone	1.0%	5%	2.7%	1.05	1.02
Olanzapine	1.4%	7%	2.1%	1.11	1.08
Typical antipsychotics	1.3–2.0%	[illegible]	2.1%	–	1.05–1.06
	§OBSERVED INCIDENCE			‖CALCULATED ODDS RATIO/MONTH	

(–) Drug not studied or value not supplied.

N=Number of antipsychotic-treated subjects studied.

* Control group is general population patients receiving prescriptions other than antipsychotic medications.
† Data on file, Lilly Research Laboratories.
‡ Control group is psychotic patients not receiving prescriptions for antipsychotic medication.

§ Observed incidence is the percentage of patients taking the medication of interest who have new onset of diabetes mellitus. It does not control for potentially important factors such as patient age or duration of treatment.
‖ Odds ratio refers to probability of becoming diabetic relative to control group. An odds ratio of 1.05 means that for every 100 cases seen in the control group, no more than 105 would be expected to develop diabetes in the comparison group.

For safety information on clozapine, quetiapine, or risperidone, see the manufacturers' respective package inserts.
For additional safety profile and other important prescribing considerations for ZYPREXA, see inside and the full Prescribing Information.

The Adverse Reactions section of the full Prescribing Information for ZYPREXA includes hyperglycemia (infrequent), glycosuria (infrequent), diabetes mellitus (infrequent), diabetic acidosis (rare), and ketosis (rare) as well as postintroduction reports of diabetic coma.

Lilly
Answers That Matter.

Important safety information

The most common treatment-emergent adverse event associated with ZYPREXA® (olanzapine) in 6-week schizophrenia trials vs placebo was somnolence (26% vs 15%). Also observed (ZYPREXA vs placebo) were:

postural hypotension (5% vs 2%)	akathisia (5% vs 1%)
dizziness (11% vs 4%)	constipation (9% vs 3%)
personality disorder* (8% vs 4%)	weight gain (6% vs 1%)

The most common treatment-emergent adverse event associated with ZYPREXA in placebo-controlled bipolar mania trials was somnolence† (35% vs 13% for placebo). Also observed (ZYPREXA vs placebo) were:

dry mouth† (22% vs 7%)	dizziness‡ (18% vs 6%)
dyspepsia (11% vs 5%)	asthenia† (15% vs 6%)
constipation (11% vs 5%)	increased appetite (6% vs 3%)
tremor (6% vs 3%)	

Transient, asymptomatic elevations of hepatic transaminase

In placebo-controlled schizophrenia studies, clinically significant ALT (SGPT) elevations (≥3 times the upper limit of the normal range) were observed in 2% (6/243) of patients exposed to ZYPREXA compared to none (0/115) of the placebo patients. None of these patients experienced jaundice. Periodic assessment of transaminases is recommended in patients with significant hepatic disease.

No baseline ECG required

No difference in clinically significant QTc prolongation with ZYPREXA compared to placebo in premarketing clinical trials.

Orthostatic hypotension

In premarketing trials of oral ZYPREXA, some patients may have experienced orthostatic hypotension associated with dizziness‡; tachycardia‡; and in some cases, syncope (15/2500, 0.6%).

Low potential for drug interactions

Coadministration of diazepam or ethanol with ZYPREXA may potentiate orthostatic hypotension. Lower doses of ZYPREXA should be considered in patients receiving concomitant therapy with fluvoxamine.

Tardive dyskinesia—as with all antipsychotic medications, prescribing should be consistent with the need to minimize the risk of TD. If its signs and symptoms appear, discontinuation should be considered.

Seizures—occurred infrequently in premarketing clinical trials (22/2500, 0.9%). Confounding factors may have contributed to many of these occurrences. ZYPREXA should be used cautiously in patients with a history of seizures or with conditions that lower the seizure threshold.

* COSTART term for nonaggressive objectionable behavior.

† In bipolar mania trials, 4 adverse events occurred with statistically significantly higher incidence with ZYPREXA than with placebo—none of these resulted in discontinuation.

‡ In acute-phase, placebo-controlled schizophrenia trials (n=366), dizziness (11% vs 4%) and tachycardia (4% vs 1%) were reported; these events were not always associated with hypotension.

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* COSTART term for nonaggressive objectionable behavior.
† In bipolar mania trials, 4 adverse events occurred with statistically significantly higher incidence with ZYPREXA than with placebo—none of these resulted in discontinuation.
‡ In acute-phase placebo-controlled schizophrenia trials (n=366), dizziness (11% vs 4%) and tachycardia (4% vs 1%) were reported; these events were not always associated with hypotension.

