SOA

3AN-06-05630CI Volume: 011
Volume 011
State of Alaska vs. Eli Lilly & Co

ELI LILLY + CO

Volume II

CIVIL

Begun: 2-29-08
end: 3-5-08

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	3/11/06		

FILING FEE RECEIPT# _____

INDEXED _____

OTHER _____

15764

CV-E-A

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 OBJECTIONS TO PLAINTIFF STATE OF ALASKA'S TRIAL DEPOSITION DESIGNATIONS

Defendant Eli Lilly and Company ("Lilly") objects to the flowing pages and lines of Plaintiff State of Alaska's Trial Deposition Designations:

I. Deposition of John C. Lechleiter, Ph.D

Start (Page:Line)	End (Page:Line)	Objection
32:6	32:19	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
33:5	33:17	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
45:20	45:23	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.

Start (Page:Line)	End (Page:Line)	Objection
58:11	59:15	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motions in Liminere: Lilly profits and prices and other Lilly drugs.
67:15	68:2	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
69:6	69:10	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
69:13	70:24	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motions in Liminere: Lilly profits and prices and other Lilly drugs.
82:20	83:19	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
84:9	84:22	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
86:24	87:14	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
88:1	88:7	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
92:22	93:7	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).

Start (Page:Line)	End (Page:Line)	Objection
94:5	95:9	Relevance; foundation; lack of personal knowledge; hearsay; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802; 901). Subject to Motion in Limine re: Lilly profits and prices.
96:13	96:20	Relevance; foundation; lack of personal knowledge; hearsay; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802; 901). Subject to Motion in Limine re: Lilly profits and prices.
102:8	103:1	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
103:17	104:24	Relevance; foundation; lack of personal knowledge; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802). Subject to Motion in Limine re: Lilly profits and prices.
105:12	105:16	Relevance; foundation; lack of personal knowledge; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403 602; 802). Subject to Motion in Limine re: Lilly profits and prices.
105:21	106:20	Relevance; foundation; lack of personal knowledge; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802). Subject to Motion in Limine re: Lilly profits and prices.
110:4	110:15	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.

Start (Page:Line)	End (Page:Line)	Objection
110:18	111:6	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
117:13	118:2	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
119:15	120:13	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motions in Liminere: Lilly profits and prices and other Lilly drugs.
121:8	121:24	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
122:22	124:9	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
125:7	126:7	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
128:15	128:22	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
133:16	134:6	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion; hearsay (Alaska R. Evid. 401; 403; 802). Subject to Motion in Limine re: Lilly profits and prices.
138:9	138:19	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).

Start (Page:Line)	End (Page:Line)	Objection
140:1	140:14	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
141:9	142:8	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
144:21	145:1	Foundation; relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
145:4	145:5	Foundation; relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403)
145:18	146:6	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
146:14	147:5	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
148:12	148:18	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
162:3	162:14	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
162:19	163:9	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
166:19	167:12	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
170:19	171:2	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion; hearsay (Alaska R. Evid. 401; 403, 802).

Start (Page:Line)	End (Page:Line)	Objection
191:19	192:17	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
239:11	239:19	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
240:13	241:13	Relevance; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401, 403; 802).
243:12	243:18	Relevance; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401, 403; 802).
244:24	245:10	Relevance; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401, 403; 802).
249:7	249:21	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: other Lilly drugs.
265:23	267:7	Hearsay; foundation; relevance; lack of personal knowledge; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802; 901).
268:20	269:2	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
276:9	276:22	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
277:24	279:6	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
279:13	279:18	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
284:18	285:1	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).

Start (Page:Line)	End (Page:Line)	Objection
285:17	286:9	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
286:15	287:2	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
297:6	297:21	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
299:20	300:4	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).
302:11	302:23	Relevance; hearsay; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 802; 901). Subject to Motion in Limine re: Lilly profits and prices.
303:6	303:18	Relevance; hearsay; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 802; 901). Subject to Motion in Limine re: Lilly profits and prices.
304:9	304:22	Relevance; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 901).
313:7	315:7	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
315:15	315:18	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
316:19	318:12	Hearsay; relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403 802).
320:14	320:18	Hearsay; relevance; lack of personal knowledge; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602).

Start (Page:Line)	End (Page:Line)	Objection
320:21	323:7	Hearsay; relevance; lack of personal knowledge; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602).
324:18	325:16	Hearsay; relevance; lack of personal knowledge; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602).
360:3	360:6	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
361:4	361:20	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
363:3	363:16	Mischaracterizes prior testimony, relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
363:19	364:2	Mischaracterizes prior testimony; relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
364:3	365:23	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
366:7	367:11	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).

II. Deposition of John C. Lechleiter, Ph.D

Start (Page:Line)	End (Page:Line)	Objection
38:7	38:11	Foundation (Alaska R. Evid. 602, 701)
47:6	47:16	Relevance (Alaska. R. Evid. 401, 402)

Start (Page:Line)	End (Page:Line)	Objection
54:16	55:7	Relevance; Ambiguous; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 611)
62:13	63:3	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
63:9	63:14	Relevance, Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
68:19	68:20	Relevance, Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
75:19	76:3	Relevance (Alaska R. Evid. 401, 402)
77:18	78:4	Relevance, Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
79:18	79:20	Relevance; Probative value outweighed by danger of unfair prejudice. (Alaska R. Evid. 401, 402, 403)
79:23	80:1	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
84:19	85:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
86:01	86:08	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
88:18	88:24	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
127:16	127:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
134:24	135:6	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
136:6	136:15	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 401, 402, 403, 602, 701)

Start (Page:Line)	End (Page:Line)	Objection
146:13	146:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
147:3	147:7	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
148:6	148:10	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Ambiguous; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
148:11	148:13	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Ambiguous; Misstates the evidence; Argumentative (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
148:14	148:22	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
150:8	150:11	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
152:12	152:20	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence; Ambiguous (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
154:18	154:23	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence; Ambiguous (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
171:9	171:17	Relevance; Probative value outweighed by danger of unfair prejudice; Ambiguous (Alaska R. Evid. 401, 402, 403, 611)
173:18	174:2	Foundation (Alaska R. Evid. 602, 701)
174:17	174:21	Foundation (Alaska R. Evid. 602, 701)
178:14	178:23	Foundation (Alaska R. Evid. 602, 701)
179:19	180:2	Foundation; Ambiguous (Alaska R. Evid. 602, 611, 701)

Start (Page:Line)	End (Page:Line)	Objection
181:11	181:18	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
181:21	182:4	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
182:5	182:8	Argumentative; Comment by counsel (Alaska R. Evid. 611)
185:15	186:9	Relevance; Probative value outweighed by danger of unfair prejudice; Comment by counsel (Alaska R. Evid. 401, 402, 403, 611)
186:22	187:12	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
189:5	189:18	Foundation; Argumentative; Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
234:16	235:04	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
241:19	241:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
242:3	242:18	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
243:2	243:20	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
244:1	244:10	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
248:9	248:20	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
249:6	249:12	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
249:19	249:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
250:5	250:9	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)

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251:9	251:13	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
357:23	358:8	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
359:15	360:10	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
361:3	361:14	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
400:16	401:7	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
404:7	404:11	Foundation; ; Misstates the evidence (Alaska R. Evid. 602, 611, 701)
411:20	412:3	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
416:19	417:6	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
420:9	420:18	Compound (Alaska R. Evid. 611)
422:12	422:20	Argumentative (Alaska R. Evid. 611)
476:7	477:10	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
480:9	480:17	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 401, 402, 403, 601, 702)
488:23	489:8	Foundation (Alaska R. Evid. 602, 701)
491:1	491:18	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 601, 602, 611, 701)
492:9	492:13	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)

(Page:Line)	End (Page:Line)	Objection
510:5	510:8	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 601, 602, 611, 701)
510:18	510:23	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 601, 602, 611, 701)
514:7	514:15	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 601, 602, 611, 701)
527:17	528:2	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
528:16	529:2	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 401, 402, 403, 601, 602, 701)
530:23	531:14	Relevance; Probative value outweighed by danger of unfair prejudice; Ambiguous; Foundation (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
535:17	536:24	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
537:7	538:7	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 401, 402, 403, 602, 701)
538:13	538:15	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
538:22	539:3	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701) (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
539:10	539:23	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)

Start (Page:Line)	End (Page:Line)	Objection
540:1	540:19	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence; Compound; Argumentative (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
545:15	546:5	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
546:7	546:11	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
546:13	547:17	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
548:17	548:21	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
549:8	549:12	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)

Lilly reserves the right to object to any deposition testimony not yet taken in this or any other matter. Lilly further reserves the right to object to any additional deposition testimony not included above if deemed necessary at the trial of this action.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **DEFENDANT ELI LILLY AND COMPANY'S OBJECTIONS TO PLAINTIFF STATE OF ALASKA'S TRIAL DEPOSITION DESIGNATIONS** has been served on counsel listed below.

Brewster H. Jamieson

Counsel List

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

Matthew L. Garretson, Esquire
Joseph W. Steele, Esquire
Garretson & Steele
9545 Kenwood Road, Suite 304
Cincinnati, OH 45242-6100

H. Blair Hahn, Esquire
Richardson, Patrick, Westbrook & Brickman, LLC
1037 Chuck Dawley Boulevard, Building A
Mount Pleasant, SC 29464-4190

Date: March 5, 2008

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

FILED IN OPEN COURT
Date: 3-5-08
Clerk: MLS

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

NOTICE OF FILING ORIGINAL AFFIDAVIT OF JOEY ESKI

Defendant, Eli Lilly and Company, by and through counsel of record, Lane Powell LLC, hereby provides the original signed Affidavit of Joey Eski, a scanned copy of the affidavit was filed with its Motion to Preclude Testimony of Joey Eski from Trial Phase 1 for Protective Order Regarding Her Trial Testimony.

DATED this 4th day of March, 2008.

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

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

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

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

_____

0098600038/163723.1

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

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

FILED IN OPEN COURT
Date: 3-5-08
Clerk: MM

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

AFFIDAVIT OF JOEY ESKI

STATE OF ALASKA)
) ss.
THIRD JUDICIAL DISTRICT)

I, Joey Eski, being first duly sworn, states as follows:

1. I am an executive sales representative with Eli Lilly and Company. I live in Anchorage, Alaska.

2. I will be out of state from March 10th through March 22nd of 2008 on a family vacation in Hawaii. My family and I have planned this vacation since January 2008. On January 14-15, 2008, I purchased four round-trip tickets from Anchorage to Hawaii, for myself, my friend, and my children, leaving Anchorage on March 10th and returning on March 22nd. Confirmations of these tickets are attached as Exhibits 1 and 2. On February 5, 2008, I purchased an additional four round-trip tickets from the island of Hawaii to the island of Maui. Confirmations are attached as Exhibit 3.

Further affiant sayeth naught.

Joey Eski

SUBSCRIBED AND SWORN TO this 2nd day of March, 2008.

JERI ANN JENSON
NOTARY
PUBLIC
STATE OF ALASKA
My Commission Expires March 9, 2011

Notary in and for the State of Alaska
My commission expires: 03-09-11

009867.0038/163707.1

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

From: Alaska/Horizon Airlines <Alaska.IT@AlaskaAir.com>
Date: Mon, 14 Jan 2008 11:19:30 -0800
To: jeski@gci.net
Subject: Alaska Airlines/Horizon Air Confirmation Letter for 3/10/08

Thank you for choosing Alaska Airlines / Horizon Air!

For questions, changes or cancellations on an Alaska Airlines or Horizon Air purchased ticket, please visit alaskaair.com -- you'll save money too! Changes made on alaskaair.com will save $25.00 per ticket over calling reservations.

Confirmation Code: GPLATF

Name: ESKI/IVY
Ticket Number: 027-2115906036
Base Fare: 0.00
Tax: 5.00
Total: 5.00
Mileage Plan: None

REMINDERS AND RESTRICTIONS

This electronic ticket is not transferable and may include non-refundable segments. If you choose to change your itinerary, any fare increases and a change fee will be collected at the time the change is made.

PAYMENT INFORMATION

The amount of $5.00 (USD) was charged to the Visa Card **********1343 held by JOEY ESKI on 1/14/2008, using electronic ticket number 027-2115906036. This document is your receipt.

Name: ESKI/ETHAN
Ticket Number: 027-2115906037
Base Fare: 0.00
Tax: 5.00
Total: 5.00

EXHIBIT 1
PAGE 1 OF 3

n: None

INDERS AND RESTRICTIONS

This electronic ticket is not transferable and may include non-refundable segments. If you choose to change your itinerary, any fare increases and a change fee will be collected at the time the change is made.

PAYMENT INFORMATION

The amount of $5.00 (USD) was charged to the Visa Card **********1343 held by JOEY ESKI on 1/14/2008, using electronic ticket number 027-2115906037. This document is your receipt.

ITINERARY

March 10 2008
Alaska Airlines 870
Depart: Anchorage, AK at 3:20 PM
Arrive: Honolulu, HI at 7:40 PM
Seats: 23B, 23A, Y Class
Meal: Available for purchase

March 22 2008
Alaska Airlines 871
Depart: Honolulu, HI at 9:10 PM
Arrive: Anchorage, AK at 5:30 AM
Seats: 19F, 18F, Y Class

INFLIGHT FOOD SERVICE

On some of your flights, in addition to our usual beverage service, you also have the option to purchase a meal for $5.00(USD or CAD) cash. Please check the details section of your itinerary to determine which flights offer food for purchase. You can find more information on Alaska's Northern Bites meal service at http://www.alaskaair.com/www2/help/faqs/MealService.asp

BAGGAGE

Each ticketed passenger is allowed, free of charge, two checked bags and one carry-on bag plus one personal item, such as a purse, briefcase, or laptop computer. The carry-on bag can measure up to 10" high, 17" wide, and 24" long (25 x 43 x 60 cm). We recommend you put identification on both the outside and inside of all baggage. At least one of your carry-on items should be stowed under the seat in front of you. The free weight allowance is 50 pounds per piece of checked baggage. Unfortunately, Alaska Airlines can not assume liability for loss, damage or delay in the delivery of fragile or perishable articles or other valuables, including but not limited to cameras and electronic equipment, medication or keys, whether with or without the knowledge of the carrier.
Visit http://www.alaskaair.com/www2/help/faqs/CheckedBaggage.asp to read our full baggage policy.

CHECK-IN INFORMATION

Check out our fast and easy Check-In Options (http://www.alaskaair.com/as/www2/flights/Check-In-Options.asp). Save time when you check in online at www.alaskaair.com. You may also check in at an

EXHIBIT 1
PAGE 2 OF 3

airport kiosk or ticket counter. Baggage may be checked at the ticket counter, or, where available, via a Check-In Kiosk. Please have this document or your confirmation code available.

To accommodate everyone wishing to travel on your flight, you must be checked-in and available to board at the designated boarding gate at least 30 minutes before scheduled departure for domestic or international flights, except on 2000 series flights between Seattle/Portland, which require only 20 minutes. Failure to do so may cause the cancellation of reserved seats and cancellation of the entire reservation.

Picture identification, such as a driver's license or passport, is required to board the aircraft. For international travel, anyone crossing an international border is required by the country of entry to produce evidence of citizenship. For more information please visit www.alaskaair.com/www2/help/faqs/Travel_Documents.asp or call 1-800-252-7522 for details.

Save time at the airport and simplify the check in process by providing the required International Travel Information online at https://www.alaskaair.com/booking/ssl/viewpnrstart.aspx

If unaccompanied minors are traveling on this itinerary, please review this important information:
http://www.alaskaair.com/as/www2/help/faqs/ChildrenTravelingAlone.asp

CHANGE OF PLANS

Save money -- You can make your reservation changes on alaskaair.com versus calling 1-800-ALASKAAIR (1-800-252-7522) and you will save $25.00 per ticket on change fees.

Refund and change options are available online at alaskaair.com for most purchased reservations. For information, see the View/Change a Reservation page located under the reservations tab at alaskaair.com.
https://www.alaskaair.com/booking/ssl/viewpnrstart.aspx

For further assistance with refunds or changes on all other reservations, including Mileage Plan Awards, contact 1-800-ALASKAAIR (1-800-252-7522) for Alaska Airlines or 1-800-547-9308 for Horizon Air. Please have your confirmation code ready for the Reservations Agent. Note: If calling from Mexico, precede these telephone numbers with 001.

For questions, changes, and cancellations on a Partner Award itinerary, Air France, American Airlines, British Airways, Continental Airlines, Delta Air Lines, KLM, LAN, Northwest Airlines, Qantas or Cathay Pacific Airways please call the Partner Desk at 1-800-307-6912.

Refunds for qualifying tickets may be obtained by calling the appropriate toll-free number listed above or by applying at any ticket counter location.

Please review U.S. Department of Transportation Consumer Notices regarding your consumer rights and limitations of liability at:
www.alaskaair.com/www2/help/faqs/ConsumerNotices.asp or simply obtain a copy when checking in.

EXHIBIT 1
PAGE 3 OF 3

From: Alaska/Horizon Airlines <Alaska.IT@AlaskaAir.com>
Date: Tue, 15 Jan 2008 11:04:58 -0800
To: jeski@gci.net
Subject: Alaska Airlines/Horizon Air Confirmation Letter for 3/10/08

Thank you for choosing Alaska Airlines / Horizon Air!

For questions, changes or cancellations on an Alaska Airlines or Horizon Air purchased ticket, please visit alaskaair.com -- you'll save money too! Changes made on alaskaair.com will save $25.00 per ticket over calling reservations.

Confirmation Code: KLATWL

Name: ESKI/JOEY
Ticket Number: 027-2115956038
Base Fare: 1166.69
Tax: 37.71
Total: 1204.40
Mileage Plan: Alaska Airlines #*****631 Gold

REMINDERS AND RESTRICTIONS

This electronic ticket is not transferable and may include non-refundable segments. If you choose to change your itinerary, any fare increases and a change fee will be collected at the time the change is made.

PAYMENT INFORMATION

The amount of $1204.40 (USD) was charged to the Visa Card **********1343 held by JOEY ESKI on 1/15/2008, using electronic ticket number 027-2115956038. This document is your receipt.

Name: SCHWENN/MICHELLE
Ticket Number: 027-2115956040
Base Fare: 50.00
Tax: 33.58

EXHIBIT 2
PAGE 1 OF 3

Total: 83.58
Mileage Plan: Alaska Airlines #*****686

REMINDERS AND RESTRICTIONS

This electronic ticket is not transferable and may include non-refundable segments. If you choose to change your itinerary, any fare increases and a change fee will be collected at the time the change is made.

PAYMENT INFORMATION

The amount of $83.58 (USD) was charged to the Visa Card **********1343 held by JOEY ESKI on 1/15/2008, using electronic ticket number 027-2115956040. This document is your receipt.

ITINERARY

March 10 2008
Alaska Airlines 870
Depart: Anchorage, AK at 3:20 PM
Arrive: Honolulu, HI at 7:40 PM
Seats: 23C, 23F, Y Class
Meal: Available for purchase

March 22 2008
Alaska Airlines 871
Depart: Honolulu, HI at 9:10 PM
Arrive: Anchorage, AK at 5:30 AM
Seats: 19E, 18E, Y Class

INFLIGHT FOOD SERVICE

On some of your flights, in addition to our usual beverage service, you also have the option to purchase a meal for $5.00(USD or CAD) cash. Please check the details section of your itinerary to determine which flights offer food for purchase. You can find more information on Alaska's Northern Bites meal service at http://www.alaskaair.com/www2/help/faqs/MealService.asp

BAGGAGE

Each ticketed passenger is allowed, free of charge, two checked bags and one carry-on bag plus one personal item, such as a purse, briefcase, or laptop computer. The carry-on bag can measure up to 10" high, 17" wide, and 24" long (25 x 43 x 60 cm). We recommend you put identification on both the outside and inside of all baggage. At least one of your carry-on items should be stowed under the seat in front of you. The free weight allowance is 50 pounds per piece of checked baggage. Unfortunately, Alaska Airlines can not assume liability for loss, damage or delay in the delivery of fragile or perishable articles or other valuables, including but not limited to cameras and electronic equipment, medication or keys, whether with or without the knowledge of the carrier.
Visit http://www.alaskaair.com/www2/help/faqs/CheckedBaggage.asp to read our full baggage policy.

CHECK-IN INFORMATION

Check out our fast and easy Check-In Options (http://www.alaskaair.com/as/www2/flights/Check-In-Options.asp). Save time

EXHIBIT 2
PAGE 2 OF 3

when you check in online at www.alaskaair.com. You may also check in at an airport kiosk or ticket counter. Baggage may be checked at the ticket counter, or, where available, via a Check-In Kiosk. Please have this document or your confirmation code available.

To accommodate everyone wishing to travel on your flight, you must be checked-in and available to board at the designated boarding gate at least 30 minutes before scheduled departure for domestic or international flights, except on 2000 series flights between Seattle/Portland, which require only 20 minutes. Failure to do so may cause the cancellation of reserved seats and cancellation of the entire reservation.

Picture identification, such as a driver's license or passport, is required to board the aircraft. For international travel, anyone crossing an international border is required by the country of entry to produce evidence of citizenship. For more information please visit www.alaskaair.com/www2/help/faqs/Travel_Documents.asp or call 1-800-252-7522 for details.

Save time at the airport and simplify the check in process by providing the required International Travel Information online at https://www.alaskaair.com/booking/ssl/viewpnrstart.aspx

If unaccompanied minors are traveling on this itinerary, please review this important information:
http://www.alaskaair.com/as/www2/help/faqs/ChildrenTravelingAlone.asp

CHANGE OF PLANS

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https://www.alaskaair.com/booking/ssl/viewpnrstart.aspx

For further assistance with refunds or changes on all other reservations, including Mileage Plan Awards, contact 1-800-ALASKAAIR (1-800-252-7522) for Alaska Airlines or 1-800-547-9308 for Horizon Air. Please have your confirmation code ready for the Reservations Agent. Note: If calling from Mexico, precede these telephone numbers with 001.

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www.alaskaair.com/www2/help/faqs/ConsumerNotices.asp or simply obtain a copy when checking in.

EXHIBIT 2
PAGE 3 OF 3

From: GO <customercare@iflygo.com>
Date: Tue, 05 Feb 2008 18:12:37 -0600 (CST)
To: jeski@gci.net
Subject: Travel Reservation March 10 for ESKI

This email confirms receipt of your reservation made on www.iflygo.com <http://www.iflygo.com> .

You may print out the itinerary and bring it to the airport as a receipt, as all transactions are ticketless.

Click here to access your reservation on the web or a mobile device.
<https://www.virtuallythere.com/new/reservationsChron.html?
host=YV&pnr=N20GENH0MR1O&name=ESKI&language=0&email=2>

Click here to view and print e-ticket receipt 5332102807254
<https://www.virtuallythere.com/new/eTicketReceiptPrint.html?
pnr=N20GENH0MR1O&pcc=GVY&language=0&name=ESKI&host=YV&ETNBR1=5332102807254&ETDTE

Click here to view and print e-ticket receipt 5332102807255
<https://www.virtuallythere.com/new/eTicketReceiptPrint.html?
pnr=N20GENH0MR1O&pcc=GVY&language=0&name=ESKI&host=YV&ETNBR1=5332102807255&ETDTE

Click here to view and print e-ticket receipt 5332102807256
<https://www.virtuallythere.com/new/eTicketReceiptPrint.html?
pnr=N20GENH0MR1O&pcc=GVY&language=0&name=ESKI&host=YV&ETNBR1=5332102807256&ETDTE

Click here to view and print e-ticket receipt 5332102807257
<https://www.virtuallythere.com/new/eTicketReceiptPrint.html?
pnr=N20GENH0MR1O&pcc=GVY&language=0&name=ESKI&host=YV&ETNBR1=5332102807257&ETDTE

****

JOEY ESKI, IVY ESKI, ETHAN ESKI, MICHELLE SCHWENN

EXHIBIT 3
PAGE 1 OF 2

Reservation code: HWFWIP

Mon, Mar 10
Flights: MESA AIRLINES, YV 1019
Operated by: MESA AIRLINES DBA GO!
From: HONOLULU, HI (HNL) Departs: 10:00pm
To: KAHULUI MAUI, HI (OGG) Arrives: 10:35pm
Class: Economy Seat(s): Check-In Required
Status: Confirmed
Meal: Smoking: No
Aircraft: CRJ-CANADAIR REGIONAL JET Mileage: 101
Duration: 35 minute(s)
Please verify flight times prior to departure

Sat, Mar 22
Flights: MESA AIRLINES, YV 1007
Operated by: MESA AIRLINES DBA GO!
From: KAHULUI MAUI, HI (OGG) Departs: 6:30pm
To: HONOLULU, HI (HNL) Arrives: 7:02pm
Class: Economy Seat(s): Check-In Required
Status: Confirmed
Meal: Smoking: No
Aircraft: CRJ-CANADAIR REGIONAL JET Mileage: 101
Duration: 32 minute(s)
Please verify flight times prior to departure

****

Please print a copy of this information and put it in a safe place so that you may refer to your itinerary and Sabre Record Locator (confirmation number) for your trip.