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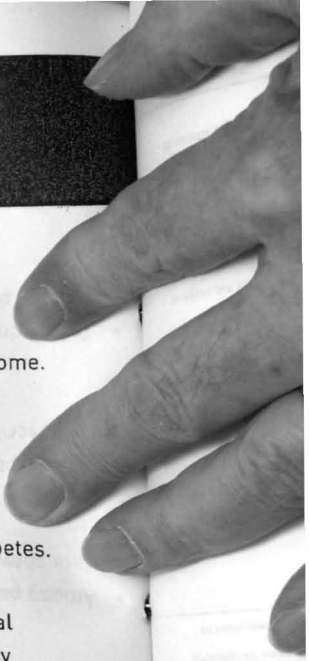
The diabetes risk your patients face may be even greater if they:[15-17]

- ☑ Are African American, Native American, Asian American/Pacific Islander, or Hispanic.
- ☑ Are 45 years of age or older.
- ☑ Have a body mass index ≥25 kg/m².
- ☑ Have dyslipidemia.
- ☑ Do not get enough exercise.
- ☑ Are hypertensive.
- ☑ Have polycystic ovary syndrome.
- ☑ Have a previous history of glucose intolerance.
- ☑ Have a family history of diabetes.
- ☑ Have a history of gestational diabetes or delivered a baby weighing >9 lbs.



For additional safety profile and other important prescribing considerations for ZYPREXA, see inside and the full Prescribing Information.

The Adverse Reactions section of the full Prescribing Information for ZYPREXA includes hyperglycemia (infrequent), glycosuria (infrequent), diabetes mellitus (infrequent), diabetic acidosis (rare), and ketosis (rare) as well as postintroduction reports of diabetic coma.

Lilly
Answers That Matter.

Consider the whole story.

- Diabetes is **common**, and people with serious **mental illness** are at an even **greater risk**

- Among patients treated with different antipsychotics, clinical trial and epidemiological data show **no consistent differences** in rates of diabetes

- **Assess** patients for **risk factors** of diabetes, irrespective of which psychotropic is prescribed

- Treatment selection should be based on the patient's underlying **psychiatric condition** and the overall **risk/benefit profile** of the medication

For additional safety profile and other important prescribing considerations for ZYPREXA, see inside and the full Prescribing Information.

The Adverse Reactions section of the full Prescribing Information for ZYPREXA includes hyperglycemia (infrequent), glycosuria (infrequent), diabetes mellitus (infrequent), diabetic acidosis (rare), and ketosis (rare) as well as postintroduction reports of diabetic coma.

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

STATE OF ALASKA,

Plaintiff,

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

VIDEOTAPED DEPOSITION OF JOEY L. ESKI

February 29, 2008
10:23 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

was at higher risk for --

Q That the label change -- the categories -- that persons with diabetes and/or hyperglycemia were at an increased risk of developing hyperglycemia if they were placed on Zyprexa. Had you ever learned that prior to October of 2007?

A No, I had not.

Q Thank you. Now, ma'am, we also have a hyperlipidemia warning.

Do you see that?

A Yep.

Q Ma'am?

A Yes, I see it.

Q Had there ever been a hyperlipidemia warning before?

A A warning?

Q Yes, ma'am.

A No.

Q Tell the jury the difference between a warning and an adverse reaction.

A Typically it's the rate of incidence, as I understand it, and a likelihood of the occurrence.

Q Right. The warning is a more severe --

A Uh-huh.
Q Let me finish my question.
A Sorry.
Q A warning is a more severe rate of incidence and a more likelihood; is that correct?
MR. BRENNER: Object to the form.
A As I -- as I understand.
Q (BY MR. ALLEN) As you understand?
A Uh-huh.
Q Is that a yes?
A Yes, as I understand.
Q And how long have you had that understanding as a sales representative for Eli Lilly?
A The entire time I've worked for the company.
Q Since 1998, right?
A Uh-huh.
Q Is that a yes?
A Yes.
Q So you have clearly understood that there was a distinction in that label and you were trained that there was a distinction in the label between a warning and an adverse reaction, true?

A Yes.
Q Ma'am?
A Yes.
Q And that distinction was important to you in regard both to severity and the rate of incidence of the listed side effect, right?
A Say it again. Sorry, I wasn't --
Q Yes. The difference between a warning and the adverse reaction -- the difference was the severity and the frequency of the rate of the side effect; is that right?
A Yes.
Q Thank you. And that was consistent with your training?
A Yes.
Q And if anybody had asked you that, not just me up until today, from 1998 to 2008, that's what you'd testify or say?
A Yes.
MR. BRENNER: Object to the form.
Q (BY MR. ALLEN) Ma'am?
A Yes.
Q Okay. Now, prior to the 2007 label change, you've testified there was no warning of hyperlipidemia; is that right?