Due to increased security measures, please have a valid picture ID available at the ticket counter. You should plan to arrive at the airport at least an hour before scheduled departure time.

If you need to make changes to or cancel your reservation, please contact go! Reservations at 1-888 IFLYGO2 (1 888-435-9462). Reservation changes may result in additional fees and penalties. Please refer to the FAQ tab on www.iflygo.com <http://www.iflygo.com> for ticketing change fees.

All tickets are non-transferable. When making a change to a non-refundable ticket, there is a $20 change fee as well as a possible change in the fare if original booking class is not available. The upgrade fee is the difference between the fare you paid and the current fare available.

If you booked a car or hotel and they did not come back with a confirmation number, please call the car or hotel company directly to verify the booking.

All go! flights are operated by Mesa Airlines.

Click here to opt out of receiving future e-mails from Virtually There.
<http://www.virtuallythere.com/new/emOptOut.html?host=YV&language=0&email=2&pcc=GVY>

GO
1-888-IFLYGO2 (1-888-435-9462) Email: customercare@iflygo.com
...the island's airline

EXHIBIT 3
PAGE 2 OF 2

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

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CIV

JUDGE'S RULINGS RE:

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

Defendant Eli Lilly and Company ("Lilly") objects to the flowing pages and lines of Plaintiff State of Alaska's Trial Deposition Designations:

I. Deposition of John C. Lechleiter, Ph.D

Start (Page:Line)	End (Page:Line)	Objection	
32:6	32:19	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overrule Sustain as to line 6-10 sustain after
33:5	33:17	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overrule
45:20	45:23	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	sustain

A

Start (Page:Line)	End (Page:Line)	Objection
58:11	59:15	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motions in Liminere: Lilly profits and prices and other Lilly drugs.
67:15	68:2	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
69:6	69:10	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
69:13	70:24	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motions in Liminere: Lilly profits and prices and other Lilly drugs.
82:20	83:19	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
84:9	84:22	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
86:24	87:14	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
88:1	88:7	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).
92:22	93:7	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).

overrule

overrule

Q- no answer

overrule

Sustain all seem to be off not many

sustain

A

Start (Page:Line)	End (Page:Line)	Objection
94:5	95:9	Relevance; foundation; lack of personal knowledge; hearsay; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802; 901). Subject to Motion in Limine re: Lilly profits and prices.
96:13	96:20	Relevance; foundation; lack of personal knowledge; hearsay; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802; 901). Subject to Motion in Limine re: Lilly profits and prices.
102:8	103:1	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.
103:17	104:24	Relevance; foundation; lack of personal knowledge; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802). Subject to Motion in Limine re: Lilly profits and prices.
105:12	105:16	Relevance; foundation; lack of personal knowledge; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403 602; 802). Subject to Motion in Limine re: Lilly profits and prices.
105:21	106:20	Relevance; foundation; lack of personal knowledge; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802). Subject to Motion in Limine re: Lilly profits and prices.
110:4	110:15	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.

sustained to not
OK 94:9 - 95:9
~~OK~~ overrule
overrule
overrule
overrule
overrule
overrule

A

Start (Page:Line)	End (Page:Line)	Objection	
110:18	111:6	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overule
117:13	118:2	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overule
119:15	120:13	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motions in Liminere: Lilly profits and prices and other Lilly drugs.	overule
121:8	121:24	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overule
122:22	124:9	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overule
125:7	126:7	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overule
128:15	128:22	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overule
133:16	134:6	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion; hearsay (Alaska R. Evid. 401; 403; 802). Subject to Motion in Limine re: Lilly profits and prices.	overule
138:9	138:19	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overule

A

Start (Page:Line)	End (Page:Line)	Objection	
140:1	140:14	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overle
141:9	142:8	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: Lilly profits and prices.	overle
144:21	145:1	Foundation; relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
145:4	145:5	Foundation; relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403)	
145:18	146:6	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
146:14	147:5	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
148:12	148:18	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
162:3	162:14	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
162:19	163:9	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
166:19	167:12	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overle
170:19	171:2	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion; hearsay (Alaska R. Evid. 401; 403, 802).	overle

A

Start (Page:Line)	End (Page:Line)	Objection	
191:19	192:17	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overle
239:11	239:19	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
240:13	241:13	Relevance; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401, 403; 802).	overle
243:12	243:18	Relevance; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401, 403; 802).	overle
244:24	245:10	Relevance; hearsay; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401, 403; 802).	overle
249:7	249:21	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403). Subject to Motion in Limine re: other Lilly drugs.	overle
265:23	267:7	Hearsay; foundation; relevance; lack of personal knowledge; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602; 802; 901).	overle
268:20	269:2	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
276:9	276:22	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overle
277:24	279:6	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overle
279:13	279:18	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overle
284:18	285:1	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overle

A

Start (Page:Line)	End (Page:Line)	Objection	
285:17	286:9	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overl
286:15	287:2	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	Overle
297:6	297:21	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overl
299:20	300:4	Hearsay; foundation; lack of personal knowledge; authentication (Alaska R. Evid. 602; 802; 901).	overl
302:11	302:23	Relevance; hearsay; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 802; 901). Subject to Motion in Limine re: Lilly profits and prices.	~~overle~~ Sustain
303:6	303:18	Relevance; hearsay; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 802; 901). Subject to Motion in Limine re: Lilly profits and prices.	Sustain
304:9	~~304:22~~ 305. 14	Relevance; authentication; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 901).	overle
313:7	315:7	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overule
315:15	315:18	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
316:19	318:12	Hearsay; relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403 802).	overl
320:14	320:18	Hearsay; relevance; lack of personal knowledge; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602).	~~Ov~~ QQ only

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Start (Page:Line)	End (Page:Line)	Objection	
320:21	323:7	Hearsay; relevance; lack of personal knowledge; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602).	overle
324:18	325:16	Hearsay; relevance; lack of personal knowledge; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403; 602).	overle
360:3	360:6	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	~~overle~~ Estam
361:4	361:20	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	ova
363:3	363:16	Mischaracterizes prior testimony, relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle
363:19	364:2	Mischaracterizes prior testimony; relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overl
364:3	365:23	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overe
366:7	367:11	Relevance; probative value is outweighed by the danger of unfair prejudice, delay and confusion (Alaska R. Evid. 401; 403).	overle

Danae TM Torres

II. Deposition of ~~John C. Lechleiter, Ph.D~~

Start (Page:Line)	End (Page:Line)	Objection	
38:7	38:11	Foundation (Alaska R. Evid. 602, 701)	overle
47:6	47:16	Relevance (Alaska. R. Evid. 401, 402)	overle

A

Start (Page:Line)	End (Page:Line)	Objection	
54:16	55:7	Relevance; Ambiguous; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 611)	~~Overr~~ sustain
62:13	63:3	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Sustain
63:9	63:14	Relevance, Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	sustain
68:19	68:20	Relevance, Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule
75:19	76:3	Relevance (Alaska R. Evid. 401, 402)	overule
77:18	78:4	Relevance, Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule
79:18	79:20	Relevance; Probative value outweighed by danger of unfair prejudice. (Alaska R. Evid. 401, 402, 403)	overule
79:23	80:1	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	
84:19	85:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule
86:01	86:08	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule
88:18	88:24	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule
127:16	127:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	sustain
134:24	135:6	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	sustain
136:6	136:15	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 401, 402, 403, 602, 701)	sustain

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Start (Page:Line)	End (Page:Line)	Objection	
146:13	146:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Sustain ~~Sust~~ ~~Overrule~~
147:3	147:7	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain ~~Overrule~~
148:6	148:10	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Ambiguous; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain
148:11	148:13	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Ambiguous; Misstates the evidence; Argumentative (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	sustain
148:14	148:22	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain
150:8	150:11	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	overule
152:12	152:20	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence; Ambiguous (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	overule
154:18	154:23	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence; Ambiguous (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	overule
171:9	171:17	Relevance; Probative value outweighed by danger of unfair prejudice; Ambiguous (Alaska R. Evid. 401, 402, 403, 611)	overule
173:18	174:2	Foundation (Alaska R. Evid. 602, 701)	overule
174:17	174:21	Foundation (Alaska R. Evid. 602, 701)	overule
178:14	178:23	Foundation (Alaska R. Evid. 602, 701)	overule
179:19	180:2	Foundation; Ambiguous (Alaska R. Evid. 602, 611, 701)	overule

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Start (Page:Line)	End (Page:Line)	Objection	
181:11	181:18	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overle
181:21	182:4	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overle
182:5	182:8	Argumentative; Comment by counsel (Alaska R. Evid. 611)	overle
185:15	186:9	Relevance; Probative value outweighed by danger of unfair prejudice; Comment by counsel (Alaska R. Evid. 401, 402, 403, 611)	overle
186:22	187:12	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overle
189:5	189:18	Foundation; Argumentative; Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	overle
234:16	235:04	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overle
241:19	241:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overle
242:3	242:18	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overle
243:2	243:20	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overle
244:1	244:10	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain
248:9	248:20	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	sustain
249:6	249:12	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Sustain
249:19	249:22	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Sustain
250:5	250:9	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	sustain

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Start (Page:Line)	End (Page:Line)	Objection	
251:9	251:13	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain
357:23	358:8	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	Overule
359:15	360:10	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	~~Sustain~~ Overule
361:3	361:14	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	Overule
400:16	401:7	Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overule
404:7	404:11	Foundation; ; Misstates the evidence (Alaska R. Evid. 602, 611, 701)	overule
411:20	412:3	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule
416:19	417:6	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule
420:9	420:18	Compound (Alaska R. Evid. 611) overule	
422:12	422:20	Argumentative (Alaska R. Evid. 611) overule	
476:7	477:10	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule
480:9	480:17	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 401, 402, 403, 601, 702)	overule
488:23	489:8	Foundation (Alaska R. Evid. 602, 701)	overule
491:1	491:18	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 601, 602, 611, 701)	overule
492:9	492:13	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	overule

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Start (Page:Line)	End (Page:Line)	Objection	
510:5	510:8	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 601, 602, 611, 701)	Sustain
510:18	510:23	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 601, 602, 611, 701)	Sustain
514:7	514:15	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 601, 602, 611, 701)	Sustain
527:17	528:2	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	~~Sustain~~ Overrule
528:16	529:2	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 401, 402, 403, 601, 602, 701)	Sustain
530:23	531:14	Relevance; Probative value outweighed by danger of unfair prejudice; Ambiguous; Foundation (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain
535:17	536:24	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)	Sustain
537:7	538:7	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation (Alaska R. Evid. 401, 402, 403, 602, 701)	Sustain ~~Sustain~~ ~~overrule~~
538:13	538:15	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain
538:22	539:3	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 602, 611, 701) (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain
539:10	539:23	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)	Sustain

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Start (Page:Line)	End (Page:Line)	Objection
540:1	540:19	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence; Compound; Argumentative (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
545:15	546:5	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
546:7	546:11	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
546:13	547:17	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)
548:17	548:21	Relevance; Probative value outweighed by danger of unfair prejudice (Alaska R. Evid. 401, 402, 403)
549:8	549:12	Relevance; Probative value outweighed by danger of unfair prejudice; Foundation; Misstates the evidence (Alaska R. Evid. 401, 402, 403, 602, 611, 701)

Lilly reserves the right to object to any deposition testimony not yet taken in this or any other matter. Lilly further reserves the right to object to any additional deposition testimony not included above if deemed necessary at the trial of this action.

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Attorneys for Defendant
Eli Lilly and Company

Dated: March 5, 2008

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **DEFENDANT ELI LILLY AND COMPANY'S OBJECTIONS TO PLAINTIFF STATE OF ALASKA'S TRIAL DEPOSITION DESIGNATIONS** has been served on counsel listed below.

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Date: March 5, 2008

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FILED IN OPEN COURT
Date: 3-5-08
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 FOR CLARIFICATION OF INSTRUCTION REGARDING PRESENTATION OF VIDEO DEPOSITION TESTIMONY

I. INTRODUCTION

To avoid confusion and unnecessary prolongation of this trial, defendant Eli Lilly and Company ("Lilly") requests that the Court clarify its February 22, 2008, directive that the parties present their videotaped deposition designations and counter-designations in a staggered fashion. The Court's adoption of the State's informal proposal to proceed in this manner will prejudice the party offering counter-designation testimony because it will be heard out of context. To avoid these issues, and consistent with the rule of completeness embodied in both the Alaska Rules of Evidence and of Civil Procedure, the parties' videotaped deposition excerpts for any specific witness should be played together in one single clip.

II. ARGUMENT

The problem created by staggered presentation is illustrated by the following representative example. The State has designated deposition testimony from the deposition of Dr. Alan Breier, Lilly's Chief Medical Officer, about an analysis of a medical study – one several discussed at his deposition. In response to some of these designations, Lilly offers a counter-designation:

> Q. You had considerable skepticism expressed about the results of this analysis by other consultants to the company, did you not?

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A. I would characterize that most people who saw the data found it very helpful. This was a unique dataset of over 6,000 patients in controlled trials. Just comparing it to the Casey report of a very small, retrospective, poorly-controlled dataset. It were these kinds of studies, the Casey report, that were in the public domain that were not terribly informative. And we felt that we had a unique set of data, a one-of-a-kind in terms of quality and length, numbers of exposures. And most of the input I received on this data was quite laudatory and positive. In fact, we not only submitted this data to the FDA, but we submitted it to regulatory bodies worldwide, and it's in the European label today. So those scientists looked at it and found it quite helpful and meaningful.

If Lilly is required to present this excerpt only after the State presents all of its Dr. Breier testimony, the jury will have no hint as to what analysis Dr. Breier is discussing, much less any clue about how this testimony clarifies or contextualizes any of his testimony designated by the State about this analysis discussed on page 213, 214, 219, 220, and 221 of the transcript. Fundamental fairness requires that Lilly's counter-designations for Dr. Breier, as well as those for the other eleven witnesses for whom the State has affirmatively designated deposition testimony, be presented contemporaneously with the affirmative designations in one single videotape clip.[1]

The current mechanism for presenting videotaped depositions to the jury requires an awkward staggering of the party's video clips for each witness. Under this approach, for each witness, one party's set of affirmative designations will be played for the jury *in full*, followed by the other party's set of responsive counter-designations *in full*. This approach removes the context of the counter-designated testimony, which each party offers to clarify, explain and contextualize the adverse parties' affirmative designations. Now, this testimony will necessarily be disconnected from the testimony to it relates. When clarifying counter-testimony is presented

[1] Certainly the State should receive the same benefit as Lilly with its counter designations.

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long after the testimony that is meant to be clarified, as will necessarily be the case under the current plan, the counter-designations will appear to the jury as nothing more than an arbitrarily-ordered series of seemingly random deposition clips, divorced from their context and effectively stripped of their meaning.

This notion of fundamental fairness is expressly embodied in the relevant Court rules and dictates a contextual approach. Alaska Rule of Evidence 106 states that "[w]hen a writing or recorded statement or part thereof is introduced by a party, an adverse party may require the introduction *at that time* of any other part or any other writing or recorded statement which ought in fairness to be considered *contemporaneously* with it."[2]

This is the "rule of completeness," which prevents misleading impressions created by taking a statement out of context.[3] As the Alaska Court of Appeals has stated, "the purpose of Rule 106 is ... [to] give[] the parties against whom written or recorded evidence has been admitted the power to *accelerate the timing* of their opportunity to introduce complementary evidence.[4] This rule is made specifically applicable to deposition testimony by Alaska Rule of Civil Procedure 32(a)(4), which provides that "[i]f only part of a deposition is offered in evidence by a party, an adverse party may require the offeror to introduce any other part which ought in fairness to be considered with the part introduced."[5]

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[2] Alaska R. Evid. 601 (emphasis added).

[3] 1 Weinstein, Weinstein's Evidence ¶ 106[02] (1982); *see* 29 Am. Jur. 2d Evidence § 359 (The purpose of the federal analog to Rule 106 "is to permit the contemporaneous introduction of writings or recorded statements that place in context other writings or recorded statements admitted into evidence which, viewed alone, may be misleading." (citations omitted)).

[4] *Sipary v. State*, 91 P.3d 296, 300 (Alaska Court of Appeals 2004) (emphasis in original).

[5] Alaska R. Civ. Proc. 32(a)(4).

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These rules are specifically designed to prevent the precise problems of jury confusion and prejudice that will result under the current staggered approach. The Commentary to Alaska Evidence Rule 601 recognizes that "[w]here time elapses between the offer of part of a statement and the offer of the remainder, the jury may become confused or find it difficult to reassess evidence that it has heard earlier in light of subsequent material."[6] The Advisory Committee to the identical federal counterpart to Alaska Rule of Evidence 106 cited two considerations as the basis for the rule: (1) "the misleading impression created by taking matters out of context," and (2) "the inadequacy of repair work when delayed to a point later in the trial."[7]

As these rules reflect, any interruption of a party's presentation of affirmative deposition testimony (whether it is Lilly or the State), is far outweighed by the prejudice that would result if the adverse party were precluded from presenting its counter testimony in meaningful context. Accordingly, consistent with the Alaska rules and fundamental fairness, the Court should direct the parties to coordinate their presentations of deposition excerpts so that any party's counter-designations will be played to the jury in context, during the same video clip as the adverse party's affirmative and counter-counter-designations.[8]

Further, because the preparation of video deposition excerpts requires significant preparation time, Lilly requests that the Court rule on this motion as expeditiously as possible.

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[6] Comm. to Alaska R. Evid. 601.

[7] Notes of Advisory Committee on 1987 amendments to Federal Rules of Civil Procedure.

[8] Short of this, Lilly will have no other option but to repeat the State's designations in conjunction with its counter designations in one clip. This is an unfavored alternative that would needlessly lengthen the trial significantly.

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Andrea E. Girolamo-Welp,
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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 DEPOSITION COUNTER-DESIGNATIONS FOR TRIAL

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:

I. Deposition of John C. Lechleiter, Ph.D, designated pages Exhibit A.

Start (Page:Line)	End (Page:Line)
40:13	40:24
71:1	71:10
92:17	92:19
111:23	112:9
120:14	121:7
122:6	122:18
124:21	125:2
149:3	149:12
267:16	268:11

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Start (Page:Line)	End (Page:Line)
275:23	276:14
277:12	277:17
280:6	280:18
292:24	293:10
300:11	300:21
310:11	310:20

II. Deposition of Denice M. Torres, designated pages Exhibit B.

Start (Page:Line)	End (Page:Line)
147:8	147:12
175:9	175:13
175:16	175:17
188:11	188:15
188:18	189:3
201:1	201:8
244:11	246:10
358:19	359:13
401:8	403:4
418:11	418:23
424:9	424:16
477:21	478:10
511:1	512:14
512:16	513:1

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Start (Page:Line)	End (Page:Line)
514:16	515:2
529:3	529:9
545:7	545:13
552:2	552:15

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

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Attorneys for Defendant
Eli Lilly and Company

Dated: March 5, 2008

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of **DEFENDANT ELI LILLY AND COMPANY'S DEPOSITION COUNTER-DESIGNATIONS** has been served on counsel listed below.

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Date: March 5, 2008

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

PLAINTIFF'S SECOND AMENDED PAGE/LINE DESIGNATIONS AS OF MARCH 3, 2008

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

CHARLES BEASLEY
JULY 26, 2006

START PAGE/LINE	END PAGE/LINE
26:10	26:14
26:21	27:4
32:12	32:22
44:7	44:14
45:18	45:22
56:4	56:15
74:13	74:16
75:19	77:10
77:11	79:6
82:11	82:16
82:18	82:22

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83:15	84:6
84:7	84:13
84:15	85:19
86:12	86:17
94:4	94:23
94:24	95:4
95:9	96:4
96:7	96:12
99:1	99:11
111:2	111:2
111:3	111:11
111:13	111:13
135:15	135:17
135:19	136:2
136:3	137:15
142:3	142:7
142:9	142:15
145:13	145:15
145:16	145:16
146:12	147:3
147:12	148:4
149:12	149:14
149:15	149:16
149:18	149:19
150:7	150:12
150:14	150:17
151:11	151:13
156:17	157:3
157:7	157:10
160:6	161:17
183:23	184:3
184:15	184:22
185:21	186:21
186:23	186:23
190:22	191:11
191:13	191:17
193:21	194:3
194:19	195:13
195:19	196:15

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202:14	202:16
205:21	205:24
207:3	207:12
209:21	210:1
218:2	218:8
218:12	219:8
223:15	223:17
230:23	231:16
232:6	232:23
233:17	233:23
234:18	234:23
235:1	235:2
235:16	235:23
236:1	236:1
236:6	236:12
236:14	236:16
237:1	237:13
237:14	237:14
238:7	238:19
242:9	242:14
243:18	243:22
244:17	246:23
247:1	247:17
250:17	250:23
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DATED this 4th day of March, 2008.

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Beasley, Charles (Vol. 01) - 07/26/2006

RPWB Desig

BEASLEY (117 SEGMENTS RUNNING 01:10:20.998)

1. PAGE 26:10 TO 26:14 (RUNNING 00:00:05.000)

Q. Good morning, Dr. Beasley. Would you state your full name for the record, please?
A. Yes, my name is Charles M. Beasley Jr.

2. PAGE 26:21 TO 27:04 (RUNNING 00:00:13.000)

Q. Okay. And are you currently employed by Eli Lilly?
A. Yes, I am.
Q. And what's your current job title?
A. My current job title is Distinguished Lilly Scholar and Chief Scientific Officer For Global Product Safety.

3. PAGE 32:12 TO 32:22 (RUNNING 00:00:20.000)

Q. Okay. And I believe you became board certified in psychiatry in 1988; is that correct?
A. That would have been correct. It's a two-step process and I believe that I completed the second part in, I believe, it was October of 1988.
Q. Okay. And you joined Eli Lilly as an Associate Research Physician in July of 1987; is that correct?
A. That's correct.

4. PAGE 44:07 TO 44:14 (RUNNING 00:00:05.000)

Q. Okay.
I'm going to hand you what has been previously marked Plaintiff's Exhibit 1349.
(Whereupon, Deposition Exhibit(s) 1349 previously marked, was presented to the witness.)

5. PAGE 45:18 TO 45:22 (RUNNING 00:00:10.000)

By the way, for the record this appears to be a PowerPoint presentation. It's 24 pages. The first page has a heading Human Metabolism.

6. PAGE 56:04 TO 56:15 (RUNNING 00:00:24.000)

Q. You've described various testing that was done on Zyprexa before it was -- went on the market. That testing was

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done by Eli Lilly, correct?
A. I would characterize it as being done by the -- by the investigators. It was designed and administered by Lilly.
Q. Okay.
A. Now, I understand your --
Q. Okay.
A. The FDA didn't actually do the studies or contract to have them done.

7. PAGE 74:13 TO 74:16 (RUNNING 00:00:07.000)

Q. Okay. And back at that time in December of 1995, were you reporting directly to Dr. Tollefson then?
A. Yes, I was.

8. PAGE 75:19 TO 77:10 (RUNNING 00:01:43.000)

second paragraph -- actually, let's talk about the first paragraph. It states, "The third meeting of the U.S. Schizophrenia Advisory Panel convened on December 10, 1995, in San Juan, Puerto Rico, to discuss olanzapine, the Eli Lilly and Company
00076:01 anti-psychiatric drug in development. Ten of the 11 schizophrenia specialists who served on the panel were present along with medical, research, and marketing executives at Eli Lilly and Company." Did I read that correctly?
A. That's correct.
Q. And this would have been about what, two, three months after the NDA had been submitted to FDA?
A. I believe that's correct. Because I think the NDA was submitted in September.
Q. September. Okay. And then the second paragraph it starts off by saying, "The meeting began with first-time presentation of efficacy and safety results from HGAJ, the pivotal phase 3 trial by Charles Beasley, Jr, MD, and a review of the developmental history and update of the integrated olanzapine database by Gary Tollefson." Do you see that?
A. That's correct.
Q. And when it uses the phrase
00077:01 "the pivotal phase 3 trial" referring to HGAJ, what does that mean?
A. That this was one of the trials that was part of the NDA.
Q. Okay. And as we talked before, it was not only one of the trials, it was the largest trial, correct?
A. That's correct.
Q. Okay. If I could direct your attention to Page 8. In the first paragraph,

9. PAGE 77:11 TO 79:06 (RUNNING 00:01:42.000)

in about the middle of that paragraph four lines from the bottom it states, "For all

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patients treated with olanzapine for any amount of time, forty percent gained greater than or equal to 7 percent body weight." Do you see that language?
A. Let me just find it here. Yes, I do.
Q. Okay. And it's generally accepted that an increase in weight of 7 percent or more is clinically significant, correct?
A. This has been a criteria established with the FDA for which the term is used potentially clinically significant.
Q. Okay. And that paragraph goes on to note that, "Patients who remained on olanzapine for 12 months gained an average of 24 pounds at the end of 12 months," correct?
A. That's correct.
Q. Okay. By the way, if 40 percent of the people who took the drug for any period of time had more than -- had equal to or more than 7 percent body weight that means that 40 percent of the people who took the drug for any length of time had potentially clinically significant weight gain, correct?
A. That's correct.
Q. Okay. And then there's a paragraph below that that's in italics which states quote, "Several advisors commented on the association of olanzapine with weight gain and encouraged Lilly to subject the data to a full analysis. Clinically significant weight gain is a risk factor for other conditions such as increased blood pressure, increased cholesterol and type II diabetes. The advisors also noted that Lilly has an opportunity to develop strategies to help manage the weight gain." Do you see that language?
A. Yes, I do.

10. PAGE 82:11 TO 82:16 (RUNNING 00:00:14.000)

Q. With respect to the weight issue, your labeling did not inform physicians that for all patients treated with olanzapine for any amount of time 40 percent gained more than or equal to 7 percent of the body weight; is that correct?

11. PAGE 82:18 TO 82:22 (RUNNING 00:00:10.000)

A. Well --
Q. You got to answer that question "yes" or "no" or "I don't know?"
A. Well, it, specifically, did not. What our label did --

12. PAGE 83:15 TO 84:06 (RUNNING 00:00:33.000)

Q. Your labeling also did not, specifically, inform physicians that patients

A

who remained on olanzapine for 12 months gained an average of 24 pounds at the end of those 12 months, correct?
A. No, it did not.
Q. Okay. And on Page 8 at the bottom there's a -- in the last paragraph, there's a heading that says Laboratory Analytes?
A. Yes.
Q. And what does that phrase mean?
A. This would refer to all of those things that are measured in blood or urine, specific measurements such as sodium,

13. PAGE 84:07 TO 84:13 (RUNNING 00:00:15.000)

glucose, or white blood cells, that are measured in a laboratory.
Q. And, in fact, the laboratory testing that was done on HGAJ subjects showed that there was a statistically significant increased incidence of high glucose and also high cholesterol; isn't that correct?

14. PAGE 84:15 TO 85:19 (RUNNING 00:01:36.000)

A. Again, without benefit of looking at the -- at the entirety of the data, my only recollection is with regard to a analysis of the, what we call the categorical incidence of elevated glucoses relative to haloperidol, based on what we call anytime data. I recall this number as being statistically significant. That is one number that needs to be appropriately put in the context of, actually, about nine analyses.
Q. You say "based on what we call anytime data I recall this number as being statistically significant." What was "this number" that you're referring to?
A. I believe it was the percentage of individuals who showed a shift from a normal glucose to what would be considered a high glucose.
Q. Okay. And you were aware of that at what point in time?
A. I don't know the specific. It would have been when the data were analyzed.
Q. It would be sometime between when the data was cutoff in February of 1995 and when it was submitted to FDA in September of 1995, correct?
A. That would have been correct.

15. PAGE 86:12 TO 86:17 (RUNNING 00:00:16.000)

Q. Do you recognize this document, sir?
A. This would have been a printout, I believe, from the NDA that would have been part of the study report for the

A

17 acute phase of study HGAJ.

16. PAGE 94:04 TO 94:23 (RUNNING 00:01:00.000)

04 Q. Who was responsible for
05 having these types of analyses done and then
06 reviewed?
07 A. Okay. That would have been a
08 group of individuals, Dr. Tollefson, myself,
09 other physicians, senior statisticians that
10 would have been involved with the -- with the
11 project.
12 And I would think, also, we
13 would include the regulatory people who would
14 be involved with guiding us in terms of the
15 NDA preparation.
16 Q. Okay. Would it be fair to
17 say that if computer analyses were done of
18 the data from the HGAJ study back in June of
19 1995 that you and Dr. Tollefson would have
20 been aware of the results of those analyses?
21 A. Yes, we would have been.
22 Q. Okay. I'd like to direct
23 your attention to Page 11.

17. PAGE 94:24 TO 95:04 (RUNNING 00:00:08.000)

24 A. Yes.
00095:01 Q. Do you see there that there's
02 a heading for lab tests of Glucose,
03 Non-fasting?
04 A. Yes, I do.

18. PAGE 95:09 TO 96:04 (RUNNING 00:00:42.000)

09 In this study, HGAJ, there
10 were, actually, two groups of patients, some
11 of whom were taking olanzapine or Zyprexa the
12 other group was taking another drug referred
13 to as a first generation anti-psychotic drug
14 called Haldol or haloperidol; is that
15 correct?
16 A. That's correct.
17 Q. Okay. And what you were
18 doing in this study was comparing the
19 incidence of these different types of
20 laboratory analytes between those folks who
21 took Zyprexa and those who Haldol, correct?
22 A. That's correct.
23 Q. On Page 11 here, this portion
24 of the printout regarding Glucose,
00096:01 Non-Fasting, shows a statistically
02 significant increased incidence of high
03 glucose in the Zyprexa group as compared to
04 the Haldol group, correct?

19. PAGE 96:07 TO 96:12 (RUNNING 00:00:20.000)

07 A. Yes. I'm seeing a -- an
08 incidence of 2.6 percent high for olanzapine,
09 1.1 percent for haloperidol. And the P value
10 there, by this test, is .031 which is less
11 than .05, which is generally considered the
12 standard for statistical significance.

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20. PAGE 99:01 TO 99:11 (RUNNING 00:00:26.000)

Q. Dr. Beasley, could I get you to look at Page 12 of Exhibit 1605. And you see at the top of the page there there's the results of some laboratory testing on cholesterol, correct?
A. Yes, I do.
Q. And it also shows a statistically significant increased incidence of high cholesterol, correct?
A. Yes, that's correct. 2.3 percent versus 0.8 percent.

21. PAGE 111:02 TO 111:02 (RUNNING 00:00:00.000)

Zyprexa came on the market in 1996, in

22. PAGE 111:03 TO 111:11 (RUNNING 00:00:25.000)

October, am I correct?
A. I believe that was the case, 13 months after the NDA filing.
Q. And the labeling that was in effect at that time when the product came out on the market, did not warn physicians that your clinical studies had found statistically significant increased incidence of high glucose in Zyprexa users, correct?

23. PAGE 111:13 TO 111:13 (RUNNING 00:00:00.000)

A. That is correct. But my

24. PAGE 135:15 TO 135:17 (RUNNING 00:00:07.000)

Q. Do you recall that by 1998 Lilly had almost 200 reports of blood sugar elevation?

25. PAGE 135:19 TO 136:02 (RUNNING 00:00:18.000)

A. Are you speaking about spontaneous adverse event reports?
Q. Yes.
A. And the year was?
Q. 1998.
A. 1998. I cannot give you the specific number in 1998. But that would seem to me to be, approximately correct.

26. PAGE 137:03 TO 137:15 (RUNNING 00:00:38.000)

For the record, this is a 26-page document bearing on the title page the title Census of Spontaneous Reports for Olanzapine During the First Two Years of Marketing September 27, '96 to September 30, 1998.
It was apparently prepared by Ken Hornbuckle and Man Fung of the Worldwide Pharmacovigilance and

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Epidemiology Department at Eli Lilly and Company. And it is marked confidential.

27. PAGE 142:03 TO 142:07 (RUNNING 00:00:15.000)

Q. Okay. And are you aware, sir, that it's generally estimated that only 1 percent, maybe 10 percent of the number of adverse events that, actually, occur in the use of a drug ever get reported?

28. PAGE 142:09 TO 142:15 (RUNNING 00:00:25.000)

A. The literature that I am familiar with estimated between 1 in 5 and 1 in 30 cases would be reported. This was in this time frame when I was more involved with doctors Funk and Hornbuckle. I believe that more recent literature has suggested it may be as low as one in a hundred.

29. PAGE 145:13 TO 145:15 (RUNNING 00:00:10.000)

Q. If I could direct your attention to Page 14, and I'm referring to the bottom most number of Page 14.

30. PAGE 145:16 TO 145:16 (RUNNING 00:00:00.000)

A. Okay.

31. PAGE 146:12 TO 147:03 (RUNNING 00:00:36.000)

Q. In any event, whoever prepared this report, well, Doctors Hornbuckle and Fung, have a bold heading there entitled Blood Sugar Elevation, correct?
A. That's correct.
Q. And then below that they have six different subcategories, including hyperglycemia, diabetes mellitus, diabetic acidosis, diabetic coma, ketosis, and glucose tolerance decreased, correct?
A. That's correct.
Q. And then below that they have another bold heading that says Unduplicated Reports, correct?
A. That's correct.

32. PAGE 147:12 TO 148:04 (RUNNING 00:00:56.000)

Q. Okay. And it shows that if you looked at all four quarters of -- or I guess eight quarters from '96 to '98 there were a total 194 unduplicated reports of what they had grouped together as blood sugar elevation, correct?
A. That's correct.
Q. Okay. And again, using the numbers we've talked about before, if we multiplied by -- well, the numbers we talked before in terms of what the range might be

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with respect to what's happening out in the real world. If we multiply the 194 by 5 that's almost a thousand and if we multiply by a hundred it would be almost 20,000 cases of blood sugar elevation, correct?
A. That is correct. As I said,

33. PAGE 149:12 TO 149:14 (RUNNING 00:00:10.999)

With respect to Exhibit 988. The one you have there. It's marked confidential on every page. Was it standard

34. PAGE 149:15 TO 149:16 (RUNNING 00:00:03.000)

drill at Eli Lilly to mark reports of adverse event reports as confidential?

35. PAGE 149:18 TO 149:19 (RUNNING 00:00:05.000)

A. Actually, I don't know whether all such reports would be so marked.

36. PAGE 150:07 TO 150:12 (RUNNING 00:00:14.000)

Q. Do you recall that by December of 1998, just a couple of months after the cutoff period for this report, Lilly was struggling about what to say regarding the link between weight gain and diabetes?

37. PAGE 150:14 TO 150:17 (RUNNING 00:00:12.000)

A. Again, in the -- I don't recall any specific information or discussion about what Lilly was going to say in any specific context in that time period.

38. PAGE 151:11 TO 151:13 (RUNNING 00:00:09.000)

Q. And it's -- the agenda is dated December 9, 1998.
A. Yes.

39. PAGE 156:17 TO 157:03 (RUNNING 00:00:30.000)

Q. Okay. Do you see that under the agenda there's several bullet points. The middle one is weight gain and link to diabetes, question mark, what does the data say and what is our action plan, question mark. Do you see that reference?
A. Yes, I do.
Q. And then there's a handwritten note at the bottom relating to weight gain, correct?
A. Yes, there is.

40. PAGE 157:07 TO 157:10 (RUNNING 00:00:07.000)

Q. The handwritten note says: "Weight gain and genetic vulnerability lead to hyperglycemia," correct?
A. Yes, it does.

A

41. PAGE 160:06 TO 161:17 (RUNNING 00:01:49.000)

Q. Do you recall talking to people in the marketing department in December of 1998 about the issue of weight gain and diabetes?
A. I don't recall, specifically. I may well have done so in the process of trying to educate individuals that were specializing in neuroscience as opposed to diabetes care about sort of the basics of diabetes.
Q. Do you recall telling people in the marketing department back in December of 1998 that the use of antipsychotic drugs could result in weight gain and that people who gain weight may develop insulin resistance which can lead to hyperglycemia and diabetes?
A. I may have been explaining that -- that there are these associations.
Q. Okay. Was it your belief at the time, back in December of 1998, that the use of antipsychotic drugs could result in weight gain?
A. Yes. I think the data for that are rather clear as reflected in our package insert, specifically, for our drugs and I think the David Allison article that I think was published by this time, to which we'd contributed, looked at antipsychotics in general and suggested that.
Q. And was it your view back in December of 1998 that people who gain weight may develop insulin resistance which can lead to hyperglycemia and diabetes?
A. I would characterize it as a risk factor for developing.

42. PAGE 183:23 TO 184:03 (RUNNING 00:00:14.000)

Q. The first of which is an e-mail on November 28, 1999, from Edmundo Muniz to Michael Clayman, Timothy Franson with copies to Gregor Brophy, Kenneth Hornbuckle, Kenneth Kwong, correct?

43. PAGE 184:15 TO 184:22 (RUNNING 00:00:11.000)

Q. Okay. And I believe you said earlier that Mr. Muniz -- am I pronouncing his name, right?
A. Muniz, Dr. Muniz, but yes.
Q. He was head of the pharmacovigilance department; is that correct?
A. That's correct.

44. PAGE 185:21 TO 186:21 (RUNNING 00:00:58.000)

Q. And in his e-mail Dr. Muniz says, "Mike and Tim, below you will find the summary of issues discussed this week

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regarding hyperglycemia and Zyprexa. There
00186:01 are two types of initiatives," and then he
02 lists what those two different types are,
03 correct?
04 A. There are two types of
05 initiatives, yes.
06 Q. And the first is a, what he
07 refers to, as a cross-functional team --
08 pardon me -- cross-functional action team led
09 by Alan Breier. Do you see that?
10 A. Yes, I do.
11 Q. And it states that the goal
12 of this team is to bring to the same table
13 all the groups and functions working to
14 address the hyperglycemia issue, correct?
15 A. Yes.
16 Q. And the hyperglycemia issue
17 was the fact that by November of 1999 there
18 were published medical articles linking
19 hyperglycemia with Zyprexa and you also had a
20 number of adverse event reports linking
21 hyperglycemia and Zyprexa, correct?

45. PAGE 186:23 TO 186:23 (RUNNING 00:00:00.000)

23 A. Yes, that would be correct.

46. PAGE 190:22 TO 191:11 (RUNNING 00:00:39.000)

22 Q. Okay. And then Dr. Muniz
23 states under that section, "while Val
24 Simmons, Man Fung, Kenneth Kwong and Charles
00191:01 Beasley have been working closely together on
02 this issue, it was felt that a broader
03 involvement of regulatory pharmacovigilance
04 Mike Clayman, Tim Franson, and Greg Brophy,
05 and Edmundo Muniz, was needed to evaluate a
06 short-term plan." Did I read that correctly?
07 A. Yes.
08 Q. Would it be fair to say, sir,
09 that this memo reflects that in November
10 of 1999 the hyperglycemia issue had -- with
11 Zyprexa had become quite an issue, correct?

47. PAGE 191:13 TO 191:17 (RUNNING 00:00:13.000)

13 A. I think what this reflects is
14 the company had very clearly intended to
15 increase the resources, both number and level
16 of resources, that were being brought to bear
17 to assess the topic.

48. PAGE 193:21 TO 194:03 (RUNNING 00:00:16.000)

21 Q. Okay. And right below that
22 section in Item B in the background,
23 Dr. Muniz states, "Two regulatory agencies,
24 EMEA and CANDA, have proactively asked
00194:01 questions about hyperglycemia and Zyprexa."
02 Do you see that?
03 A. Yes.

49. PAGE 194:19 TO 195:13 (RUNNING 00:01:00.000)

Q. And in fact, by this point in time, November of 1999, the European regulatory agencies had already requested that hyperglycemia be a precaution in the European label; isn't that correct?
A. I -- the European label does not make a distinction between warnings and precautions. There's one unified section. I don't have specific recollection of when they requested that it be included as a warning.
Q. If I were to suggest to you that it was requested in late 1998 and that Lilly finally added it to the warnings slash precaution section of the European labeling in July of 1999, would that refresh your recollection?
A. I could well believe that that was correct. Again, I don't remember the specific.

50. PAGE 195:19 TO 196:15 (RUNNING 00:00:48.000)

Q. And regardless of the precise month, you would agree with me that at least by this point in time, November of 1999, hyperglycemia had been added to the precaution slash warning section in Europe, correct?
A. That's correct.
Q. Okay. In fact, there's even a hand written note at the bottom of this e-mail saying precaution in Europe, correct?
A. Yes.
Q. Okay. And by this point in time, hyperglycemia was mentioned in the U.S. labeling but only in the adverse reaction section, correct?
A. Hyperglycemia, among other diabetic related terms, yes.
Q. In the adverse reaction section, not in the precaution section, not in the warning section, correct?
A. That's correct.

51. PAGE 202:14 TO 202:16 (RUNNING 00:00:05.000)

Q. Am I correct that GPLC stands for Global Product Labeling Committee?
A. That's correct.

52. PAGE 205:21 TO 205:24 (RUNNING 00:00:08.000)

Q. And was the Zyprexa label the subject of a GPLC session in the weeks or months following this e-mail?
A. I don't recall.

53. PAGE 207:03 TO 207:12 (RUNNING 00:00:22.000)

Q. And, Dr. Beasley, if I could refer you to the second physical page of the document.
A. Um-hum.
Q. There is a heading towards

A

the top of the page below the confidential label that says, "Olanzapine Labeling Change on Hyperglycemia For February 21, 2000, GPLC Meeting." Do you see that?
A. Yes, I do.

54. PAGE 209:21 TO 210:01 (RUNNING 00:00:11.000)

Q. And regardless of whether you personally drafted the text that's in here, would it be fair to say you not only reviewed but approved this language?
A. Yes.

55. PAGE 218:02 TO 218:08 (RUNNING 00:00:20.000)

Q. Okay. So your analysis, as reflected in this document, for the clinical trial data yielded results that showed that the frequency of hyperglycemia was common or frequent, correct?
A. Yes, by this nomenclature, absolutely.

56. PAGE 218:12 TO 219:08 (RUNNING 00:00:47.000)

Q. Okay. And then there's a box below that that says, "How Has this Proposal Arisen?"
A. Yes.
Q. And then the language of that says, "Recent review of random glucose levels of patients in olanzapine clinical trials revealed that the incidence of treatment-emergent hyperglycemia in olanzapine group, 3.6 percent, was higher than the placebo group, 1.05 percent. For common events, instances from clinical trials provide more meaningful information." Did I read that correctly?
A. That's correct.
Q. Okay. Now, this recent review that's being referred to there was the review that you and Dr. Kwong had done on your own initiative because you felt it was important to do; is that correct?
A. That's correct.

57. PAGE 223:15 TO 223:17 (RUNNING 00:00:03.000)

Q. And that incidence in the olanzapine group was almost 3 and-a-half times higher than the placebo group, correct?

58. PAGE 230:23 TO 231:16 (RUNNING 00:00:50.000)

Q. Okay. If I could direct your attention to the following page. You also indicate in here that there were a number of literature reports published regarding hyperglycemia and olanzapine, correct?
A. I'm seeing the literature reports and I think these would have reviewed, briefly, summarized such reports.

A

Q. Okay. And you also make reference to Dr. Daniel Casey from Oregon presenting a seminar at Lilly at the end of 1999 in that box, correct?
A. That's correct.
Q. Is this the same Dr. Daniel Casey who was one of the expert advisors who you spoke with at the December 1995 meeting in Puerto Rico?
A. Yes, he was.

59. PAGE 232:06 TO 232:23 (RUNNING 00:00:44.000)

Q. Okay. Now, the section of the document goes on to say that Dr. Casey, "performed chart review of 136 veteran patients who had been exposed to olanzapine therapy for at least four months, with an average of 1.4 years. Of the 39 patients who had normal fasting glucose levels before olanzapine therapy, seven or 18 percent had fasting glucose levels of 126 milligrams per deciliter or higher during olanzapine therapy." And then it notes that that, "threshold met the 1998 ADA diagnostic criteria for diabetes," do you see that language, sir?
A. That's correct.
Q. Now, the ADA refers to the American Diabetic Association?
A. That's correct.

60. PAGE 233:17 TO 233:23 (RUNNING 00:00:23.000)

Q. So what he found during that review was that 18 percent of the people who had normal fasting glucose levels before they started using Zyprexa had thresholds that met the 1998, ADA diagnostic criteria for diabetes after they used Zyprexa, correct?
A. That's correct.

61. PAGE 234:18 TO 234:23 (RUNNING 00:00:20.000)

Q. Okay. Well, you never warned doctors in your Zyprexa labeling of Dr. Casey's finding that 18 percent of people who had used Zyprexa for at least four months had fasting glucose levels that met the ADA criteria for diabetes, correct?

62. PAGE 235:01 TO 235:02 (RUNNING 00:00:02.000)

00235:01 is a retrospective chart. The answer to your
02 question is no.

63. PAGE 235:16 TO 235:23 (RUNNING 00:00:22.000)

Q. And, sir, your company never warned in your labeling that in your analysis in February of 2000 you had found that the incidence of treatment-emergent hyperglycemia in patients treated with Zyprexa was 3.6 percent as compared to the placebo group

where the incidence was 1.05 percent, correct?

64. PAGE 236:01 TO 236:01 (RUNNING 00:00:00.000)

A. No, but we did place the

65. PAGE 236:06 TO 236:12 (RUNNING 00:00:23.000)

Q. In fact, the label change that ultimately came about within months after your proposal here in February, asserted that there was, essentially, no change in glucose levels between patients who used Zyprexa and those who were on placebo, correct?

66. PAGE 236:14 TO 236:16 (RUNNING 00:00:07.000)

A. My recollection is that we did report something close to 3.6 percent for olanzapine.

67. PAGE 237:01 TO 237:13 (RUNNING 00:00:32.999)

Sir, maybe you don't remember what your labeling, actually, said, so let me show that to you. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 4858.

(Whereupon, Deposition Exhibit(s) 4858 previously marked, was presented to the witness.)

MR. SUGGS: For the record this is a May 9, 2000, letter to FDA from Gregory T. Brophy with several

68. PAGE 237:14 TO 237:14 (RUNNING 00:00:00.000)

attachments.

69. PAGE 238:07 TO 238:19 (RUNNING 00:00:31.000)

Q. Okay. Now, it has in the upper right-hand corner of the first page a bold label that says, "Special Supplement Changes Being Effected." Do you see it?

A. Yes, I do.

Q. And am I correct that there is a provision of the FDA regulations which permits a drug company to add a warning to the labeling without prior FDA approval as long as the label change strengthens the warnings?

A. That's correct. Or provides new information on safety, as I understand.

70. PAGE 242:09 TO 242:14 (RUNNING 00:00:13.000)

Q. The second numbered item in this letter refers to the change that was, actually, made regarding hyperglycemia, am I

A

correct?
A. It's with reference to the laboratory findings of hyperglycemia.

71. PAGE 243:18 TO 243:22 (RUNNING 00:00:12.000)

with respect to the language that was used in the label change, did you tell doctors that the incidence of hyperglycemia was common or frequent? Did you use those words?
A. We did not use those words.

72. PAGE 244:17 TO 246:23 (RUNNING 00:03:17.000)

Q. Can you -- would you read for the jury the language that is used?
A. Yes. "In the olanzapine clinical trial database, as of September 30, 1999, 4,577 olanzapine-treated patients begin paren, representing, approximately, 2,255 patient-years exposure," end paren, "and 445 placebo-treated patients who had no history
00245:01 of diabetes mellitus and whose baseline random plasma glucose levels were 140 milligrams per deciliter or lower were identified. Persistent random glucose levels greater than or equal to 200 milligrams per deciliter," paren, "suggestive of possible diabetes," end paren, "were observed in 0.8 percent of olanzapine treated patients," paren, "placebo 0.7 percent," end paren". Transient," paren, "i.e., resolved while the patients remained on treatment," end paren, "random glucose levels greater than or equal to 200 milligrams per deciliter were found in 0.3 percent of olanzapine treated patients," again, paren, "placebo, 0.2 percent, end paren. Persistent random glucose levels greater than 160"-- excuse me -- "greater than or equal to 160 milligrams per deciliter observed in 1.0 percent of olanzapine treated patients," begin paren", placebo, 1.1 percent," end paren. "Transient random glucose levels greater than or equal to 160 milligrams per deciliter but less than 200 milligram per deciliter were found in
00246:01 1.0 percent of olanzapine treated patients," paren, "placebo, 0.4 percent," end paren.
Q. And that's the final language that went into the labeling, correct?
A. That's correct.
Q. And this is the language that came out of the end process that began with you and Kenneth Kwong suggesting a label change because your review of random glucose level of patients revealed an incidence of treatment-emergent hyperglycemia in the Zyprexa group of 3.6 percent as compared to 1.05 percent in the placebo group, correct?
A. And again, I believe what I have testified to is that the numbers that you have just quoted were, in fact, the result of the initial preliminary data

A

analysis.
Q. And after you tortured the data for some period of time you came up with this language which, essentially, shows no difference between Zyprexa users and placebo users in terms of hyperglycemia, correct?

73. PAGE 247:01 TO 247:17 (RUNNING 00:00:48.000)

00247:01 A. And again, I would disagree
02 with your characterization of tortured. I
03 would again refer to checking and double
04 checking. There is a numerical deference
05 with more on olanzapine but the numbers are
06 certainly closer together.
07 Q. Is it your testimony that the
08 change here that we see, from what was in the
09 rationale for original proposal versus what
10 came out of the end of the process, is
11 because you checked your arithmetic and you
12 found the numbers were wrong?
13 A. Well, it would not be
14 appropriate to characterize it as arithmetic.
15 It's the process of checking the computer
16 programs that result in finding the results
17 that you have.

74. PAGE 250:17 TO 250:23 (RUNNING 00:00:12.000)

17 that in just a minute. Let's finish up with
18 this label change that you guys did in May of
19 2000. What happened, five months later, was
20 that FDA came back and made you take it
21 out -- made you take that language out of the
22 label; is that correct?
23 A. That's correct.