Q Is that a yes.
A Yes.
Q So a package insert change is significant, is it not?
A Sure.
Q Because it's going to change your agenda when you go meet with doctors, right?
MR. BRENNER: Objection to the form.
A Sure.
Q (BY MR. ALLEN) And it's going to change your discussions, isn't it?
A Yes.
Q And it's going to change what information you convey, true?
A Yes.
Q If the warning is different, as you've told us, that's significant, isn't it?
A Uh-huh.
MR. BRENNER: Objection.
Q (BY MR. ALLEN) Is that yes? Is that yes?
A If the warning is different --
Q It's significant, isn't it?
A I mean, we're going to communicate it.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

RESPONSE TO STATE'S ADDITIONAL SUBMISSION OF EXHIBITS TO BE PRE-ADMITTED FOR USE DURING OPENING STATEMENT

On March 3, 2008, the State of Alaska ("the State") identified eighteen additional exhibits and deposition designations to be pre-admitted for use during Opening Statements. In response, Eli Lilly and Company ("Lilly") submits this supplement to its previously filed Motion to Rule on Before-Trial Admission of the State's "Pre-Admit" List.

The following chart lists the State's newly identified "pre-admit" exhibits. The first column, titled "Trialx#," is a list of the State's "pre-admit" list, sorted in numerical order. The second column delineates the bases for Lilly's objections to each document.

	Trialx#	Objections
1	5913	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims M.I.L. regarding Other Lilly Litigation; Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
2	10014[1]	Hearsay; agree to admit – notice

[1] Document 10014 was identified in the index accompanying the binder that the State produced yesterday to Lilly, but a document 10014 was not included in the binder.

3	10037	M.I.L. regarding Profits, Price, and Net Worth Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)
4	10039	M.I.L. regarding Profits, Price, and Net Worth Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)
5	10092	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Lilly promotional material; safety information dictated by "fair balance" mandated by federal law Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
6	10093	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Lilly promotional material; safety information dictated by "fair balance" mandated by federal law; Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
7	10100[2]	Lilly objects to the introduction of any call note not identified in the State's Supplemental Responses to Lilly's 4th Set of Interrogatories. Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
8	10147	Hearsay; agree to admit – notice
9	10156	Hearsay; agree to admit – notice

[2] The State originally designated exhibit 10198, but during a meet-and-confer yesterday evening, counsel for the State noted that it would withdraw exhibit 10198 and substitute page 2 of exhibit 10100, attached as Exhibit A for the Court's consideration.

10	10157	Hearsay; agree to admit – notice
11	10158	Hearsay; agree to admit – notice; M.I.L. Recent Regulatory; M.I.L. re: N.Y. Times Articles
12	10159	Hearsay; agree to admit – notice
13	Eski Exhibit 8	*See* Motion to Preclude Testimony of Joey Eski from Trial Phase One or Protective Order Regarding Her Trial Testimony filed March 3, 2008 Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
14	Joey Eski Deposition Excerpts	*See* Motion to Preclude Testimony of Joey Eski from Trial Phase One or Protective Order Regarding Her Trial Testimony Objections to Form made throughout.
15	Jack Jordan Deposition Excerpts	Agree to admit
16	Denice Torres Deposition Excerpts	Agree to admit
17	John Lechleiter Deposition Excerpts	Agree to admit
18	Video Excerpt of Viva Zyprexa Presentation	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal sales representative training material Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

DATED this 4th day of March, 2008.

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By: _____
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A It wasn't a surprise to my providers, but it is in the warning section and we brought that to their attention.

Q (BY MR. ALLEN) Are you -- isn't the warning label -- I thought you said to me earlier, you said it's up to the FDA. Do you recall that?

A I do.

Q And so you've told me, I bet you, you follow what the FDA says, right?

A I try to.

Q So if the FDA says, go give a warning, you'll go give a warning?

A Absolutely.

Q So it's a big difference when something's in the warning section, right?

MR. BRENNER: Objection.

A It's a big difference in terms of -- that we go and proactively alert people, yes.

Q (BY MR. ALLEN) Yeah. You go alert people, right?

A Uh-huh.

Q Is that a yes?

A Yes.

Q So a warning is like an alert, is it