75. PAGE 252:07 TO 253:06 (RUNNING 00:00:57.000)

07 Q. And if we just cut to the
08 chase here, what happened was FDA five months
09 after you made that label change on your own
10 without prior FDA approval, FDA came back on
11 October 11, 2000, and said you have to take
12 that language out, correct?
13 A. That's correct.
14 Q. And the reason why they made
15 you take it out is because the FDA said, this
16 is on the second page of the document, "The
17 descriptive data that is provided expresses a
18 certain level of implied safety with respect
19 to treatment emergent hyperglycemia." Do you
20 see that language, sir?
21 A. Yes, I do.
22 Q. And in fact, that that was
23 the case. The data that you reported in
24 there, the statements that you had in the
00253:01 labeling showed that there was, essentially,
02 no difference between hyperglycemia in
03 Zyprexa users versus placebo patients. And
04 the FDA concluded that that expresses a
05 certain level of implied safety; is that
06 correct?

A

76. PAGE 253:08 TO 253:10 (RUNNING 00:00:08.000)

A. I think you've asked me two questions. With respect to the FDA's impression, that is correct. I view these

77. PAGE 255:19 TO 256:13 (RUNNING 00:00:49.000)

Q. Okay. And you had received a request from Ralph Dittmann -- by the way, who was Ralph Dittmann?
A. Ralph Dittmann was a German -- he was a German psychiatrist in our German affiliate.
Q. And he was asking you for information on hyperglycemia, correct?
A. Let me see if I can --
Q. If you look at the top of the second page.
A. Yes.
Q. Okay. And you wrote back to him and you said, in part, "Our continuous analyses show that olanzapine does result in statistically significant mean increases in random glucoses relative to placebo and haloperidol." Did I read that correctly?
A. That's correct.

78. PAGE 258:03 TO 258:09 (RUNNING 00:00:18.000)

Q. Okay. I want to make sure I understand the time frame here. In February of 2000, a year before this e-mail, you and Kenneth Kwong do an analysis which finds an incidence of treatment-emergent hyperglycemia three and-a-half times higher in Zyprexa users versus placebo users, correct?

79. PAGE 258:11 TO 258:23 (RUNNING 00:00:25.000)

A. And again you've characterized that, I believe, as a final finding.
Q. I'm not characterizing as final, partial, whatever. You did an analysis that you thought was important enough and you felt confident enough in to submit to the Global Product Labeling Committee which said that the incidence of treatment-emergent hyperglycemia was three and-a-half times higher in Zyprexa users as compared to placebo users, correct?
A. That is correct and I'm

80. PAGE 259:03 TO 259:12 (RUNNING 00:00:26.000)

Q. Three months later, you and others jen-up language that goes into the labeling under the special supplement changes being effected, which shows, essentially, no difference between the incidence of hyperglycemia in Zyprexa users versus placebo users. And five months after that, FDA makes you take out that language because they say

it's -- it gives an implied sense of safety, correct?

81. PAGE 259:19 TO 260:01 (RUNNING 00:00:14.000)

A. I agree with you with respect to the action of the FDA. In your question you characterized our actions in a certain fashion that I would disagree with.
Q. And then five months after the FDA makes you take out that language, which they said was expressing a certain

82. PAGE 260:02 TO 260:19 (RUNNING 00:00:39.000)

level of implied safety with respect to treatment-emergent hyperglycemia, you do another analysis which finds a statistically significant mean increase in random glucose for Zyprexa relative to placebo and haloperidol, correct?
A. That was my understanding at the time having not been involved in those analyses.
Q. And, sir, if I could direct your attention to the remaining language in that paragraph, you go on to state, "These increases are occurring as early as week one," correct?
A. Yes.
Q. That would be week one after beginning use of the drug?
A. That's correct.

83. PAGE 263:14 TO 264:05 (RUNNING 00:00:45.000)

talk about that right now. Do you recall that in October of 2000, you and various representatives of Eli Lilly had a meeting with a group of outside experts in Atlanta?
A. Yes, I do.
Q. Okay. And those were -- those people that you met with, those outside experts, were an academic advisory board, correct?
A. That's correct.
Q. Now, Eli Lilly is a drug company which makes, not only psychiatric drugs, but also makes and distributes a number of drugs for the treatment of diabetes, correct?
A. That's correct.

84. PAGE 266:08 TO 266:15 (RUNNING 00:00:21.000)

Q. Okay. And do you recall that people in Lilly referred to these outside experts as being in the Who's Who of diabetes?
A. I don't recall that characterization but these were certainly a number of very, very prominent academic individuals.

A

PAGE 269:08 TO 272:17 (RUNNING 00:03:13.000)

Q. And for the record this is an e-mail dated October 9, 2000, from Robert Baker to Charles Beasley, Christopher Bomba, Alan Breier, Thomas Brodie, Patrizia Cavazzoni, James Gregory, John Holcombe, Jack E. Jordan, Suni Keeling, Michael Murphy, John Richards, Eugene Thiem, and Mauricio Tohen and Paula Trzepacz, correct?

A. Yes.

Q. And in this e-mail Dr. Baker states that -- in the first paragraph, "For your information, the Lilly diabetes slash endocrine group held an academic advisory board meeting this weekend in Atlanta."

So that would have been days before October 9, correct?

A. Yes.

Q. Okay. And we know that on October 11, the FDA comes out and says you've got to take that label language out, right?

A. Correct.

Q. Okay. So within days after you meet with the outside experts, FDA tells you to take the label out, right?

A. Yes.

Q. Dr. Baker in Exhibit 6998, goes on in his e-mail to say, "They kindly allotted two hours for discussion of olanzapine's potential hyperglycemia risks and Charles Beasley, Chris Bomba, Patrizia Cavazzoni, Suni Keeling and I attended. Unfortunately, this consultation reinforced my impression that hyperglycemia remains quite a threat for olanzapine and may merit increasing even further medical attention and marketing focus on the topic." Did I see that?

A. Yes, that's correct.

Q. Okay. In the second paragraph he goes on to state, "They were, however, concerned by our spontaneous AE reports." That's referring to adverse event reports, correct?

A. That's correct.

Q. "And quite impressed by the magnitude of weight gain on olanzapine and implications for glucose. Much of their input for helpful steps came back to addressing weight gain."

Did I read that correctly?

A. That's correct.

Q. And you had been warned about the weight gain problem by another panel of outside experts as we said -- as we talked about right at the beginning of your deposition back in December of 1995, correct?

A. That's correct. And this was something that we described and from my perspective, given Dr. Breier's efforts, we were attending to.

Q. And continuing on in his

e-mail Dr. Baker said, "Citing methodological questions, at least the vocal members were not reassured adequately by our analyses, such that the finding that relative risk was not higher than comparative drugs. Disconcertingly, one member compared our approach to Warner-Lambert's reported argument that Rezulin did not cause more hepatic problems than other drugs in its class." Do you see that language, sir?

A. Yes, I do.

Q. Were you familiar with what Warner-Lambert was doing with respect to Rezulin?

A. No. I was familiar with the drug and I was familiar with the fact that it was, ultimately, withdrawn from the market.

Q. Because of safety problems, correct?

A. Because of the perception that it had a risk of hepatic dysfunction.

86. PAGE 274:05 TO 274:10 (RUNNING 00:00:10.000)

Friday. Let me show you another e-mail regarding this meeting that you had with the outside experts in October of 2000. I hand you what's been previously marked as Exhibit 1449.

87. PAGE 276:08 TO 277:23 (RUNNING 00:01:32.000)

Q. So I want to direct your attention first to that e-mail from Thomas Brodie to Robert Baker and Eugene Theim. It's on -- it starts in the middle of the first page. And first of all, who was Thomas Brodie?

A. I don't know who Mr. Brodie was.

Q. Do you know who Eugene Thiem was?

A. I think he was an individual involved in the marketing area in the U.S. Affiliate.

Q. Okay. And the subject is the meeting with endocrinologic consultants, correct?

A. Yes.

Q. And Mr. Brodie says, "Robert," referring to Robert Baker, "clearly this group of Endocrinologists, who spoke up and I would rate those who did speak up as the leaders of the pack, are very concerned with the approach Lilly is taking towards the issue that Zyprexa leads to diabetes. I can only hope that you and all of the team who attended the NADAB meeting are gaining the ear of senior leadership and articulating this finding. Although the board's recommendation is, probably, not the way Lilly, typically, does business, I do believe

they made a very strong point that unless we come clean on this, it could get much more serious than we might anticipate." Do you see that language, sir?
A. Yes, I do.
Q. Okay. Now, you did, indeed, have the ear of senior leadership within the corporation, did you not?
A. Yes, I would characterize my position as, at least, having their ear.

88. PAGE 278:16 TO 278:23 (RUNNING 00:00:16.000)

Q. And the man that you had the ear of was Dr. Gary Tollefson, correct?
A. That's correct.
Q. And did you have the ear of any others who were -- would be regarded as senior leadership in the company?
A. I believe that I also was able to speak freely with Dr. Breier.

89. PAGE 283:11 TO 288:09 (RUNNING 00:04:44.000)

Q. Okay. And now, sir, if I could direct your attention to the third physical page. At the top of the page is an e-mail from Robert Baker to you, Alan Breier, Christopher Bomba, Patrizia Cavazzoni, Suni Keeling, again referring to the meeting with endocrinologic consultants, correct?
A. Yes.
Q. And in that e-mail Dr. Baker does two things, number one, he forwards to you and the others there that original e-mail that he'd gotten from Thomas Brodie, the one where he said that, "Although the board's recommendation is, probably, not the way
00284:01 Lilly, typically, does business, I do believe
02 they made a very strong point that unless we
03 come clean on this it could get much more
04 serious than we might anticipate," correct?
05 THE WITNESS: Excuse me. I
06 was looking at this and I believe
07 that was on Page 1, as I recall.
08 Q. Well, sir, the language I
09 just read was -- you're correct is in the
10 e-mail at the bottom of Page 1. It's also in
11 the e-mail that's at the bottom of Page 3,
12 because on page -- what Page 3 does is
13 reflect an e-mail that Robert Baker sent to
14 you and others forwarding that e-mail from
15 Thomas Brodie, correct?
16 A. Yes.
17 Q. And it was in that e-mail
18 from Thomas Brodie that Mr. Brodie said that,
19 "I can only hope that you and all of the team
20 who attended the meeting are gaining the ear
21 of senior leadership and articulating this
22 finding," correct?
23 A. That's correct.
24 Q. And so, in fact, by Robert
00285:01 Baker sending this memo on to Alan Breier, he

A

put this in the ear of senior leadership of the company, correct?
A. That's correct.
Q. So Alan Breier was informed in October of 2000, that these consultants were saying that, "they made a very strong point that unless we come clean on this it could get much more serious than we might anticipate," correct?
A. That's correct.
Q. Okay. And then in his e-mail to Robert Baker -- pardon me -- in Robert Baker's e-mail to you and others at the top of this Page 3, he has -- he starts off by saying, "My take was that this board of academic endocrinologists was impressed enough by the magnitude of weight gain and the number of reports in the spontaneous adverse event database that they were predisposed to skepticism to any analysis that did not find hyperglycemia rates of olanzapine than comparators," correct?
A. That's correct.
Q. Then he goes on to have a message to you and also to Alan Breier, correct?
A. That's correct.
Q. And he says to you, "Do you think it appropriate to look at secondary analysis that does not exclude baseline abnormals and another looking at mean changes in glucose," correct?
A. That's correct.
Q. And the looking at mean changes in glucose is the continuous analysis that we referred to earlier, correct?
A. That's correct.
Q. And that's the one that when you did it, a couple months later, your understanding in February 2001 was that it did, indeed, show a statistically significant increase in random glucose for Zyprexa relative to placebo and haloperidol, correct?
A. That is my -- that was my understanding of those analysis at the time. I am not -- I have no knowledge of the ultimate outcome of what may have been continuing analysis here.
Q. Okay. Because by that point you were out of it, right, you were gone?
A. I was transitioning out of it, yes.
Q. They took you out of the Zyprexa group and they sent you over to deal with Cialis, correct?
A. That's correct.
Q. Okay. Now, let's continue on with what Robert Baker was telling Alan Breier, one of the senior management at Lilly here in this e-mail of October 2000. Dr. Baker says, "Alan, I believe that what Tom is referring to as," quote, "not the way Lilly, typically, does business," end quote,

A

"are suggestions to more vocally assert that olanzapine may have a problem on the glucose issue and rather than moving forward with our analyses turning all info over to an independent board for review, conclusions and dissemination."

Do you see that language, sir?

00268:01 A. Yes, I do.

02 Q. And so what Baker was telling
03 Breier -- and by the way, Breier was not at
04 the meeting, correct?
05 A. No.
06 Q. Okay. So Baker's telling
07 Breier that these experts were saying that
08 you should, actually, assert that Zyprexa may
09 have a problem on the glucose issue, correct?

90. PAGE 288:11 TO 288:17 (RUNNING 00:00:16.000)

11 Q. Is that what he says?
12 A. That was apparently
13 Dr. Baker's recollection at the time.
14 Q. Yeah. So he's saying that
15 the experts are saying, "Hey, go out and tell
16 doctors that Zyprexa may have a problem with
17 glucose."

91. PAGE 288:19 TO 288:21 (RUNNING 00:00:02.000)

19 Q. Right?
20 A. Again, that was apparently
21 Dr. Baker's recollection at the time.

92. PAGE 291:22 TO 292:11 (RUNNING 00:00:52.000)

22 Q. Sir, would you agree with me
23 that the e-mail that's at the bottom of
24 Page 3 of this exhibit is the same e-mail
00292:01 that we were just talking about in the prior
02 exhibit?
03 A. I believe it is.
04 Q. Okay. And then what's above
05 that, which actually starts on Page 2, is
06 your e-mail response back to Dr. Baker?
07 A. I haven't read it yet but
08 that would appear to be -- the 9th at 3:42,
09 the 10th at 8:33 -- he would have presumably
10 sent that late in the afternoon and I would
11 have seen it the next -- the next morning.

93. PAGE 292:20 TO 292:22 (RUNNING 00:00:05.000)

20 Q. And in this e-mail you're
21 giving your take on the situation, correct?
22 A. That's correct.

94. PAGE 293:06 TO 294:08 (RUNNING 00:01:06.000)

06 Q. Okay. And then in the second
07 paragraph you say, "These guys were really
08 concerned about the weight gain, not only
09 because of the diabetes risk but all the
10 other potential health risks. They initially

A

thought it might simply be a response improvement in schizophrenia with a few outliers, a rather naive view, but they ain't shrinks. When they understood that this is seen in non-psychotic normals and animals on fixed diets, less concern with animals, and that olanzapine is the worst offender other than clozapine they advocated a different marketing strategy than we are taking. They believe we should," quote, "aggressively face the issue," end quote, "and work with physicians to address methods of reducing weight gain."

Did I read that correctly?

00294:01 A. That's correct.

Q. Now, when you make a reference to nonpsychotic normals, am I correct that you're referring to clinical studies done by Lilly which showed that normal people, nonpsychotics, when they take Zyprexa have significant weight gain?

A. Yes.

95. PAGE 295:10 TO 296:10 (RUNNING 00:01:06.000)

Q. Okay. And when you refer to the animals on fixed diets in this e-mail, am I correct that that's referring to scientific studies conducted by Lilly which showed that animals on fixed diets also showed significant weight gain?

A. I don't recall the specific basis, at this point six years later, for this statement on my part. Again, Dr. Breier, on toxicology, were conducting studies with animals and studies had been previously conducted. So I cannot recall the specific studies that I was referring to.

Q. Okay. But if your e-mail is correct, and you were the one that wrote

00296:01 this?

A. Right.

Q. That there were findings of significant weight gain in animals on fixed diets, that means you were seeing weight gain in animals whose diet was controlled, experimentally, so that they were not just free to feed as they wished, but they were given a fixed amount of food, correct?

A. That would be correct.

96. PAGE 297:09 TO 298:07 (RUNNING 00:01:10.000)

Q. It wasn't like the experimental rats were going out to get Snickers or ice cream bars?

A. No, they didn't move around their cages as much.

Q. Okay. Now, did these experts give you any examples of what they meant when they said that Lilly should aggressively face the issue?

A. I can't recall any.

A

Obviously, I have my impression that -- of what they meant.
Q. Okay. You go on to say at the bottom of that first paragraph that, again, talking about the weight gain "When you translate 1 to 2 percent gain of 40 plus kilos into the absolute number based on 5 million patients, the number is 50,000 to 100,000. 100,000 people putting on 90 pounds of weight is a lot."
A. And that was a speculation on my part as a possibility to underscore this to the people we communicated with.

97. PAGE 298:21 TO 298:22 (RUNNING 00:00:01.000)

Q. And, sir, do you recall writing a memo some months later in which you

98. PAGE 298:23 TO 299:11 (RUNNING 00:00:37.000)

said it would be ludicrous to state that such a patient is not at long-term increased cardiac risk relative prior to gaining that weight, especially if in temporal relation with that weight gain, the patient developed an increase in fasting glucose and lipid levels?
A. I don't recall that specifically, but I may well have written that. Gaining body fat is clearly recognized as a risk factor for cardiovascular disease. I think I learned that in my first year physiology course.

99. PAGE 300:03 TO 301:22 (RUNNING 00:01:52.000)

Q. If I could direct your attention to Page 3 of the document. That's an e-mail from Ernie Anand to Andrea Smith asking if there was a standby statement to clarify Lilly's position as to whether Zyprexa can cause cardiovascular complications due to weight gain and diabetes which are clinically recognized risk factors.
Do you see that, sir?
A. Yes.
Q. And then this gets forwarded on to you as reflected on Page 2 of the document, which is an e-mail from you to Andrea Smith with copies to Ernie Anand, Patrizia Cavazzoni, Margaret Sowell, Anna Thornton, in which you respond and say, "One thing that we can say definitively is that olanzapine causes weight gain and for, approximately, 50 percent of patients in trials who remained on the drug for more than six months, the amount of gain was more than ten pounds. Some patients, in clinical trials gained as much as 80 plus pounds. Lacking empirical data to the contrary, it would be ludicrous to state that such a patient is not at long-term, increased cardiac risk relative to prior to gaining

that weight, especially, if in temporal association with that weight gain the patient developed an increase in fasting glucose and lipid levels."

Do you see that language, sir?

A. Yes.

Q. Do you recall writing that e-mail on or about March 15, 2001?

A. No. I mean, again, I do not recall.

Q. You don't dispute that you, indeed, did write that, though?

A. No, not at all.

Q. Turning your attention, if I could, sir, back to Exhibit 1453.

THE WITNESS: 1453.

100. PAGE 304:21 TO 305:11 (RUNNING 00:00:35.000)

Q. Okay. You go on in your e-mail about ten lines down from there to say -- actually, 1, 2, 3, 4, 5, 6, 7, 8, 9 -- ten lines from the top, "The problem is the arbitrary nature of the cut point and the potential for big shifts depending on those cut points and the fact that we chose the cut points, not really they came from the ADA website. They specifically referred to the data as being tortured." Did I read that correctly?

A. That's correct.

Q. Do you know who it was that referred to the data as being tortured?

A. No, I do not.

101. PAGE 305:12 TO 306:10 (RUNNING 00:01:01.000)

Q. Dropping down to the next paragraph, in the second sentence you say, "They," referring to the outside consultants, "They want the continuous data, using all data, analyzed over time co-varying for both static, diabetic diagnosis, baseline, obesity, et cetera, and dynamic co-variants, weight gain, alteration in hyperglycemia dose. Similar to David Allison, one or two would be happy to take all our data and perform the correct analyses, like we don't have competent statisticians." Did I read that correctly?

A. That's correct.

Q. And apparently, you'd had some problems with the statisticians, as we've already discussed, because of that sequence of events that we talked about where you went to your original proposal of the labeling change in February and the basis for that proposal then, and you came out with a much different label based on what you referred to as computer error?

102. PAGE 306:12 TO 307:19 (RUNNING 00:01:36.000)

A

A. I don't believe that our statisticians are incompetent or -- incompetent. There is a process of going through repeated analyses, performing them by multiple people until you are certain you get them correct, like adding a long column of figures.

Q. You go on to say towards the end of that paragraph, "I will say that I believe we should have a full time, dedicated, sophisticated, statistical resource that does nothing but hyperglycemia, no meetings, no surveys, zilch, until we have completely tortured the data." Did I read that correctly?

A. That's correct.

Q. And did you completely torture the data?

A. Well, and again, what I mean by torture the data here, in reference to the paragraph above where it was used in a positive context, that we thoroughly analyzed the data. Coming out of this meeting, we had the two individuals that were interested in working with us, we had Dr. Cavazzoni assigned full time, and I believe, although I could be incorrect, that Dr. Breier took steps to see that additional statistical resources were added.

We also increased the time commitment of the endocrinologist that was working with us on these matters.

103. PAGE 307:22 TO 308:11 (RUNNING 00:00:36.000)

Q. And the additional statistical work that you did, at least your understanding of it, up until the time you left the Zyprexa project in later -- some months later in 2001, was that the continuous analyses that the outside consultants had asked for showed that olanzapine does result in a statistically significant mean increases in random glucose relative to placebo and haloperidol; isn't that correct?

A. And that was my understanding at the time of where those analysis stood. I do not know if those were the final analyses of those data.

104. PAGE 310:01 TO 311:11 (RUNNING 00:01:27.000)

Q. I'd like to direct your attention to the last paragraph of your e-mail. It says, "With regard to the marketing side of this issue of impaired glucose tolerance slash diabetes, the message was clear. Don't get too aggressive about denial, blaming it on schizophrenia, or claiming no worse than other agents until we are sure of the facts and sure that we can convince regulators and academicians. W-L with Rezulin was the example. Sounds like

A

what, Dan" -- strike that. "Sounds exactly like what Dan Casey was saying." Did I read that correctly?
A. That's correct.
Q. Now, the W-L that's referred to is Warner-Lambert, correct?
A. I believe that would be correct.
Q. And we've talked about that Rezulin example before. And when you said that sounds exactly like what Dan Casey was saying, when had Dan Casey told Lilly that you shouldn't be too aggressive about denial, blaming it on schizophrenia, or claiming that Zyprexa was no worse than other agents.
A. Well, again, I don't recall, specifically, when Dr. Casey would have made those suggestions to us.
Q. Sir, in fact, despite these recommendations by your outside consultants, in fact, what Lilly did, for years after this, was to insist that the rate of hyperglycemia and diabetes with Zyprexa was comparable to other drugs, correct?

105. PAGE 311:13 TO 311:19 (RUNNING 00:00:21.000)

A. I do not have specific knowledge of the marketing materials that were put together over time and have been used over time. I did recall -- I did review one initial marketing piece that did present the data that was presented in our package insert.

106. PAGE 317:20 TO 318:09 (RUNNING 00:00:32.000)

Q. In fact, these were the endocrinologists who raised the questions in October of 2000, that were the advisory board to the endocrinology side of the company, the Diabetes Care side, correct?
A. That's correct.
Q. So when the information concerning Zyprexa was brought to the independent endocrinology board, that was not on the Zyprexa team, they're the individuals that raised the questions that Mr. Suggs discussed with you in October of 2000, isn't that right?
A. That's correct.

107. PAGE 339:16 TO 339:19 (RUNNING 00:00:00.000)

(Whereupon, Deposition Exhibit(s) 1 duly received, marked and made a part of the record.)

108. PAGE 341:16 TO 342:04 (RUNNING 00:00:33.000)

Q. This is the American Diabetes Association, and let me show that. The title's All About Diabetes. And it's put out

A

by the American Diabetes Association, Cure, Care and Commitment. Do you see that?
A. Yes.
Q. And you've already told this jury that they're much more qualified than you to discuss issues concerning the seriousness or lack of seriousness of diabetes, right?
A. I think that would be the generally held opinion, yes.

109. PAGE 343:05 TO 343:18 (RUNNING 00:00:41.000)

Q. This says, "Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. The cause of diabetes continues to be a mystery" -- oh, let me see -- "continues to be a mystery, although both genetics and environmental factors such as" -- what, sir?
THE WITNESS: As -- you're asking me to read the --
Q. Yeah. Such as what?
A. "As obesity and lack of exercise appear to play roles."

110. PAGE 344:02 TO 346:01 (RUNNING 00:01:52.000)

Q. You testified under oath that diabetes is a known risk factor -- I mean, excuse me -- obesity is a known risk factor for diabetes, right?
A. That's correct.
Q. And in fact, you testified that the weight gain that you saw in Zyprexa -- I think -- you can correct me, because you'll probably get it -- you testified that 40 percent of patients who take Zyprexa have clinically significant weight gain within six months?
A. Actually, I think the best representation -- that's from the HGAJ study. I think the best representation is, actually, the combining of the data which would suggest it's 56 percent of individuals.
Q. Have clinically significant weight gain within six months?
A. Potentially, clinically significant defined as 7 percent or greater.
Q. Which would put them at an increased risk of developing hyperglycemia and diabetes?
A. It would be a risk factor and might put them at risk.
Q. Sir, smoking's a risk factor for cancer, is it not?
A. Yes, it is.
Q. And so people tell people don't smoke because you want to decrease your risk for lung cancer, correct?
A. That's correct.

A

Q. And if you continue to smoke you increase your risk for lung cancer, correct?
A. You are at an increased risk.
Q. Right. It's not -- when you go to the doctor, do they try to advise you to increase your risk for diabetes or decrease your risk for diabetes?
A. Oh, they would clearly suggest that you take steps to do those things that would decrease your risk.
Q. And you, certainly, then would agree with me that Zyprexa causes clinically significant weight gain which is a risk factor for diabetes, correct?

111. PAGE 346:04 TO 348:04 (RUNNING 00:01:54.000)

A. I have said that there is a strong association, and I believe that in some patients Zyprexa can cause weight gain. I've also testified that weight gain is a risk factor for diabetes.
Q. Right. Now, you've also taken -- and you certainly -- it's not a preferable thing to increase your risk factor for diabetes since diabetes is such a severe disease, is it not?
A. Well, again, one does not want to increase any risk factor that would put one at -- at increased risk of any disease, including diabetes.
Q. Right. And diabetes, we know, and hyperglycemia, itself, is a -- has numerous severe medical complications, does it not?
A. There are a number of complications that are associated with both hyperglycemia and, more importantly, diabetes.
Q. Right. Such as heart disease and stroke?
A. Yes. You've got a new page here.
Q. You, probably, don't need to read the page. You can just tell us, diabetes carries with it the risk of heart disease and stroke, kidney disease, eye complications including blindness, diabetic neuropathy, that's loss of feeling and sensation in your periphery, right?
A. Yes. It's -- actually, in diabetes, it's usually a painful sensation.
Q. Right. Nerve damage and foot complications, which I know from experience can lead to gangrene and amputations, right?
A. That's correct.
Q. Skin complications. Depression. It can cause depression in and of itself?
A. It has been associated with depression, yes.
Q. Right. Just, just so we're

00348:01 all communicating now, you and I will now
02 both agree, and you can tell the jury under
03 oath, that diabetes and hyperglycemia are
04 serious medical conditions?

112. PAGE 348:07 TO 349:01 (RUNNING 00:00:50.000)

07 Q. Are they not?
08 A. Okay. Diabetes clearly has
09 very serious potential outcomes. The
10 condition can, therefore, be considered
11 clinically serious. Many cases would not
12 meet the regulatory definition of
13 seriousness.
14 Q. Well, how about when I say
15 you can get amputations, heart disease, loss
16 of vision, peripheral neuropathy, are you
17 telling this jury that doesn't meet the FDA
18 regulation definition of serious?
19 A. Those things that you just
20 mention would meet the FDA criteria.
21 Q. Right. And aren't all those
22 things as reported in this document, Beasley
23 No. 1, secondary factors that occur
24 following -- can occur following diabetes?
00349:01 A. Can occur, yes, sir.

113. PAGE 372:18 TO 372:23 (RUNNING 00:00:19.000)

18 Q. Okay, sir, I don't think you
19 need to pull it out, it's Exhibit 1453, but
20 it is in that stack here. Just so the record
21 is clear, this is your e-mail that you wrote
22 on October 10, 2000, following -- this is
23 No. 1453.

114. PAGE 386:04 TO 386:22 (RUNNING 00:00:45.000)

04 knew that in the -- this is your words, I'll
05 read it, "These guys," talking about after
06 the meeting, "were really concerned about the
07 weight gain, not only because of diabetes
08 risk but all the other potential health
09 risks."
10 So we have right here a
11 statement that the people at the meeting were
12 concerned about weight gain and diabetes,
13 right?
14 A. You know, that is my
15 recollection of their main topic of interest
16 was the weight gain.
17 Q. Sir, and I'm not trying to
18 argue with you. You didn't call it topic of
19 interest. You said these guys were really
20 concerned. Isn't that what you said? Not
21 me?
22 A. Yes.

115. PAGE 393:01 TO 393:09 (RUNNING 00:00:15.000)

00393:01 Q. Let's go back and continue to
02 look at what you said on that day internally
03 at your company. You said, "They were naive
04 to think" -- by the way when you said it was

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a rather naive view you were saying the reason weight gain was occurring wasn't because people were getting better on schizophrenia, that's what you're saying here, right?

116. PAGE 393:12 TO 394:24 (RUNNING 00:01:36.000)

A. Well, it was the issue with their belief -- and I'm not sure how they got this impression -- that it was a few outliers, that would influence the mean change.

Q. And you thought that was a rather naive view, correct?

A. That's correct.

Q. When they understood this is seen in nonpsychotic normals, which you told Mr. Suggs, we see weight gain in individuals who are not schizophrenic and psychotic, correct?

A. That's correct.

Q. And animals on fixed diets. "We see it on the animal model in testing when they have fixed food intake," correct?

A. That was clearly my understanding of preclinical studies at the time. I don't recall those studies sitting here today.

Q. But you would have tried to be accurate when you wrote this e-mail?

A. Yes.

Q. Okay. "That's concerned with animals and that olanzapine is the worst offender other than clozapine. They advocated a different marketing strategy than we are taking." Did I read that correctly?

A. That's correct.

Q. And that's a long way it took me to get there is what you were saying is Zyprexa, as opposed to other second generation antipsychotics such as Seroquel, Risperdal, Ability, Geodon, Zyprexa is the worst offender concerning the issue of weight gain?

117. PAGE 395:03 TO 395:18 (RUNNING 00:00:33.000)

Q. True?

A. And these are certainly the -- what I wrote here and what that characterizes is the fact that -- and again, I would come back to the David Allison analysis, it comes in number two. It's not necessarily far away from some of the other second generation.

Q. It's number two worst offender behind clozapine for causing weight gain, correct?

A. That's correct.

Q. And that's certainly what you wrote in your e-mail, Exhibit 1453, on October 10, 2000, at 8:33 in the morning?

A

18 A. That's correct.

A

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

PLAINTIFF'S SECOND AMENDED PAGE/LINE DESIGNATIONS AS OF MARCH 3, 2008

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

ROBIN WOJCIESZEK
DECEMBER 11, 2007

START PAGE/LINE	END PAGE/LINE
6:10	6:12
6:15	6:17
10:2	10:4
11:6	11:25
12:15	12:17
14:2	14:20
15:20	16:4
16:7	17:1
17:23	18:19
19:1	20:22
20:24	22:22

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23:4	23:8
24:2	26:9
28:13	28:15
28:17	30:23
31:20	31:23
33:24	37:8
37:16	38:13
38:22	38:23
48:1	48:13
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55:24	56:8
56:11	56:12
56:16	56:21
56:23	57:22
58:1	62:17
73:1	73:8
73:10	73:21
74:25	75:22
78:25	80: 3
81:3	81:19
81:21	81:22
83:6	83:13
83:20	84:1
84:3	84:12
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84:20	85:1
86:21	87:7
87:14	87:24
94:4	94:19
95:18	95:19
95:25	96:5
96:22	97:16
98:19	100:25
101:2	101:4

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DATED this 4th day of March, 2008.

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Certificate of Service

I hereby certify that a true and correct copy of **Plaintiff's Second Amended Page/Line Designations as of March 3, 2008 – Robin Wojcieszek** was served by messenger on:

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Barry Boise, via email (boiseb@pepperlaw.com)
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Wojcieszek, Robin (Vol. 01) - 12/11/2007

Wojcieszek

FINAL 2 26 08 (45 SEGMENTS RUNNING 00:49:02.653)

1. PAGE 6:10 TO 6:12 (RUNNING 00:00:03.933)

Q Would you state your full name for the record, please.
A Robin Pitts Wojcieszek.

2. PAGE 6:15 TO 6:17 (RUNNING 00:00:07.867)

Q And what's your occupation?
A I am a pharmacist, and I work at Eli Lilly & Company in regulatory affairs.

3. PAGE 10:02 TO 10:04 (RUNNING 00:00:06.500)

Q Okay. And when did you begin working for Eli Lilly?
A I began working for Lilly in August of 2002.

4. PAGE 11:06 TO 11:25 (RUNNING 00:01:12.667)

Q Did you have any job responsibilities with Zyprexa after you came to Lilly?
A Yes.
Q Okay. And could you describe those for me?
A I began working on Zyprexa in April of 2003 as a regulatory scientist.
Q And who did you report to?
A Greg Brophy.
Q And who reported to you?
A I don't have anyone reporting to me.
Q How did you come to be designated as the person to testify on behalf of Lilly in this deposition?
A I was responsible for some of the supplemental applications that are referred to in this communication or in this deposition, and I have primary responsibility for interactions with FDA regarding Zyprexa and labeling changes.
Q Okay. And how long have you had that responsibility?
A Since 2003.

5. PAGE 12:15 TO 12:17 (RUNNING 00:00:06.933)

Q Okay. Are you also the prime person responsible for communicating with FDA regarding Symbyax?
A Yes, I am.

6. PAGE 14:02 TO 14:20 (RUNNING 00:01:19.367)

Q Okay. Let's first talk about the first item in the notice of deposition, which is regarding Lilly's responses to a letter from FDA in March of 2007, which was the subject of Plaintiff's Second Set of Interrogatories and Document Requests to Defendants in the Alaskan litigation. And I'm going to hand you -- I'll hand you what we'll have marked as Plaintiff's Exhibit 2.

A

(Plaintiff's Exhibit 2 was marked for identification.)

Q And this appears to be a copy of a fax of a letter. It bears several dates on the front page, the earliest in time of which was March 28, 2007, and I noticed that on the very last page there is an electronic signature of Thomas Laughren at FDA that's dated March 28, 2007. Do you see that?

A Yes, I do.

Q Was this letter faxed to you on March 28, 2007?

A Yes, it was.

7. PAGE 15:20 TO 16:04 (RUNNING 00:00:23.500)

Q Now, the letter from FDA makes reference to a number of regulatory filings with FDA by Lilly regarding Symbyax; correct?

A Correct.

Q And Symbyax is a combination drug containing both Zyprexa and Prozac; correct?

00016:01 A That's correct.

02 Q Or, I guess, the generic terms would be containing
03 both olanzapine and fluoxetine; correct?
04 A That's correct.

8. PAGE 16:07 TO 17:01 (RUNNING 00:01:03.365)

07 Q Okay. And in those regulatory submissions, Lilly
08 was seeking approval from FDA to market the
09 combination drug Symbyax for use in treatment
10 resistant depression or TRD; is that correct?
11 A That's correct.
12 Q Okay. And it indicates that these prior
13 submissions had occurred in September of 2006, in
14 November of 2006, December of 2006, and February of
15 2007; correct?
16 A That's correct.
17 Q Okay. And am I correct that those submissions made
18 by Lilly to FDA included information from clinical
19 studies of the combination drug?
20 A That's correct.
21 Q Okay. And among other things, that clinical data
22 included information regarding changes in the blood
23 glucose of patients who were exposed to the
24 combination drug as compared to people who were
25 just receiving placebo; is that correct?

00017:01 A That's correct.

9. PAGE 17:23 TO 18:19 (RUNNING 00:01:06.595)

23 Q Okay. I want to make sure I understand. So that
24 the submissions that occurred in the fall of 2006
25 to support the additional indication for

00018:01 treatment resistant depression included data from
02 studies that had been conducted in support of the
03 original Symbyax submission in 2002 as well as
04 other studies after that point, the last of which
05 had been completed by the fall of 2005. Is that a
06 fair statement?
07 A That's a fair statement, yes.
08 Q Okay. And the earliest of those studies that had
09 been done in support of the 2002 submission, I
10 presume, would have been completed sometime before
11 2002; is that correct?

A

A That's correct.
Q Do you know when it was that they would have been completed?
A I don't know the exact dates, but, typically, they're done about six months prior to a submission.
Q So probably 2001 sometime?
A Some of them were, yes.

10. PAGE 19:01 TO 20:22 (RUNNING 00:02:30.999)

Q Okay. So it'd be fair to say that the data that's being referenced here in this letter is the data that was generated between, say, early 2002 and 2005 in that time frame; correct?
A Majority of the data, yes.
Q Okay. Now, in order to approve Symbyax for use in treatment resistant depression, FDA needed to approve the labeling for the drug; correct?
A Correct.
Q Okay. And on the first page of the letter in -- there's a bolded heading that states "Updated Information on Risks of Weight Gain, Hyperglycemia, and Hyperlipidemia." Do you see that?
A Yes, I do.
Q In the first paragraph right after that heading, it states "A primary concern with this application and the primary basis for our not taking a final action is our view that we lack important safety information needed to adequately update the labeling with all relevant risk information. In particular, we are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine use, whether taken alone or in combination with fluoxetine. You must fully address these concerns before we will be able to take a final action on this application." Do you see that language that I read?
A Yes.
Q And I read it correctly; correct?
A Yes, you did.
Q And it was clear, was it not, that the concerns about weight gain, hyperglycemia, and hyperlipidemia that it's referring to in connection with Symbyax had to deal with the Zyprexa portion of the drug and not the Prozac portion; correct?
A That's correct.
Q Okay. And, in fact, FDA has not requested any change in the labeling of Prozac regarding weight gain, hyperglycemia, and hyperlipidemia recently, have they?
A No, they have not.
Q Okay. Now, if I could direct your attention to the following page, in the first full paragraph on that page, FDA is talking about the data that they would like to see presented in the labeling; correct?

11. PAGE 20:24 TO 22:22 (RUNNING 00:02:35.133)

A What they're asking for is regarding -- if you look at the previous paragraph, it's an extension of

what type of information that they would like to see prior to making any labeling change.
Q. Ah, okay. Good point. So the FDA is telling you before they can approve a labeling change to allow for a further indication of treatment resistant depression they wanted to see the type of data that they're referring to in the first full paragraph on page 2; correct? Is that a fair statement?
A. That's -- that's a fair statement.
Q. Okay.
A. Yes.
Q. And what they said in that paragraph was "Regarding data displays, an overall strategy will be to subgroup patients on the basis of their status at baseline so that clinicians can better understand the risks associated with treatment of patients falling into different risk categories. For example, we note that your proposed Symbyax label includes information only on proportions of patients who are relatively normal at baseline with regard to random blood glucose (less than 140 milligrams per deciliter); i.e, 2.9 percent of such patients receiving OFC had on-treatment levels greater than or equal to 200 milligrams per deciliter compared to .3 percent of placebo-treated patients." Do you see that language?
A. Yes, I do.
Q. Now, when they talk about OFC, that's another way of talking about Symbyax or the combination of olanzapine and fluoxetine; is that correct?
A. That's correct.
Q. Okay. And was it your understanding that blood glucose levels greater than or equal to 200 milligrams per deciliter was regarded as diagnostic for diabetes by the American Diabetes Association?
A. Yes. Based on the -- kind of the ADA guidelines, that's correct.
Q. So what the FDA was saying here was that the data that you had presented to them already indicated that 2.9 percent of the patients who had rand- -- who had baseline random blood glucose of less than 140 wound up having on-treatment levels greater than or equal to 200 compared to .3 percent of placebo-treated patients; correct?

12. PAGE 23:04 TO 23:08 (RUNNING 00:00:12.400)

A. That -- that was an analysis included in the application.
Q. Okay. And was that an analysis that had been done by Lilly or by FDA?
A. By Lilly.

13. PAGE 24:02 TO 26:09 (RUNNING 00:03:04.267)

Q. This particular analysis, however, showed essentially a tenfold higher rate of patients going from nondiabetic levels of blood glucose to blood glucose levels over 200; correct?
A. For this particular analysis?

A

Q Yes.
A Yes.
Q Okay. And do you know who within Lilly did that analysis, finding that tenfold difference?
A That would have been done with our statistical group, with the medical group doing an evaluation of the results.
Q Okay. And I'm presuming that at some point they provided you in regulatory affairs with that data or write-up of the data, which you then submitted to FDA; correct?
A That's correct.
Q Okay. They then go on to say in their letter, FDA does, "However, we note that 46 percent of patients who were borderline to high at baseline (140 to 200) had such on-treatment levels compared to only 5 percent of placebo-treated patients." Do you see that?
A Yes.
Q Okay. And it was your understanding that they were saying there that when you looked at the data that Lilly had generated, it showed that those folks who had somewhat elevated levels of blood glucose in the 140 to 200 range that when you looked at those folks, about 46 percent of those people who were exposed to the combination drug went over 200 as compared to only 5 percent of the placebo-treated patients; correct?
A That's correct.
Q Okay. And that, again, would -- presuming would have been another analysis done by Lilly itself; correct?
A That's correct.
Q Okay. So in both of these statements here about what that data showed, FDA was really talking about what Lilly's own analysis had shown. And this was not some separate analysis that FDA had done. Is that a fair statement?
A That's a fair statement.
Q Okay. Continuing down in the letter a couple of lines, the FDA said, I believe, making reference to that latter analysis where the 46 percent of patients had blood levels over 200 after treatment, they go on to say "In addition, we were troubled that this important finding was not included in your proposed label." Do you see that?
A Yes.
Q Okay. And do you know who it was that made the decision not to include that information in the proposed label?
A That's a decision that's made -- it's actually a very cross-functional group of individuals within medical, regulatory, and global patient safety.

14. PAGE 28:13 TO 28:15 (RUNNING 00:00:06.900)

Q Ah, okay. Okay. So this analysis was done, you believe, probably in the summer of 2006?
A Yes.

15. PAGE 28:17 TO 30:23 (RUNNING 00:02:33.334)

that was in that 2002 to -- strike that. The

A

analysis that was done in the summer of 2006, as referred to in this first full paragraph on page 2, was an analysis of data that had been actually generated sometime between 2002 and 2005. Fair statement?

A That's correct.

Q Okay. I'd like to direct your attention to the third full paragraph on the second page of the FDA's letter, the one that starts off "Our overall goal..." Do you see that?

A Yes, I do.

Q It states "Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information.
We do not feel that current labeling for either Symbyax or Zyprexa provides sufficient information on these risks, and we fully intend to insure that these labels are enhanced with the best available information to characterize these risks." Do you see that language?

A Yes, I do.

Q Now, are you aware that in the Zyprexa litigation, not only in this case in Alaska, but in thousands of other cases around the country, Lilly has been asserting that its Zyprexa label was already sufficient and adequate?

A Yes.

Q But at least the -- and Lilly has never, to your knowledge, admitted that its labeling was inadequate, has it?

A Yes, that's correct.

Q Okay. But in this March 2007 letter, FDA told the company that it felt the Zyprexa labeling was not adequate; correct?

A That's correct.

Q Okay. Now, after receiving this communication from FDA in March of 2007 that it did not believe that the Zyprexa label was adequate, the company did not change the label in April, did it?

A No, we did not.

Q Or May?

A No.

Q Or June?

A No.

Q Or July?

A No.

Q Or August?

A No.

Q Or September?

A No.

Q There was, finally, a label change in October of 2007; correct?

A That's correct.

16. PAGE 31:20 TO 31:23 (RUNNING 00:00:13.466)

Q Okay. The second full paragraph on page 2 of the FDA letter makes reference to a New York Times article. Do you see that?

A Yes, I do.

A

Q And I gather that FDA was -- was wanting to know Lilly's response to the information that was
00034:01 presented in this article; is that correct?
A That's correct.
(Plaintiff's Exhibit 4 was marked for identification.)
Q I'm going to hand you what we'll have marked as Plaintiff's Exhibit 4. Before I do that, am I correct that there were essentially three parts to Lilly's response to FDA regarding the New York Times article?
A Yes.
Q Okay. One was -- Part 1 was submitted in February of 2007, Part 2 was submitted in May of 2007, and Part 3 in June of 2007; correct?
A Part 3 was in July.
Q I'm sorry. July 29 of 2007; correct?
A No. If I recall, it was July 2.
Q Okay. Okay. I'm going to hand you what I've marked as Plaintiff's Exhibit 4, and I realize this is Part 2. But at least in the way the documents were presented to me, this is -- I have to refer to parts in here to try to track through the sequence.
A Okay.
Q And for the record, Part 2 is a 77-page document produced to the state bearing the title "Regulatory Response, Response to the FDA Query Regarding the
00035:01 New York Times Articles, Part 2" and bears the date May 10, 2007. Did I describe that accurately?
A Yes, you did.
Q And were you involved in preparing this response and then submitting it to FDA?
A Yes.
Q Okay. If I could direct your attention to page 41, they're numbered in the upper right-hand corner, there is on that page a copy of a letter from FDA to Lilly to the attention of your boss, Gregory Brophy, that is dated January 12, 2007. Do you see that?
A Yes.
Q And is that the January 12 letter that was referred to in the FDA's March 27 -- or March 28 letter?
A Yes, it is.
Q Did we mark that as 2, Exhibit 2?
A It's 2.
Q And in the second paragraph of FDA's January 12 letter, they state "Recent articles in the New York Times reported on clinical trial data from 70 clinical trials on Zyprexa that showed patients taking Zyprexa experienced high blood sugar levels and weight gain that may have differed from information Eli Lilly revealed publicly and to the
00036:01 FDA." Did I read that correctly?
A Yes.
Q And then if you can drop down to the last paragraph on the page, the FDA says "By this letter, we are asking you to ensure that you are in compliance with all applicable statutes and regulations, and we further request that you submit to the agency all data and information, including but not

limited to those referenced in the recent New York Times articles that bear on the safety of Zyprexa. In particular, we are interested in receiving data and analyses bearing on these concerns about weight gain and hyperglycemia that have not already been submitted to the agency. Additionally, if you are in possession of other information not specifically required to be submitted by statute or regulation, but that would nevertheless be useful to FDA in evaluating the safety of Zyprexa regarding these concerns of weight gain and hyperglycemia, we request that you please submit this information to us as well." Do you see that language?

A Yes.

Q So, basically, what they were -- they were asking for was for Lilly to submit data and analyses about weight gain and hyperglycemia that had not already been submitted, and they were telling you to submit any other information that would be useful to FDA in analyzing the safety of Zyprexa regardless of whether such information was specifically required to be submitted by statute or regulation; is that correct?

A That's correct.

18. PAGE 37:16 TO 38:13 (RUNNING 00:01:12.966)

that. At any time after receiving this letter in January of 2007, did Lilly tell FDA, no, we are not going to comply with your request to submit information bearing on this issue even if it's not called for by statute or regulation?

A What we did is we -- with receipt of this letter in January of this year, shortly after receipt, we had a teleconference with FDA to get a better understanding and clarity of what they would like us to submit that we are not required to submit under the regulations, so getting clarity around that.

Q Okay. But it's fair to say that Lilly never told the FDA, no, if it's not called for by statute or regulation, we're not giving it to you?

A Right. No.

Q FDA -- pardon me. Lilly never said that; correct?

A No.

Q Okay. So FDA would have been under the impression that if you had information that bore on the safety of Zyprexa, you were going to provide it to them even if it wasn't specifically called for by regulation or statute; correct?

19. PAGE 38:22 TO 38:23 (RUNNING 00:00:06.233)

A Post -- post this letter we did commit and responded to this request.

20. PAGE 48:01 TO 48:13 (RUNNING 00:00:46.232)

Suppose that there was a particular document that was found. It was come across. It tended to indicate that Zyprexa was probably causally related to higher blood sugars.

Who within the team that was working on

responding to FDA's request here, who on the team would have decided whether that was something to be included or not in what was submitted to FDA?
A We had -- ultimately, Dr. Charles Beasley was involved in determining what was deemed as potentially discrepant.
Q You said he was involved. Was he the play caller on that?

21. PAGE 48:15 TO 48:22 (RUNNING 00:00:21.738)

A He was -- there were some additional physicians that were involved in the review, but he made -- had the oversight of kind of those definitions.
Q He would have been the most senior person involved in making that decision as to what was discrepant and should be submitted versus what was not?
A That's correct.

22. PAGE 55:24 TO 56:08 (RUNNING 00:00:48.195)

Q Now I'm going to hand you what's been previously marked as Plaintiff's Exhibit 5565. For the
00056:01 record, this is an e-mail chain. The most recent of which in time was dated February 22, 2001, from Jared Kerr to Mark Millikan, but I'm particularly interested in the e-mail right below that, which is from Charles Beasley to Ralf Dittman with copies to Alan Breier, Patrizia Cavazzoni, Mark Millikan, Anna Thornton, and Gary Tollefson regarding olanzapine and hyperglycemia. Have you ever seen

23. PAGE 56:11 TO 56:12 (RUNNING 00:00:02.224)

Q Have you ever seen this document before?
A No.

24. PAGE 56:16 TO 56:21 (RUNNING 00:00:17.432)

Q Is the Charles M. Beasley, Jr., that is there listed there as the author of the -- the e-mail on the middle of the first page, is that the same Charles Beasley that was on the -- responding to the FDA's request for information?
A Yes.

25. PAGE 56:23 TO 57:22 (RUNNING 00:01:19.733)

I take it back. The third sentence states "Our continuous analyses show that olanzapine does result in statistically significant mean increases
00057:01 in random glucose relative to placebo and haloperidol." Do you see that language?
A Yes.
Q It also goes on to say about three lines up from the bottom over on the far right-hand side, the sentence starts off by saying "These changes are accounted for in part but not entirely by weight increase." Do you see that language?
A Yes.
Q This document was not included as part of any response to the FDA, was it?
A No.

Q Were you --
A It doesn't look familiar.
Q Were you aware that this document even existed before I showed it to you today?
A No.
Q Okay. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 6128, and this is another e-mail chain. And I'm particularly concerned with the e-mail that is on the second page.

26. PAGE 58:01 TO 62:17 (RUNNING 00:06:38.000)

Q Directing your attention in particular to the e-mail on the second page, which is an e-mail from Charles M. Beasley on March 15, 2001, to Andrea Smith, Ernie Anand, Patricia Cavazzoni, Margaret Sowell, and Anna Thornton, the subject being "Olanzapine and Cardiovascular Risk."

If I could direct your attention to the third line down in that e-mail that states "One thing that we can say definitively is that olanzapine causes weight gain, and for approximately 50 percent of patients in trials who remained on the drug for more than six months, the amount of gain was greater than 10 pounds.

"Some patients in clinical trials gained as much as 80-plus pounds. Lacking empirical data to the contrary, it would be ludicrous to state that such a patient does not at long-term increased cardiac risk relative to prior to gaining that weight, especially, if in temporal association with that weight gain the patient developed an increase in fasting glucose and lipid levels." Do you see that language?

A Yes.
Q That e-mail was not submitted to FDA as part of the response, was it?
A No, it was not.
Q Okay. And have you ever seen this e-mail before I showed it to you today?
A No.
Q Okay. By the way, the Zyprexa labeling, even today, does not state that olanzapine causes weight gain, does it?
A No.
Q Dr. Beasley said he could say that definitively back on March of 2001; correct?
A Not understanding the overall context of what data he's referring to or the situation, I don't feel comfortable answering that question.
Q Okay. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 7802. For the record, this is a one-page document that appears to be a chart. I'll represent to you that the database that was provided to us by Eli Lilly says that this document is dated June 24, 2002.

And I'll also represent to you that the database provided to us by Lilly says that it came from the files of Michelle Sharp, and I believe that Michelle Sharp was at least once a colleague of yours in regulatory affairs; correct?
A That's correct.

A

And back in 2002 she had regulatory responsibility for Zyprexa, did she not?
A Yes.
Q Okay. And the title of this document is "Listing of Treatment-Emergent Abnormal Lab Findings in Olanzapine-Treated Patients, Placebo-Controlled F1D-MC-HGFU, Studies 1 and 2 Combined." Do you see that?
A Yes.
Q And then there is a listing of various laboratory findings, abnormal laboratory findings, and do you see that there's a listing for glucose, nonfasting, high?
A Yes.
Q And do you see that it indicates that the percentage of olanzapine patients who had high glucose was 2.2 percent, and that the percentage for placebo patients was 0 percent?
A Yes, I do.
Q And do you see that there are, to the right of that, several -- several As, the letter As?
A Yes.
Q Okay. And if you look down at the bottom, there's a little legend as to what the letters mean.
A Uh-huh.
00061:01 Q And it says, according to this, that the letter A means "Event probably causally related." Do you see that?
A Yes.
Q And this document was not submitted to FDA as part of the response in 2007, was it?
A No. I'm not -- no, it was not.
Q In fact, have you ever seen this document before I showed it to you this morning?
A No, I have not.
Q Okay. I'm going to hand you what's been previously marked as Plaintiff's Exhibit 8666, which is another e-mail chain. I'm concerned really only with the -- the one on the first page, which is the last one.
It is dated June 27, 2002. It is from Dr. Simeon Israel Taylor to a number of individuals, and if I could direct your attention to the last two sentences in the first paragraph over towards the right, do you see where the sentence starts off "however"? It's about two lines from the bottom.
A Yes.
Q Okay. It states "However, I feel that we need to deal with the scientific facts, whatever they are.
00062:01 Ultimately, I expect that a fair-minded scholarly evaluation of the available data is likely to support several conclusions.
"No. 1, Zyprexa, like other members of the class, causes weight gain.
"Two, like other causes of weight gain, Zyprexa-induced weight gain probably increases the risk of diabetes." Do you see that language?
A Yes.
Q And this was not provided to FDA in the response in 2007, was it?
A I'm taking a minute to --
Q Sure.

A

14 A -- look through it. No.
15 Q Okay. And, in fact, had you ever seen this
16 document before I showed it to you this morning?
17 A No.

27. PAGE 73:01 TO 73:08 (RUNNING 00:00:23.999)

00073:01 Q Do you recall that about two months after receiving
02 Part 3 of your submission --
03 A Okay.
04 Q -- and after having reviewed that and all the prior
05 submissions that Lilly made to the agency, the
06 agency wrote to Lilly on August 28, 2007,
07 requesting that Lilly make substantial changes to
08 the Zyprexa labeling to protect the public health?

28. PAGE 73:10 TO 73:21 (RUNNING 00:00:54.700)

10 A They sent us a communication on that date
11 requesting labeling changes.
12 Q And they did that because they thought it was in
13 the best interest of the public health; correct?
14 A That was a statement made in that particular
15 letter.
16 (Plaintiff's Exhibit 8 was marked for
17 identification.)
18 Q Let me hand you what we'll have marked as
19 Plaintiff's Exhibit No. 8. For the record,
20 Exhibit 8 is a letter dated August 28, 2007, from
21 Thomas Laughren to Ms. Wojcieszek. Did I pronounce

29. PAGE 74:25 TO 75:22 (RUNNING 00:01:10.000)

25 And in the third paragraph they said "We have
00075:01 reviewed the data that you have submitted thus far
02 as well as the available literature, and we would
03 like to request that you make the labeling changes
04 listed below pertaining to the effect of olanzapine
05 and Symbyax on body weight, lipids, and glucose."
06 Do you see that language?
07 A Yes.
08 Q Okay. So notwithstanding the fact that Lilly had
09 taken the position that the labeling did not need
10 to be changed and the FDA, after reviewing all of
11 the material that you had submitted thus far by
12 August 28, was of the view that, indeed, the
13 labeling did need to be changed; correct?
14 A That's correct. The one point that we were also
15 trying to get clarity is what data they were
16 referring that they had reviewed thus far.
17 Q Okay. They go on to say "We anticipate that
18 additional labeling changes will be necessary when
19 we have reviewed the results of the additional
20 analyses that we have requested." Do you see that
21 language?
22 A Yes.

30. PAGE 78:25 TO 80:03 (RUNNING 00:01:21.000)

25 Q Okay. Referring back to the FDA's letter in that
00079:01 same paragraph, FDA goes on to say "Given that
02 you're completing these analyses and our review of
03 them will take some time, we believe that it is in
04 the best interest of the public health to make

interim labeling changes now based on the data that we already have available." Do you see that language?
A Yes.
Q Okay. And then FDA proceeds to lay out the language that they were suggesting with respect to changes to the wording section; correct?
A Correct.
Q Okay. But with the full contemplation that these changes might well only be interim and that there may be additional changes that may or may not come into play after you submit all of your other data; correct?
A That's correct.
Q Okay. And the first section that they have changes that they request have to do with the hyperglycemia and diabetes mellitus section of the warnings of Zyprexa; correct?
A Correct.
Q Okay. And what they show there is by strike outs and underlining the language that they want eliminated and the language they want to replace it; correct?
A Correct.

31. PAGE 81:03 TO 81:19 (RUNNING 00:01:07.486)

Q Okay. And in the -- at the end of the first paragraph it states "Olanzapine and clozapine treatments have been associated with a greater potential to induce hyperglycemia than other atypical antipsychotics." Do you see that?
A Yes.
Q And what does the word "induce" mean?
A It means that there's some sort of a kind of relationship of olanzapine and hyperglycemia.
Q Well, in fact, the word induce indicates that it's a causal relationship, does it not?
A It could mean that.
Q In fact, the ordinary definition -- the ordinary dictionary definition of the word induce definitely indicates that it's a causal relationship. If I induce something, that means that I have brought -- brought about that result; correct?

32. PAGE 81:21 TO 81:22 (RUNNING 00:00:06.900)

Q You may answer.
A Again, it could be defined that way.

33. PAGE 83:06 TO 83:13 (RUNNING 00:00:30.433)

Q Okay. And then FDA also proposed that on the following page a completely new section in the warnings section regarding weight gain; correct?
A Correct.
Q Up until this point in time, Lilly had never discussed weight gain in the warning section of the Zyprexa labeling; correct?
A At this time it was not in our current label;

34. PAGE 83:20 TO 84:01 (RUNNING 00:00:20.999)

Q Okay. And then also in this letter the FDA was

A

requesting a completely new section on -- in the warning section for Zyprexa regarding hyperlipidemia; correct?
A That's correct.
Q Now, hyperlipidemia refers to fats in the blood; correct?

35. PAGE 84:03 TO 84:12 (RUNNING 00:00:42.577)

A It -- it refers to, yes, things such as triglycerides, cholesterol, lipids, that's correct.
Q That's what hyperlipidemia means is elevated levels of triglycerides and cholesterol; correct?
A Correct.
Q Okay. And after receiving this letter in which FDA laid out the language it wanted to see in the labeling, Lilly did not accept the language requested by FDA and instead sought to change the language; correct?

36. PAGE 84:14 TO 84:18 (RUNNING 00:00:19.831)

A In response to this -- this communication, we initiated discussions and proposals with FDA shortly after receipt.
Q Lilly did not accept the language that was laid out by FDA in their August 28, 2007, letter; correct?

37. PAGE 84:20 TO 85:01 (RUNNING 00:00:27.467)

A We provided our proposal in response to their request based on data that we had available short -- you know, during this time frame.
Q Your response to FDA was not, okay, we'll make the -- we'll make the label change that you've suggested; correct?
A Correct.

38. PAGE 86:21 TO 87:07 (RUNNING 00:01:24.461)

Q Okay. If I could, I'll mark -- strike that. I'll mark as the next exhibit Plaintiff's Exhibit 9. I stuck it on my copy. And for the record, Exhibit 9 is a document entitled "FDA Briefing Document." In the upper left-hand corner it says "Revised September 12, 2007."
A That's correct.
Q And was this actually submitted to FDA?
A It was -- the information included in this was e-mailed to FDA --
Q Okay.
A -- in preparation for our meeting on September 17.

39. PAGE 87:14 TO 87:24 (RUNNING 00:00:37.100)

Q And I'm going to hand you what I've marked as Exhibit No. 10, but keep Exhibit 9 handy.
A Okay.
Q A document which purports to be meeting minutes of a meeting between FDA and Lilly on September 17, 2007?
A That's correct.
Q And did you prepare the minutes that are in Exhibit 10?

A

A Yes. In addition to my colleague, Catherine Melfi, from regulatory who was also in attendance.

40. PAGE 94:04 TO 94:19 (RUNNING 00:00:52.142)

Q If I could direct your attention to the last two sentences of the warning language that Lilly had proposed after FDA's request, they start at the very, very bottom of the page, the last three words on the page "in contrast."
A Yeah.
Q Okay. They say "In contrast, the association between atypical antipsychotics and glycemic control appears to fall along a continuum, although relevant risk estimates have been inconsistent. Clozapine appears to have the greatest association while olanzapine may have a slightly greater association than quetiapine and risperidone and greater association than ziprasidone." Did I read that correctly?
A Yes.

41. PAGE 95:18 TO 95:19 (RUNNING 00:00:08.133)

Q But you took about -- you took out any reference to language that indicates a causal relationship?

42. PAGE 95:25 TO 96:05 (RUNNING 00:00:19.900)

A We -- we did not include that in our proposal.
Q Okay. And, in fact, to this day, Lilly denies that olanzapine can induce or cause hyperglycemia; correct?
A We don't feel that the -- that we have data to support that particular statement FDA included.

43. PAGE 96:22 TO 97:16 (RUNNING 00:01:13.800)

Q If I could have you look at Exhibit 10, please, which is the minutes of the September 17, 2007, meeting Lilly had with FDA. And was this meeting at the FDA headquarters?
A Yes, it was.
Q Would Dr. Thomas Laughren have been the leader of the FDA side?
A Yes.
Q Okay. And within the Lilly participants, was there one leader?
A I facilitated the meeting, and Dr. Corya was the medical lead. So the two of us co-facilitated the discussion.
Q Okay. And the purpose of this meeting was to discuss Lilly's response to FDA's August 28, 2007, letter. And just so, I guess, the record is clear, the response that you're referring to there would have been what we had marked as Exhibit 9; is that correct?
A Yes.

44. PAGE 98:19 TO 100:25 (RUNNING 00:03:08.646)

Q Point 2 was "FDA's requested labeling recommends that all patients on olanzapine should be monitored regularly for worsening of glucose control." And

A

that was different from what had been before; correct?
A That's correct.
Q There had been -- the labeling change that was made in 2003 had suggested that there be monitoring of glucose for patients who had diabetes or risk factors for diabetes; correct?
A Correct.
Q And here FDA was -- was recommending that -- that all patients on olanzapine should be monitored regularly for worsening of glucose control regardless of whether they had diabetes or risk factors for diabetes; correct?
A That's correct.
Q Okay. And in the minutes here, it indicates that "Lilly accepts the recommended monitoring; however, Lilly believes that the recommendation should cover the class of atypical antipsychotics"; correct?
A That's correct.
Q Okay. And as far as you know sitting here today, you're not aware of any such change to the other labeling of atypical antipsychotics saying there should be a monitoring of every patient; correct?
A That's correct.
Q Okay. And then in italics at the bottom of that section you note what FDA's response was; correct?
A Right.
Q And that was that FDA is not convinced that all patients on atypical antipsychotics require the same level of monitoring, but does agree with Lilly's assertion that all patients should get baseline glucose measurements; correct?
A Correct.
Q Okay. And then Point 3 stated that "FDA's requested labeling places olanzapine and clozapine in the same category in terms of association with glucose dysregulation; however, Lilly asserted that available data, including both Lilly clinical trial data and the available literature, support a differential association between clozapine and olanzapine and reiterated the belief that the association between antipsychotics and glucose dysregulation appears to fall on a continuum." Did I read that correctly?
A Yes, you did.
Q And then you note there that FDA agreed there was a continuum on which the atypicals fall in terms of association with -- with glucose dysregulation; correct?
A Correct.
Q By the way, with respect to the monitoring of all patients that FDA was insisting on here in 2007, that had been required by the Japanese label in -- as of April of 2002; correct?

45. PAGE 101:02 TO 101:04 (RUNNING 00:00:07.133)

A It was -- that's my understanding based on, you know, the history. I was not involved in that particular issue.

A

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

PRETRIAL DISCLOSURES PURSUANT TO ARCP RULE 26 (A)3(B) - PAGE/LINE DESIGNATIONS AS OF MARCH 3, 2008

MICHAEL BANDICK
JUNE 6, 2006

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DATED this 4th day of March, 2008.

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Certificate of Service

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022908

BANDICK 97 SEGMENTS (RUNNING 00:35:25.027)

1. PAGE 49:12 TO 49:24 (RUNNING 00:00:15.633)

Q. State your name for the Court and Jury, please, sir.
A. My name is Michael Edwin Bandick.
Q. Mr. Bandick, my name is Scott Allen, I'm from Houston, Texas. I'm here to take your deposition today, do you understand that?
A. I do.
Q. You understand the court reporter has sworn you in and you're under oath?
A. I do.

2. PAGE 54:05 TO 54:07 (RUNNING 00:00:08.700)

Q. When did you become employed by Eli Lilly?
A. May of 1991.

3. PAGE 55:22 TO 56:10 (RUNNING 00:00:23.033)

Q. And you're at, your title's described here under Denice Torres, who was director of global marketing, there are four
00056:01 people who reported directly to her; is that correct?
A. Yes, it is.
Q. And you were one of those four individuals?
A. Yes.
Q. And your title is listed Mike Bandick, Director Marketplace Management; is that correct?
A. Yes, it is.

4. PAGE 56:23 TO 57:03 (RUNNING 00:00:09.500)

Q. I've also seen documents, Mr. Bandick, that indicated you were Brand
00057:01 Manager for Zyprexa for Lilly?
A. I did have that role previously.

5. PAGE 58:04 TO 58:10 (RUNNING 00:00:22.933)

Q. What year were you Brand Manager, years?
A. Part of 2000, part of 2001.
Q. Okay, when were you Director of Marketplace Management for Zyprexa?
A. From the latter part of 2001 to the early part of 2004.

6. PAGE 58:15 TO 58:23 (RUNNING 00:00:17.433)

You said as Brand Manager fo

2000/2001, your answer was something like: I handled one segment of Zyprexa's market. Right?
A. That's correct.
Q. What segment did you handle?
A. The primary care segment.
Q. That's the PCP segment?
A. It was also called PCP.

7. PAGE 82:07 TO 82:11 (RUNNING 00:00:10.967)

Q. Next question: Did you assist in writing documents that were prepared for the sales force to give to physicians about Zyprexa?
A. Sometimes.

8. PAGE 115:23 TO 116:01 (RUNNING 00:00:12.567)

Q. In your role and roles in the marketing of Zyprexa, why would you want to send audiences messages about Zyprexa?

9. PAGE 116:02 TO 116:10 (RUNNING 00:00:28.733)

A. As I indicated earlier, conveying a concept can be a very valuable piece of what we think those audiences would need to know. And I guess the difficulty I'm having in answering your question is the work that we did was always in the context of a particular situation. So without that context it's hard for me to give you a very satisfactory answer.

10. PAGE 127:09 TO 127:11 (RUNNING 00:00:10.367)

let me rephrase the question. Can you describe to the jury, please, sir, what markets did Eli Lilly market Zyprexa to?

11. PAGE 127:12 TO 127:16 (RUNNING 00:00:18.233)

A. Primarily, physicians who could be either in psychiatry or other specialties. Would you like me to -- Is that a satisfactory answer to you?

12. PAGE 130:18 TO 131:19 (RUNNING 00:00:57.000)

Q. You agree you shouldn't withhold important information from doctors and patients about a drug product and in this case in particular Zyprexa?
A. That's not what I said.
Q. Okay. Well, then I'll ask you another question. Do you agree you shouldn't withhold important information from doctors and patients about Zyprexa?
A. Without a specific reference to what you might mean by important information I'm not sure how to answer your question.
Q. Thank you.
Now you said the doctors to whom you market the products are psychiatrists and primary care physicians; is that correct?

A. Yes.
Q. Tell the jury what primary care physicians are?
A. Primary care physicians are comprised of family practice, general practice, and internal medicine. And they see patients of all ages on a wide variety of health issues.

13. PAGE 152:14 TO 152:24 (RUNNING 00:00:44.000)

Q. Thank you. Did Lilly market Zyprexa for use in treating symptoms of mood?
A. No.
Q. Did Lilly market and/or promote Zyprexa for treatment of symptoms of anxiety?
A. No.
Q. Did Lilly market and/or promote Zyprexa for the treatment of symptoms of depression?
A. No.

14. PAGE 153:05 TO 153:08 (RUNNING 00:00:09.433)

Q. Did Lilly market and/or promote Zyprexa for the treatment of behavioral disorders?
A. No.

15. PAGE 154:04 TO 154:11 (RUNNING 00:00:14.067)

Q. Did Lilly market or promote Zyprexa for the treatment of irritability symptoms?
A. No.
Q. Did Lilly market or promote Zyprexa for thought disorders in nonpsychotic patients?
A. No.

16. PAGE 164:20 TO 165:08 (RUNNING 00:00:43.233)

Do you agree that Lilly cannot actively promote and/or market Zyprexa outside of the FDA approved indications on the label?
A. Yes. I agree that Lilly cannot promote Zyprexa outside of the approved indication on its label. There are opportunities to share data that might fall outside of that.
So when you said promote and market, I'm dividing the two, and I would say it's true that Lilly would not be promoting Zyprexa outside of its approved label.

17. PAGE 169:01 TO 169:07 (RUNNING 00:00:28.000)

Q. Okay. Can Lilly under FDA regulations or the GPP direct the Zyprexa sales force to actively proceed to a physician's office on a routine sales call and promote Zyprexa for the treatment of symptoms?
A. No.

18. PAGE 197:03 TO 197:15 (RUNNING 00:00:35.400)

Q. One of the marketing roles of the Zyprexa sales force was to overcome obstacles presented by the doctors when they would ask questions about Zyprexa?
A. That's a phrase that is used in sales training as a way to help direct a sales representative in the context of a call.
Q. One of the roles of the Zyprexa sales force in the area of marketing was to accurately respond to doctor's questions concerning the risk of Zyprexa?
A. That's correct.

19. PAGE 200:24 TO 201:08 (RUNNING 00:00:22.733)

to my question. Part of the tool or channels of marketing for Zyprexa was Lilly giving money to medical organizations?
A. There were medical associations that received that type of funding, yes.
Q. As part of the marketing activities for Zyprexa from Eli Lilly?
A. Yes.

20. PAGE 201:24 TO 202:03 (RUNNING 00:00:13.433)

Q. Tell the jury, please, those medical organizations or associations to whom money was given as part of the channel or tool in the marketing of Zyprexa?

21. PAGE 202:04 TO 202:11 (RUNNING 00:00:16.500)

A. The only two associations that come to mind are the American Psychiatric Association and the American Diabetes Association.
Q. How many millions of dollars was given to those organizations over the period of let's say 1995 to 2004 at the time you left?

22. PAGE 202:14 TO 202:14 (RUNNING 00:00:01.100)

A. I don't have any idea.

23. PAGE 214:13 TO 215:05 (RUNNING 00:00:42.933)

And tell this journey any other indications besides schizophrenia and bipolar mania that were ever added and approved by the FDA for Zyprexa?
A. I don't recall the date, but later, after March of 2000, there was a broadening of the bipolar indication to include maintenance, bipolar maintenance.
Q. So the three FDA approved indications for Zyprexa since it's been on the market are schizophrenia, bipolar mania and bipolar mania maintenance, correct?
A. Bipolar maintenance.
Q. Okay. Any other indications approved by the FDA other than those you just identified?
A. Not that I'm aware of.

24. PAGE 327:14 TO 328:04 (RUNNING 00:00:34.167)

You've heard the term "fair and balanced" before have you not, in regard to marketing documents?
A. I've heard the term "fair balance."
Q. What does that mean to you?
A. That there is an appropriate balance between what would be considered advantages or disadvantages, efficacy, safety.
Q. For example, you cannot, you, being the marketing department, in order to reach fair balance, you cannot overemphasize the benefits of Zyprexa and underemphasize the risk of Zyprexa?

25. PAGE 328:11 TO 328:11 (RUNNING 00:00:04.000)

A. That's my understanding of

26. PAGE 372:10 TO 372:13 (RUNNING 00:00:09.433)

Q. Mr. Bandick, I handed you at the break what's been marked as Bandick Exhibit No. 7. Do you recognize this document?

27. PAGE 372:23 TO 372:23 (RUNNING 00:00:00.833)

A. Yes, I do.

28. PAGE 373:07 TO 374:09 (RUNNING 00:01:09.033)

Q. It is a document entitled the "Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes." And it's published by the American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists and the North American Association for the Study of Obesity, in 2004; is that correct?
A. It was published in Diabetes Care and those four associations are associated with it.
Q. And you read this in your role at Eli Lilly before you left your employment, did you not?
A. Yes, that's true.
Q. And just for the record, as reflected in this exhibit, this is a consensus development document involving a conference that was held in November of 2003; is that correct?
A. Yes, I believe it is.
Q. And individuals as reflected in this document, individuals from Eli Lilly made a presentation at that conference, correct?
A. That is correct.

29. PAGE 374:18 TO 374:20 (RUNNING 00:00:04.767)

Q. By the way, did you attend this conference?
A. Yes, I did.

30. PAGE 375:22 TO 376:02 (RUNNING 00:00:13.533)

Q. Why were you selected to attend?
A. Many of the things that we did involved a collaboration between marketing and medical.

31. PAGE 376:19 TO 377:09 (RUNNING 00:00:37.067)

Q. Okay. Now, this conference was convened to answer several questions, was it not?
A. Yes, it was.
Q. Okay. I'm just going to have you skip over to Page 597 of Bandick Exhibit No. 7, the consensus statement, and you see question three?
A. Yes.
Q. The question is: "What is the relationship between the use of these drugs and the incidence of obesity and diabetes, question mark." Did I read that correctly?
A. Yes.

32. PAGE 378:04 TO 378:22 (RUNNING 00:00:39.500)

Q. The first heading, the bold heading, obesity, do you see that?
A. Yes, I do.
Q. It says under there: "There is considerable evidence, particularly in patient with schizophrenia, that treatment with the second general antipsychotics can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after one year of treatment. There is, however, considerable variability in weight gain among the various second generation antipsychotics." And it references Table 2. Did I read that correctly?
A. Yes.
Q. And you see table two underneath that statement?
A. Yes, I do.

33. PAGE 379:14 TO 380:05 (RUNNING 00:00:38.533)

Q. According to table two, which is directly in front of you, at a conference you attended, what second generation antipsychotics carried the largest risk of weight gain and risk for diabetes according to Table 2?
A. According to this panel, clozapine and olanzapine, Clozaril and Zyprexa, had a higher relative risk for weight gain.
Q. And for diabetes?
A. And to answer the other part of your question, according to this table they also identify clozapine and olanzapine as having a relatively higher risk for diabetes.

34. PAGE 398:11 TO 399:05 (RUNNING 00:00:49.400)

Q. Why don't you turn, now, sir, to Page 598 in Bandick Exhibit No. 7, which is the consensus statement, and go to question No. 4. Do you see that?
A. Yes.
Q. The question No. 4 reads: Given the above risks, how should patients be monitored for the development of significant weight gain dyslipidemia, and diabetes, and how should they be treated if diabetes develops, question mark."
Did I read that correctly?
A. Yes.
Q. The answer says: "Given the serious health risks, patients taking SGAs should receive appropriate baseline screening and ongoing monitoring." Did I read that correctly?
A. Yes.

35. PAGE 399:14 TO 399:22 (RUNNING 00:00:23.533)

Q. Do you agree with that?
A. Based on my conversations with Lilly clinicians I believe that would be reasonable.
Q. And when did you form that belief?
A. I don't recall.
Q. What year?
A. Probably, 2003.

36. PAGE 401:22 TO 402:02 (RUNNING 00:00:09.533)

Q. I've handed you what I've marked as Bandick Exhibit No. 9, which I'll represent to you is a 2005 PDR reference on Zyprexa.
Do you have that in front of

37. PAGE 402:03 TO 402:04 (RUNNING 00:00:02.167)

you?
A. It appears that I do.

38. PAGE 403:07 TO 403:11 (RUNNING 00:00:14.500)

Q. Okay. Look at the precaution section which begins on the fourth page of Bandick Exhibit No. 9.
Are you there with me?
A. I believe so.

39. PAGE 403:17 TO 403:20 (RUNNING 00:00:09.433)

Q. And there's a section in the precaution section entitled "Laboratory Tests," isn't there?
A. Yes, there is.

40. PAGE 405:12 TO 405:19 (RUNNING 00:00:20.800)

Q. My simple question was: In the precaution section of the label is there any laboratory testing recommended for patients who take second generation antipsychotics to have their fasting plasma glucose monitored?

A. Not under laboratory tests in the precaution section.

41. PAGE 408:04 TO 409:09 (RUNNING 00:01:23.267)

Sir, let's go to the summary of the consensus statement, Exhibit No. 7, on Page 600. Do you see the summary, sir?
A. Yes, I do.
Q. I'm going to read it out loud as follows: "The SGAs are of great benefit to a wide variety of people with psychiatric disorders. As with all drugs, SGAs are associated with undesirable side effects. One constellation of adverse effects is an increased risk for obesity, diabetes, and dyslipidemia." Did I read that correctly?
A. Yes.
Q. I'm going to skip down to the next paragraph, it says: "These three adverse conditions are closely linked, and their prevalence appears to differ depending on the second generation antipsychotic used. Clozapine and olanzapine are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia." Did I read that correctly?
A. That's what it says in this document.
Q. As the Brand Manager and the Director of Marketplace Management for Zyprexa in the years you have indicated, do you agree with that statement?
A. Lilly disagreed with that statement.

42. PAGE 411:08 TO 411:21 (RUNNING 00:00:49.867)

Q. Do you have Exhibit No. 10 in front of you?
A. I do.
Q. You have seen this document before, have you not?
A. I have.
Q. When did you see this document?
A. I first saw this document when it was published in April 2002.
Q. This document, it's dated April 2002. It's Exhibit No. 10. Can you briefly describe for the jury what it is?

43. PAGE 411:22 TO 412:02 (RUNNING 00:00:15.200)

A. This is the English translation of a Dear Health Care Professional letter that was distributed to physicians in Japan following a label change for Zyprexa in Japan.

44. PAGE 415:14 TO 416:13 (RUNNING 00:01:11.467)

Q. What the Japanese government did is they put a black box warning on Zyprexa in Japan, didn't they?
A. It was comparable to what in the U.S. we would call a black box warning.

Q. And what they said -- and let me read a portion of this exhibit -- it says: "Emergency safety information regarding diabetic ketoacidosis and diabetic coma due to increased blood glucose during administration of an antipsychotic agent, Zyprexa tablets, olanzapine. Since the marketing of this product in June 2001, nine serious cases, parens, including two cases of death, close parens, with hyperglycemia, diabetic ketoacidosis and diabetic coma have been reported for which causal relationship with this product cannot be denied, parens, estimated number of patients treated with this product 137,000 as of the end of December 2001."
Did I read that correctly, sir?
A. Yes.

45. PAGE 418:21 TO 419:22 (RUNNING 00:00:58.200)

Q. The black box said, among other things, "Do not administer to patients with diabetes mellitus and those who have a history of diabetes mellitus.
No. 2. During administration of this product, observe sufficiently with such as measurement of blood glucose.
No. 3. Explain sufficiently to the patient and family members.
And it goes on to say, "Upon administration of this product, explain sufficiently to the patient and family members possible occurrence of serious adverse reactions, such as diabetic ketoacidosis and diabetic coma, et cetera. Provide guidance to them to see a physician suspending administration if such symptoms as thirst, polydipsia, polyuria, or frequent urination, et cetera, appear."
Did I read that correctly?
A. Yes.
Q. Did Lilly change its label for Zyprexa in the United States consistent with what was required by Japan in April of 2002?
A. No, it did not.

46. PAGE 421:17 TO 421:20 (RUNNING 00:00:13.033)

Q. Did Lilly send doctors in the United States a Dear Doctor letter informing them about the equivalent of a black box warning on the Japanese label in April 2002?

47. PAGE 421:23 TO 422:01 (RUNNING 00:00:05.000)

A. I don't recall a Dear Health Care Professional letter being distributed on that topic.

48. PAGE 435:02 TO 435:04 (RUNNING 00:00:06.400)

Q. Have you ever informed the sales force of foreign regulatory action concerning a black box on antipsychotics?

49. PAGE 435:10 TO 435:10 (RUNNING 00:00:01.667)

A. I don't recall an example.

50. PAGE 435:15 TO 435:18 (RUNNING 00:00:07.700)

Q. Well, let me see if I can refresh your recollection. I'm going to hand you what's been marked as Bandick Exhibit No. 11. Provide it to your counsel.

51. PAGE 436:15 TO 436:17 (RUNNING 00:00:09.700)

Q. Okay. Can you tell the jury the date of this e-mail that you wrote?
A. October 18, 2002.

52. PAGE 438:23 TO 439:05 (RUNNING 00:00:19.000)

Q. You sent this e-mail around the world, in essence?
A. That's true.
Q. And the subject is risperidone, which is Risperdal, Cerebral Vascular Warning in Canada, right?
A. Yes.

53. PAGE 443:12 TO 444:04 (RUNNING 00:00:37.300)

Q. And it says: "We would like to point out actual label changes such as the recent addition of a black box warning pending to the Risperdal label in Canada."
A. And the context for that remark the first part of the sentence is avoiding speculation on potential label changes, because we thought that would be inappropriate. However, if there was an actual label change that that would be something that would potentially be appropriate. And as you pointed out under do was to share information selectively as appropriate. That does not represent a proactive tell-every-customer-you've-got. If it came up that was something that could be cited as a fact.

54. PAGE 450:22 TO 451:04 (RUNNING 00:00:19.733)

Q. You think the actions concerning the black box label change, the equivalent of a block box label change in Japan on Zyprexa, do you see any inconsistency in your action concerning that action in Japan versus what you did concerning the Risperdal label in Canada?

55. PAGE 451:07 TO 451:10 (RUNNING 00:00:07.700)

A. I see them as very different situations.
Q. Do you see any inconsistency in what you did, sir, Mr. Bandick?

56. PAGE 451:13 TO 451:15 (RUNNING 00:00:05.300)

A. I can't evaluate the consistency or inconsistency, I see them as different situations.

A

57. PAGE 452:21 TO 452:22 (RUNNING 00:00:05.000)

Q. Sir, you recognize this document, Exhibit 12, do you not?

58. PAGE 452:23 TO 453:08 (RUNNING 00:00:22.000)

A. Yes, I do.
Q. You wrote it?
00453:01 A. Yes, I did.
Q. When did you write it?
A. August of 2000.
Q. Okay. Sir, this document, read the title to the jury, please.
A. Zyprexa Primary Care Strategy and Implementation Overview.
Q. Why did you write this?

59. PAGE 453:09 TO 453:14 (RUNNING 00:00:18.967)

A. This was about one month into my role as Brand Manager for Zyprexa in primary care, and I believe this was a, an overview for an internal audience, probably other members of the Zyprexa Marketing Team and, perhaps, other internal audiences.

60. PAGE 457:24 TO 458:07 (RUNNING 00:00:21.033)

Q. I'll read the background.
00458:01 "Background: Following several months of study by the Lilly USA Zyprexa Brand Team the affiliate approved the recommendation that Lilly actively promote Zyprexa to selected current primary care prescriber targets."
Did I read that correctly?
A. Yes.

61. PAGE 461:17 TO 462:01 (RUNNING 00:00:15.000)

Q. Okay, sir, why don't you look at your challenges section of your memo Exhibit 12, okay? Do you have it there in front of you?
A. I do.
Q. Why don't you read it out loud to the jury, please.
THE WITNESS: The whole
00462:01 section?

62. PAGE 462:03 TO 462:19 (RUNNING 00:00:33.833)

A. Most PCPs currently prescribe a low volume of antipsychotics and mood stabilizers.
Q. Can you read it very slowly and distinctly so the jury can hear you when they hear the tape back.
A. Certainly.
Q. Go ahead.
A. "Most PCPs currently prescribe a low volume of antipsychotics and mood stabilizers. Many PCPs will refer patients in need of psychotropic treatment to a specialist rather than treat that patient. Key barriers to uptake include PCPs lack of training in this category, limited time with patients, and an aversion to perceived risk. Zyprexa's primary indications, schizophrenia

63. PAGE 462:20 TO 462:23 (RUNNING 00:00:14.833)

and bipolar, are not viewed as PCP treated conditions so there's not a specific indication for Lilly reps to promote in the PCP segment."

64. PAGE 463:12 TO 463:16 (RUNNING 00:00:14.267)

Q. Let's look at the first part, "Zyprexa's primary indications, schizophrenia and bipolar." Aren't those the only indications for Zyprexa at that time?
A. Yes, that's correct.

65. PAGE 464:06 TO 464:16 (RUNNING 00:00:26.333)

Q. Okay. Then I'm going to read it like that and we're going to continue. Continuing: Zyprexa's only indications, schizophrenia and bipolar, are not viewed as PCP treated conditions. so there's not a specific indication for Lilly reps to promote in the PCP, primary care physician segment; is that correct?
A. That's what's written there.
Q. You wrote it, didn't you?
A. Yes, I did.

66. PAGE 470:10 TO 471:16 (RUNNING 00:01:02.300)

Q. Why don't you go down, after challenges, which we just read, there's a segment on position, right?
A. Um-hum.
Q. Sir?
A. Yes, that's true.
Q. You underlined this sentence, do you not, the first sentence under position?
A. I did underline the first sentence in that section.
Q. And you say this: "Position: Zyprexa. The safe, proven solution in mood, thought, and behavioral disorders."
Did I read that correctly?
00471:01 A. You did.
Q. Didn't you tell me hours ago in this deposition that there was no indication for Zyprexa for the treatment of mood?
A. That's correct.
Q. Didn't you tell me hours ago there was no indication, approved indication, for Zyprexa for the treatment of thought disorders?
A. That's correct.
Q. Didn't you tell me hours ago that there was no approved indication for Zyprexa for the treatment of behavioral disorders?
A. Yes, that's true.

67. PAGE 472:10 TO 472:14 (RUNNING 00:00:10.367)

Q. My only question was: When you prepared Exhibit No. 12, you wrote that you intended to position Zyprexa as a safe, proven solution in mood, thought, and

behavioral disorders?

68. PAGE 472:19 TO 472:23 (RUNNING 00:00:13.767)

A. As I indicated, a position and a desired position in a prelaunch planning document, does not represent the same as a verbatim to a sales organization or a promotion to a customer.

69. PAGE 473:07 TO 473:10 (RUNNING 00:00:06.266)

Q. Sir, you've seen Exhibit No. 13, haven't you, Bandick?
A. Give me a moment with it please.

70. PAGE 476:05 TO 476:15 (RUNNING 00:00:25.100)

Q. Quit looking at the document and tell me what the Viva Zyprexa launch meeting was?
A. Viva Zyprexa launch meeting referred to the initial launch in primary care in October of 2000.
Q. And that was a launch in Orlando, Florida, right?
A. Yes, I believe so.
Q. Did you speak at that launch?
A. Yes, I did.

71. PAGE 478:08 TO 478:19 (RUNNING 00:00:19.833)

Isn't one of the things this document did is answer the question why you were entering the primary care physician market, you, being Lilly?
A. Yes, that is one of the questions that it answers.
Q. You're right there on the page I see. You're on Page 68, aren't you?
A. Yes, I am.
Q. You helped prepare this slide, didn't you?
A. Yes, I believe I did.

72. PAGE 479:02 TO 479:05 (RUNNING 00:00:08.533)

Q. Did you all get up -- did you all have a song that was created for this presentation?
A. Yes.

73. PAGE 479:24 TO 480:06 (RUNNING 00:00:18.700)

Q. Okay. Now I want to go back to this question of why Lilly entered the primary care physician market, that's on Page 68, and it says right here, "Zyprexa, primary care, why are we entering this market, question mark?" Right?
A. Yes.

74. PAGE 480:09 TO 481:01 (RUNNING 00:00:47.100)

four, five bullet points down. Can you read to the jury what you said as to why Lilly was entering the primary care market for Zyprexa?
A. One of several reasons on this page reads: "Zyprexa's success is

crucial to corporate performance. PCPs represent last major untapped segment."
Q. Zyprexa's success is crucial to corporate performance was one of the reasons listed as to why Lilly was entering this market, right?
Sir?
A. The context for this document was that this was a sales organization audience and we were providing motivation for them to understand how they fit into the bigger picture.

75. PAGE 489:03 TO 489:09 (RUNNING 00:00:16.933)

Q. Sir, the Viva Zyprexa song, the first two lines: "The whole new purpose gonna set my soul, set my soul on fire."
Did I read that correctly?
A. Yes.
Q. There was a whole new purpose for Zyprexa in the fall of 2000?

76. PAGE 489:12 TO 489:14 (RUNNING 00:00:06.200)

A. I didn't write the lyrics to the song, I don't know what the lyricist had in mind with "whole new purpose."

77. PAGE 491:10 TO 491:19 (RUNNING 00:00:18.800)

Q. Let's go down to the third versus: "Yeah, we're helping patients, Viva Zyprexa, many wonderful indications, Viva Zyprexa."
Did I read that correctly?
A. You did.
Q. Many wonderful indications. There was only two indications, weren't there, sir?
A. That's correct.

78. PAGE 491:24 TO 492:11 (RUNNING 00:00:19.233)

Q. So there wasn't many wonderful indications, were there, sir?
A. I assume this had more to do with getting the right number of syllables into that line.
Q. You don't think it had something to do with mood, thought, irritability and anxiety?
A. I'm quite certain the person who wrote the lyrics to this song was not aware of our strategy or our promotional message.

79. PAGE 493:03 TO 493:12 (RUNNING 00:00:22.534)

Q. Last, lyrics of the last stanza: "Can't rest now I've got to run, I'm gonna tell everyone, might tell a doctor 50 times, give a perfect message on every shot, keep Zyprexa at the top, Viva Zyprexa, Viva Zyprexa."
Did I quote from the lyrics correctly?
A. You left out a couple of lines in that stanza, but yes.

80. PAGE 496:09 TO 497:03 (RUNNING 00:00:48.700)

Q. Can you turn to Page 77 of the Primary Care Sales Force Resource Guide?
A. Yes.
Q. Exhibit 17. Who's the patient profile No. 1?
A. It says Donna is a --
Q. No. Who's the patient profile No. 1? Who?
A. I'm not sure what you mean.
Q. The person's name, patient profile No. 1, who is that?
A. In this particular case the patient profile is symbolized by the name Donna.
Q. Right. Let's go ahead to patient profile number on page 9, patient profile No. 2. Who's that?
A. This patient profile is symbolized by the name Mark.

81. PAGE 499:14 TO 499:18 (RUNNING 00:00:09.000)

Q. Okay. Do you recall marketing to Donna, Mark and Martha?
A. You'd asked me that earlier and I didn't know what you meant then and I'm still not sure what you mean.

82. PAGE 503:02 TO 504:12 (RUNNING 00:01:20.633)

Q. Sir, you recognize the Exhibit No. 16, Issue Management Planning on Diabetes. Lilly Answers That Matter?
A. There are aspects of it that are familiar. I'm not sure that I recall this exact document.
Q. Okay. Why don't we go to Page 2?
A. Okay.
Q. Diabetes. What is a position, sir? A position as used in marketing?
A. Well, in the context of this document it would be similar to saying our point of view.
Q. Okay. And isn't it, in fact -- this document is a marketing document, is it not?
A. This document would have come from a marketing source.
Q. Okay. Our position would be our point of view. "Our position: Diabetes hyperglycemia may appear in patients taking antipsychotics and/or mood stabilizers including Zyprexa at comparable rates with the possible exception of Clozapine." Did I read that correctly?
A. Yes.
Q. We saw earlier today the consensus statement from April 2004, says that diabetes occurs in a greater rate in Zyprexa than it does in the other second generation antipsychotics, correct?
A. That is the conclusion that that group drew.

83. PAGE 506:01 TO 506:12 (RUNNING 00:00:28.800)

Q. Okay. The reason for the position that's reported in your marketing document Exhibit 16 is as follows, follow along with me: "Showing that diabetes is a common occurrence for all antipsychotics and not just Zyprexa will help reduce the perception that diabetes is linked to, specifically, to Zyprexa, and in turn, will help to eliminate this risk from the risk/benefit equation."
Did I read that correctly?
A. Yes, you did.

84. PAGE 509:22 TO 509:24 (RUNNING 00:00:07.633)

Q. Issues Management Planning Weight Gain, Exhibit 15, November 2001. You've seen that document before, haven't

85. PAGE 510:01 TO 510:18 (RUNNING 00:00:35.200)

you?
A. As with the last document which was dated one day differently from this one, I'm familiar with much of the content, I'm not sure I recall the specific document.
Q. Okay. This is the Issues Management Planning Weight Gain, Lilly Answers That Matter. Our Position is on Page 2. You following me?
A. Yes.
Q. Our position: Weight gain can occur with Zyprexa as with other antipsychotics and mood stabilizers. For most patients this can be managed allowing them to receive the overwhelming benefits Zyprexa offers."
Did I read that correctly?
A. Yes, you did.

86. PAGE 511:03 TO 511:11 (RUNNING 00:00:17.166)

Q. Okay. What is the rationale for the position as contained in this exhibit --
A. It says --
Q. -- No. 15?
A. In this document it says: "To minimize the liability of weight gain while at the same time increasing focus on Zyprexa's superior efficacy."

87. PAGE 515:16 TO 515:18 (RUNNING 00:00:05.567)

You all marketed and sold Zyprexa to the elderly for dementia, didn't you?

88. PAGE 515:21 TO 515:24 (RUNNING 00:00:01.533)

A. No.
(Whereupon, Deposition Exhibit(s) 19 duly received, marked and made a part of the record.)

89. PAGE 516:02 TO 516:03 (RUNNING 00:00:03.333)

Q. What's Exhibit 19, do you

03 recognize that? My question is do you

90. PAGE 516:04 TO 516:09 (RUNNING 00:00:31.533)

04 recognize the document, sir?
05 A. No, I don't.
06 Q. You don't? Why don't we just
07 turn to Page 7 of this document, okay?
08 Page 7. Are you with me?
09 A. Yes, I am.

91. PAGE 516:24 TO 517:13 (RUNNING 00:00:34.900)

24 Q. And on Page 7 it says:
00517:01 "Zyprexa IntraMuscular olanzapine for
02 injection. Safety in agitation associated
03 with dementia in a clinical trial."
04 Did I read that correctly?
05 A. Yes.
06 Q. Then you go: "In patients up
07 to 97 years old, mean age of 77, favorable
08 adverse event profile, the most common
09 treatment-emergent adverse event in dementia
10 patients was somnolence 4 percent versus
11 3 percent with placebo."
12 Did I read that correctly?
13 A. Yes.

92. PAGE 518:23 TO 518:24 (RUNNING 00:00:04.866)

23 Isn't it true Lilly marketed
24 Zyprexa for dementia patients?

93. PAGE 519:03 TO 519:07 (RUNNING 00:00:09.767)

03 A. No.
04 Q. Okay. Well let me ask you
05 another question, isn't it true Lilly
06 marketed Zyprexa for depressive symptoms
07 related to dementia?

94. PAGE 519:10 TO 519:10 (RUNNING 00:00:01.134)

10 A. Not that I'm aware.

95. PAGE 519:17 TO 519:19 (RUNNING 00:00:09.233)

17 Q. Why don't you turn to
18 Page 18. What's the title of that page?
19 A. Improves depressive symptoms.

96. PAGE 521:13 TO 521:15 (RUNNING 00:00:07.100)

13 Q. What's the title of Page 20?
14 A. Zyprexa Safely Stabilizes
15 Behavioral Symptoms.

97. PAGE 521:21 TO 522:09 (RUNNING 00:00:25.300)

21 Q. Didn't you market Zyprexa for
22 the treatment of symptoms?
23 A. No.
24 Q. Why don't you go down to the
00522:01 third section on this page where it says:
02 "Zyprexa IntraMuscular, olanzapine for
03 injection." You follow me?
04 A. Yes.
05 Q. Read out loud what it says
06 right there?
07 A. "First and only psychotropic
08 indicated for the treatment of agitation

09 associated with dementia."

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:35:25.027)

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

PRETRIAL DISCLOSURES PURSUANT TO ARCP RULE 26 (A)3(B) - PAGE/LINE DESIGNATIONS AS OF MARCH 3, 2008

JACK JORDAN
JUNE 6, 2006

Start	Stop
21:22	21:24
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29:20	29:24
30:01	30:05
31:04	31:11
59:08	59:20
61:20	61:24
62:01	61:12
84:16	84:17
84:20	84:22
102:18	102:22
113:06	113:13

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114:01	114:04
136:07	136:12
136:15	136:16
163:22	137:07
137:10	138:06
163:09	163:22
164:15	164:19
166:21	166:22
167:01	167:02
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168:14	168:17
174:24	175:10
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296:17	296:24
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301:20	302:02
306:01	306:07
308:18	309:21
318:15	318:23
339:06	339:11
342:08	342:09
342:11	342:15

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343:02	343:08
344:16	345:09
347:12	348:04
355:20	356:02
362:20	363:03
363:16	364:18
366:19	366:23
368:05	368:14
369:02	369:11
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413:06	413:08
421:05	421:13
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437:20	438:07
456:06	458:10
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465:08	465:19
490:22	490:24
492:18	493:23

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Certificate of Service
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Jordan, Jack E. (Vol. 01) - 10/26/2006 — 1 CLIP (RUNNING 00:27:28.693)

022908

JORDAN — 65 SEGMENTS (RUNNING 00:27:28.693)

1. PAGE 21:22 TO 22:02 (RUNNING 00:00:05.733)

Q. How are you this morning?
A. I'm fine.
Q. Can you tell the jury your name, please, sir?
A. My name's Jack E. Jordan.

2. PAGE 29:20 TO 30:05 (RUNNING 00:00:22.293)

Q. Tell the jury what you mean by "position your product?"
A. Positioning is ultimately how you want your customers to think about your product. So, for example, staying with the Ford truck analogy, it would be that if you drive this truck you're tough, could be a positioning. I'm Ford tough. That's part of what they're trying to have their customers think about their product.

3. PAGE 31:04 TO 31:11 (RUNNING 00:00:18.000)

Q. Can you tell the jury, please, what you teach and what you know about how you get your customers to think what you want them to think?
A. Ultimately, that gets into the marketing mix, which is the next step. And most of that revolves around your promotional activities.

4. PAGE 59:08 TO 59:20 (RUNNING 00:00:35.433)

Q. You have an MBA?
A. It's called a Master's of Science and Management but it's an MBA equivalent.
Q. Right. And after you completed your, the equivalent of a master's in business at Purdue University in 1988, what did you do next?
A. I went to work for Eli Lilly and Company.
Q. And you worked for Eli Lilly from 1988 until when, sir?
A. Until April of 2004.

5. PAGE 61:20 TO 62:12 (RUNNING 00:01:22.089)

Q. You were the Brand Leader for the drug Zyprexa for Eli Lilly from when to when?
A. From May of 1998 until about August of 2003.
Q. We will, of course, explore it in some detail, but can you tell us as an executive, as a Brand Leader for Zyprexa from May of 1988 until August of 2003, can you

Pretrial Disclosures Pursuant to ARCP Rule 26(A)3(B) - Page/Line Designations as of March 3, 2008 - Jack Jordan
Case No. 3AN-06-5630 Civ

tell this jury in layman's terms what it means to be a brand leader in that position?
A. It's really two areas of responsibility: One was to be responsible for the marketing strategy for the U.S., and the second area was to make sure there was alignment across the organization around that strategy.

6. PAGE 84:16 TO 84:17 (RUNNING 00:00:03.033)

Q. You were Mr. Bandick's superior, were you not?

7. PAGE 84:20 TO 84:22 (RUNNING 00:00:05.833)

A. When he was the Zyprexa Brand Manager for that year, year and-a-half, he did report to me, yes.

8. PAGE 102:18 TO 102:22 (RUNNING 00:00:16.433)

Now you, during this time period from 1998 to 2003, where were you physically located in your job -- here in Indianapolis?
A. I was, yes.

9. PAGE 113:06 TO 113:13 (RUNNING 00:00:27.417)

Q. Thank you. Now from 1998 to 2003, you've told us your title regarding Zyprexa. Were you responsible for the marketing or brand leadership of any other Lilly products during that time period?
A. During that time period, I did have responsibility for a period of time for the Symbyax, the Symbyax marketing team.

10. PAGE 113:24 TO 114:04 (RUNNING 00:00:12.267)

Q. Symbyax for the jury, tell the jury what that product was?
A. Symbyax was and is a combination of Zyprexa-olanzapine, and Prozac-fluoxetine.

11. PAGE 136:07 TO 136:12 (RUNNING 00:00:14.267)

Q. At its heighth, at its heighth during the time you were Brand Leader and Marketing Director for Zyprexa in the United States, how many sales representatives were involved in the promotion and representation of Zyprexa?

12. PAGE 136:15 TO 136:16 (RUNNING 00:00:04.200)

A. We had, approximately, a couple thousand sales reps.

13. PAGE 136:22 TO 137:07 (RUNNING 00:00:19.867)

Q. Okay. And the sales division -- was there different sales forces in Eli Lilly?
A. Yes.
Q. Sigma Sales Force?
A. Yes.
Q. The -- and, of course, we know, and you would agree and tell this jury,

06 the Sigma Sales Force promoted Zyprexa,
07 correct?

14. PAGE 137:10 TO 138:06 (RUNNING 00:00:35.800)

10 A. They were the launch sales
11 force for primary care, yes.
12 Q. Then you have a Neuroscience
13 Sales Force; is that correct?
14 A. Yes.
15 Q. And that's a separate sales
16 force from the Sigma Sales Force; is it not?
17 A. Yes.
18 Q. And they were, the
19 Neuroscience Sales Force had job
20 responsibilities for promotion and detailing
21 of Zyprexa, do they not?
22 A. That was part of their
23 responsibility, yes.
24 Q. Then you had a Long-Term Care
00138:01 Sales Force, did you not?
02 A. We did, yes.
03 Q. And that was a separate sales
04 force from the Sigma Sales Force and the
05 Neuroscience Sales Force, correct?
06 A. Yes.

15. PAGE 163:09 TO 163:22 (RUNNING 00:00:31.033)

09 Q. Sir, can you testify whether
10 or not, in your opinion as the Marketing
11 Director and Brand Leader for Zyprexa, as to
12 whether or not Zyprexa was the single most
13 important product for Eli Lilly from at least
14 the fall of 2000 until the time you left in
15 2003?
16 A. Our CO had highlighted, I
17 believe, it was four or five products that
18 were going to be the priority during those
19 years.
20 Q. Did any product take a
21 priority over Zyprexa?
22 A. Not that I know of.

16. PAGE 164:15 TO 164:19 (RUNNING 00:00:10.467)

15 Q. Zyprexa was the biggest
16 profit maker for Eli Lilly from at least the
17 fall of 2000 until the time you left; is that
18 correct?
19 A. Yes.

17. PAGE 166:21 TO 166:22 (RUNNING 00:00:03.233)

21 Q. You're accompanied here today
22 by many lawyers, are you not?

18. PAGE 167:01 TO 167:02 (RUNNING 00:00:02.000)

00167:01 A. There are a lot of lawyers in
02 the room, yes.

19. PAGE 167:10 TO 167:20 (RUNNING 00:00:26.100)

10 Q. Okay. I have counted to your
11 right, Mr. Gold, Mr. Fahey, Ms. Greenberg,
12 Mr. Dinsmore, and Ms. Seabrook. Five lawyers
13 lined up along the table to your right; is
14 that correct?

A. That's correct. There are five lined up, yeah.
Q. Have you met or had interaction -- these are all lawyers either for yourself or for Eli Lilly, are they not?
A. I think so, yeah.

20. PAGE 168:14 TO 168:17 (RUNNING 00:00:06.400)

Q. Tell the jury how you know these individuals?
A. I met them in preparing for today.

21. PAGE 174:24 TO 175:10 (RUNNING 00:00:20.300)

Q. Let's assume then you left
00175:01 the company, and you told us you left the company in 2004. What lawyers have you met with concerning Zyprexa between the time you left the company in 2004 until today, besides Mr. Gold, Mr. Fahey, Ms. Greenberg and Ms. Seabrook?
A. Nina Gussack.
Q. And what law firm is she with?
A. She's with Pepper Hamilton.

22. PAGE 175:24 TO 176:14 (RUNNING 00:00:25.900)

What other lawyers did you
00176:01 meet with besides Mr. Gold, Mr. Fahey, Ms. Greenberg, Ms. Seabrook, and Nina Gussack, until the time you left Eli Lilly until today?
A. George -- I don't know his last name.
Q. Lehner? Mr. Lehner? He was back here earlier and then he left?
A. Yeah.
Q. Sir?
A. Yes.
Q. And he's from Pepper Hamilton and Eli Lilly's lawyers, correct?
A. That's my understanding, yes.

23. PAGE 189:17 TO 190:02 (RUNNING 00:00:22.200)

Q. Can you market a product -- can you promote a product off-label?
A. No.
Q. Why can't you promote a product off-label?
A. The regulatory environment in the U.S. is that you need to do studies, and get them approved by the FDA, and then your
00190:01 promotion needs to be consistent with the label that's granted by the FDA.

24. PAGE 209:15 TO 209:20 (RUNNING 00:00:10.266)

Q. I mean, Eli Lilly's medical department or sales reps are not entitled to call the doctor's office or go to the doctor's office and affirmatively discuss off-label uses, are they?
A. No.

25. PAGE 223:13 TO 223:17 (RUNNING 00:00:12.367)

Let me, before I do that, let me ask this: The on-label indication of schizophrenia is a diagnosis, is it not? Schizophrenia is a diagnosis?
A. It is, yes.

26. PAGE 223:22 TO 223:24 (RUNNING 00:00:07.100)

Q. Okay. Bipolar mania is a diagnosis, is it not?
A. Yes, it is, yes.

27. PAGE 236:04 TO 236:07 (RUNNING 00:00:09.133)

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.

28. PAGE 237:24 TO 238:06 (RUNNING 00:00:20.267)

Now, did the FDA ever approve
00238:01 Zyprexa as a mood stabilizer?
A. Did they ever approve it as a mood stabilizer? No.
Q. Did Lilly ever promote Zyprexa as a mood stabilizer?
A. Yes.

29. PAGE 243:24 TO 244:08 (RUNNING 00:00:20.200)

Q. So you did instruct your
00244:01 sales representatives to go to the doctors and discuss symptoms and not diagnoses first; is that correct?
A. Within the context of the sales process, describing the patient up front, we would talk about symptoms and then get into indications when we shared the data of the studies, yes.

30. PAGE 246:09 TO 246:13 (RUNNING 00:00:10.967)

Q. My question is: You at Eli Lilly knew there was not a specific indication in the primary care physician market to promote to primary care physicians. You knew that, did you not?

31. PAGE 246:16 TO 247:04 (RUNNING 00:00:30.767)

A. No. The patients were in the primary care physician's office, it was they were not diagnosing those patients.
Q. So Eli Lilly when it, according to you, when it marketed Zyprexa to primary care physicians was trying just to help the doctors do a better job of diagnosing their patients?
A. The research that we had, it
00247:01 was taking them, seven, eight, nine years to diagnose their patients in the primary care office so, yes, we did go there to help them with the diagnosis.

32. PAGE 296:17 TO 296:24 (RUNNING 00:00:18.867)

Q. My question is -- My question

is, sir, it would be wrong to encourage doctors and to drive a depression story on Zyprexa unrelated to schizophrenia or bipolar mania, correct?
A. If it's a promotional activity you can't promote for a depressive symptom outside of the core indications.

33. PAGE 297:18 TO 297:20 (RUNNING 00:00:03.427)

MR. ALLEN: Sir, I'm going to hand you what's been marked as Exhibit No. 5.

34. PAGE 301:20 TO 302:02 (RUNNING 00:00:12.467)

Q. Thank you, sir.
This e-mail concerned a conference call of December the 9th, 2000, did it not? "Hi Crew, wanted to give you a summary of the Zyprexa conference call that was held today." Right?
A. Yes.

35. PAGE 306:01 TO 306:07 (RUNNING 00:00:15.333)

Q. Now in this question and answer document it says "What if the doctor says," this is question No. 8 following question seven, "what if the doctor says I don't see those types of patients?" Do you see that question?
A. I do.

36. PAGE 308:18 TO 309:21 (RUNNING 00:00:59.600)

Q. Okay, go ahead. The document says: "The doctor's thinking that he does not see schizophrenic or bipolar patients."
Continue with reading the document, please, sir.
A. "But he probably does see patients with symptoms of behavior, mood, and thought disturbances."
Q. Or thought disorders -- disturbances, right?
A. Yes.
Q. Is there a difference between schizophrenic and bipolar patients and patients with behavior, mood, or thought disturbances?
A. There might or there might not be.
Q. Okay. Continue reading the answer to the question "what if the doctor says I don't see those types of patients?"
A. "Need to focus on symptoms and patient types of Martha, David, and Christine. Even if the doctor does not have diagnosis, he should treat anyway. He needs to treat the symptoms until a patient can see a psychiatrist. Ask him if he uses drugs like Haldol or risperidal, and Zyprexa has less side effects than either of them."

37. PAGE 318:15 TO 318:23 (RUNNING 00:00:19.766)

Q. My only question, there's only one question on this table, Mr. Jordan:

It would be wrong of Eli Lilly to train its sales representatives to tell doctors to go ahead and prescribe Zyprexa without a diagnosis of schizophrenia or bipolar manis. That would be wrong?
A. Anything that would be outside the label would be inappropriate.

38. PAGE 339:06 TO 339:11 (RUNNING 00:00:11.800)

Q. Wasn't thought, mood -- and my question, back to my original question, was Zyprexa ever indicated for thought, mood, or behavioral disorders?
A. Those aren't indications, so, obviously, not.

39. PAGE 342:08 TO 342:09 (RUNNING 00:00:03.533)

Q. Sir, do you recognize Exhibit No. 8 as coming from your files?

40. PAGE 342:11 TO 342:15 (RUNNING 00:00:07.500)

A. I don't know if it did or didn't. My handwriting's there, so.
Q. Yes, sir. That is your handwriting at the bottom, correct?
A. It is.

41. PAGE 343:02 TO 343:08 (RUNNING 00:00:13.267)

Q. Okay. It says: "Zyprexa is an agent of choice to help patients with debilitating thought, mood, and behavioral disorders achieve the highest level of long-term functioning." Did I read that correctly?
A. You did.

42. PAGE 344:16 TO 345:09 (RUNNING 00:00:32.400)

Q. Sir, do you remember the primary care physician launch in October of 2000?
A. I do.
Q. Were you intimately involved in that launch?
A. The person that reported to me, Mike Bandick, was responsible for the launch, yes.
Q. And so he had to report to you, so you had to approve his work, right?
A. Yeah. I had a good feel on what was going on, yes.
Q. You did not only have a good feel, you appeared at the launch, itself, and spoke to the audience in Orlando, Florida, correct?
A. I did.

43. PAGE 347:12 TO 348:04 (RUNNING 00:00:28.133)

Q. This was -- by the time of the launch of Zyprexa Year X was upon you, correct, by that time?
A. It was, yes.
Q. You had lost your patent protection on Prozac, right?

A. We had, yes.
Q. You were anticipating generic competition, correct?
A. We were.
Q. You knew you would have decreased revenues in Prozac, right?
A. We did.
Q. Prozac was your No. 1 selling multibillion dollar blockbuster as of that time, right?
A. It was.

44. PAGE 355:20 TO 356:02 (RUNNING 00:00:19.700)

Q. Isn't it true your entire company was geared up around the Viva Zyprexa primary care physician launch? Isn't it true, sir?
A. It was an opportunity that we certainly were excited about helping that patient group and increase revenues, yes.

45. PAGE 362:20 TO 363:03 (RUNNING 00:00:16.734)

You have read Exhibit No. 11, is that true?
A. I have, yes.
Q. It's a document that was represented came from your files. It's entitled Zyprexa Primary Care Strategy and Implementation Overview; is that correct?
A. It is, yes.

46. PAGE 363:16 TO 364:18 (RUNNING 00:00:56.300)

Q. I apologize. Maybe you could help the jury, just help the jury and tell the jury what a strategy and implementation overview is?
A. In the context of this document, it was a document that as I read it Mike Bandick put it together, must have been in the job for a month, maybe a little longer, just kind of his thoughts about where things were going to go.
Q. Mike Bandick, in fact, is the Brand Manager for Zyprexa in August of 2000, was he not?
A. For primary care, yes, he was.
Q. And Zyprexa was being launched into primary care, right?
A. It was, yes.
Q. That's -- the Viva Zyprexa launch is synonymous with the primary care physician launch; one in the same, right?
A. Yeah. That was the theme at the primary care launch was Viva Zyprexa, yes.
Q. And it had a song surrounding it, right?
A. It did, yes.

47. PAGE 366:19 TO 366:23 (RUNNING 00:00:11.366)

Q. Right. And Eli Lilly viewed the potential market for Zyprexa in the primary care market as a huge market, right?

A. No. It says this customer group is huge.

48. PAGE 368:05 TO 368:14 (RUNNING 00:00:24.300)

Q. Right. Was one of the challenges listed for launching in the primary care physician market is it listed as follows: "Zyprexa's primary indications, schizophrenia and bipolar, are not viewed as PCP-treated conditions. So there's not a specific indication for Lilly representatives to promote in the PCP market."
Did I read that correctly?
A. You read that correctly.

49. PAGE 369:02 TO 369:11 (RUNNING 00:00:26.467)

Q. He said, quote/unquote, there's not a specific indication for Lilly representatives to promote in the PCP segment, didn't he, sir?
A. He was relatively new on the job. And consistent with what I said earlier is the patients, our research showed that the patients were in the primary care physician's office, they just weren't being identified and treated.

50. PAGE 373:22 TO 375:07 (RUNNING 00:01:20.700)

Q. Okay, sir. Anyhow, the position, tell the jury again if you haven't already, can you explain to the jury what a
00374:01 position is with regard to a medical product such as Zyprexa? What a position is?
A. A position is, ultimately, how you want your customers to think about your product.
Q. Right. And the position listed in this document is "the safe, proven, solution for mood, thought, and behavioral disorders;" is that correct?
A. That's how Mike wrote it in this document, yes.
Q. The very next sentence says, begins, "We will emphasize safety to address the barriers to adoption." Did I read that correctly?
A. You did.
Q. And when you say "will emphasize safety," that means we, in positioning the product for our customers, including the doctors, will emphasize to them that this product is safe, right?
A. As written in this document, yes.
Q. Then going down under
00375:01 position it says, "quote, mental disorders, close quotes, is intentionally broad and vague providing latitude to frame the discussion around symptoms and behaviors rather than specific indications."
Did I read that correctly?
A. You did.

51. PAGE 388:07 TO 388:23 (RUNNING 00:00:38.166)

Q. Now after the launch of Zyprexa into the primary care market, you, in the marketing as the brand leader didn't just leave things to chance, you wanted to see if the proper message was getting out to the doctors, didn't you?
A. We did do message recall, yes.
Q. And you wanted to see whether or not your campaign had been successful and doctors were responding to your message; isn't that true?
A. With all our segments we did do message recall, yes.
Q. Who is Zohar Porat?
A. She was a market research associate.

52. PAGE 389:06 TO 389:20 (RUNNING 00:00:33.234)

MR. ALLEN: Sir, I'll hand you what's been marked as Jordan Exhibit No. 13.
MR. GOLD: Thank you, sir.
QUESTIONS BY MR. ALLEN:
Q. This is entitled Qualitative Telephone Focus Groups, Sales Rep and DM -- DM stands for district managers, doesn't it, sir?
A. It does, yes.
Q. Sales Rep and District Manager Topline Reaction to PCP Launch, December 2000, Zohar Porat, Lilly, Answers That Matter; is that correct?
A. Yes.

53. PAGE 396:07 TO 397:08 (RUNNING 00:01:06.067)

Q. Of the Sales Rep and District Manager Topline Reaction to the Primary Care Physician Launch. Can you read for the jury out loud the first bullet point under Recommendations?
A. Now, I'm going to assume this is a summary, given, you haven't given it to me, of the first part of the detail piece where they talk about symptoms and then go on to diagnosis as part of the message which is what I saw trained. So in that context: "Continue focusing on patient symptomology and having PCPs identify specific patients rather than on patient diagnosis."
Q. Let's see if I can read this a little slower for the jury. The first bullet point under Recommendations on the last page of Exhibit 13 reads as follows:
00397:01 "Continue focusing on patient symptomatology
02 and having primary care physicians identify
03 specific patients rather than on patient
04 diagnoses." Did I read that correctly?
05 A. You're reading's correct but
06 I don't know, I don't know that it's
07 represented correctly without seeing
08 everything.

Zyprexa-Alaska

54. PAGE 413:06 TO 413:08 (RUNNING 00:00:05.200)

Q. Donna. You remember Donna, do you not, sir?
A. I do, yes.

55. PAGE 421:05 TO 421:13 (RUNNING 00:00:19.767)

Q. Now, sir, let's go to Exhibit 15. Are you there with Donna?
A. On Page 4, yes.
Q. Yes, sir. We have a circle next to Donna that says "anxiety, irritability, mood swings, and disrupted sleep," right?
A. Yes. Those are what's identified.

56. PAGE 422:16 TO 423:06 (RUNNING 00:00:36.534)

Q. And now we go to the page on Donna. It says, "Donna. Single mom in her mid-30s, presents in drab clothing and seems ill at ease. Quote, I feel so anxious and irritable lately, close quotes. Her history is: Reports she has been sleeping more than usual, has trouble concentrating at work and at home. Several appointments earlier she was talkative, elated, and reported little need for sleep."
Next bullet point: "You have treated her with various medications including antidepressants."
Did I read that correctly?
A. You did.

57. PAGE 436:14 TO 436:22 (RUNNING 00:00:21.800)

Q. Are you at the page Zyprexa Primary Care Vision and Strategy?
A. I am. 71?
Q. Yes. And the vision for the PCP launch was "expand Zyprexa's market by redefining how primary care physicians treat mood, thought, and behavioral disturbances." Did I read that correctly?
A. You did.

58. PAGE 437:20 TO 438:07 (RUNNING 00:00:30.000)

Q. And, in fact, Zyprexa, Page 72, Strategic Intent says: "Zyprexa can and will become an everyday agent in primary care," correct?
A. Given that antidepressants are one of the most frequently used products by primary care physicians, and if you think about potentially up to a third actually have bipolar disorder, there was the opportunity that doctors would write it every day. Primary care physicians would write it every day, yes.

59. PAGE 456:06 TO 458:10 (RUNNING 00:02:13.933)

Q. You're familiar with the 2001 marketing plan, aren't you?
A. I am, yes.
Q. Okay. You signed the letter

attached to the 2001 marketing plan, did you not?
A. I did, yes.
Q. I will read your letter, portions into the record. Turn to your letter.
"Dear Zyprexa Teammates, Last year, you often hesrd me say "2000 is the critical year." Now that 2000 is complete, we can be proud that we delivered outstanding results in the critical year -- all caps the, exclamation points. We had many successes, not the least of which was that we fulfilled our promise by selling $1.7 billion of Zyprexa. We launched into new markets, launched a new indication, launched new formulations, forged new relationships with a broader range of customers, improved our internal alignment, and re-established the Zyprexa Team as truly incredible. Thanks for the outstanding performance in 2000. Exclamation point.
The "blank" patent expiration" -- that would be the Prozac expiration, wouldn't it?
A. I'm assuming.
Q. "The Prozac patent expiration presents Lilly with even greater challenges than anticipated and provides new opportunities for the Zyprexa team. Oddly enough, 2000 may be, all caps, the critical year. But 2001 is different -- it's not just critical -- it's a chance to do the extraordinary. Yes, we face challenges. We have to deliver over $400 million of incremental net sales in the same year that Zeldox is launching, and our current competitors will continue to challenge us."
Did I read that correctly?
A. You did, yes.
Q. The title of the or the theme of the 2001 marketing plan was Limitless, isn't that true? Limitless?
A. It was, yes.
Q. That's how you positioned your marketing plan for the year 2001?
A. It was the position for what I would hope that people would have a year of top level performance, yeah.

60. PAGE 459:14 TO 459:21 (RUNNING 00:00:20.434)

Q. Yes. And the high level position of the position on diabetes is at follows, I'm reading: Quote, "Diabetes may occur in patients taking antipsychotics and/or mood stabilizers. Zyprexa and other agents have a comparable rate of diabetes." Did I read that correctly?
A. You did, yes.

61. PAGE 461:12 TO 462:10 (RUNNING 00:00:58.333)

Q. Right. I've handed you Exhibit 22. It's Issues Management Planning Diabetes.
You've seen this document

before, have you not, sir?
A. I don't know.
Q. Do you see on the second page "Diabetes. Our Position?" The second page, "Diabetes. Our Position?"
A. Yes.
Q. And doesn't it say just like the 2001 marketing plan, "our position is stated as "Diabetes slash hyperglycemia may occur in patients taking antipsychotics and/or mood stabilizers, including Zyprexa, at comparable rates with the possible exception of Clozapine." Doesn't it say that?
A. It does.
Q. And isn't that consistent with the stated position on diabetes as contained in the 2001 marketing plan?
A. Yes.

62. PAGE 464:18 TO 465:06 (RUNNING 00:00:35.833)

Q. And the rationale for the position as stated in Exhibit 22 is "showing that diabetes is a common occurrence for all antipsychotics and not just Zyprexa will help reduce the perception that diabetes is linked, specifically, to Zyprexa, and in turn, will help to eliminate this risk from the risk/benefit equation." Isn't that what it says?
A. It does say that, yes.
Q. Yes. And so wasn't Eli Lilly trying to reduce the perception that diabetes is, specifically, linked to Zyprexa?

63. PAGE 465:08 TO 465:19 (RUNNING 00:00:36.400)

A. Again, as our medical folks did extensive analysis, we saw diabetes as an issue in this patient population because of its incidence. And as they reviewed the data it was comparable across products.
The concern was if the confusion in the marketplace made choosing a product just on one specific attribute and not see the entire, all the data for all the molecules, we were concerned that physicians might make an inappropriate choice for that specific patient.

64. PAGE 490:22 TO 490:24 (RUNNING 00:00:06.834)

Q. What is Project BAD? Do you remember Project BAD?
A. I do, yes.

65. PAGE 492:18 TO 493:23 (RUNNING 00:01:13.133)

Q. Okay, sir. Exhibit 25 is Project BAD, August the 2nd, 2002. Defining Success. Do you see that, sir, Defining Success, the second category?
A. Yes, I do.
Q. The third bullet point under Defining Success of Project BAD, can you read that out loud to the jury, please?
A. It says, "Reduce negative

Zyprexa-Alaska

impact of diabetes issue on the Zyprexa business."

Q. Yes, sir. Now, did you or did you not, in marketing, try to reduce the negative impact the issue of diabetes was having on the Zyprexa business?

A. Insofar as customers were -- there was a lot of confusion in the marketplace and we felt like if we could clear up that confusion through good data, we thought it would have a positive impact on the business, yes.

Q. What was the confusion?

A. A lot of -- I shouldn't say -- we were hearing from the marketplace through market research that they were hearing that Zyprexa was causing diabetes. Even went so far as some customers saying they heard that Zyprexa was going to be pulled from the market because of a diabetes issue.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:27:28.693)

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered plaintiff State of Alaska's Motion in Limine to Preclude Testimony or Argument that Zyprexa's® Labeling "Warned" of Diabetes, Hyperglycemia or Weight Gain, defendant Lilly's Opposition, as well as applicable law:

IT IS HEREBY ORDERED that Plaintiff's motion is DENIED.

ORDERED this 3rd day of ~~February~~ March, 2008.

Mark Rindner

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 27, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-3911

009867\0038\163653.1

I certify that on 3-3-08 a copy of the above was mailed to each of the following at their addresses of record:

Sanders Jamieson

Administrative Assistant

FEB 27 2008

LANE POWELL LLC
301 West Northern Lights Boulevard, Suite 301
Anchorage, Alaska 99503-2648
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

ORDER

Eli Lilly's Motion Requesting Confidential Protections of Regulatory Communications Not Subject to Public Disclosure is denied. The Court finds that the public's right of access to the Court, particularly in a case involving the State, and the First Amendment considerations involved outweigh the interest Lilly seeks to protect. This is particularly true where, as in the case, Lilly seeks not just to keep confidential records filed with the Court, but to prevent the public and the media from attending trial when such records are being discussed. The cases cited by Lilly in support of its motion generally involve the protection of records filed with the Court, rather than the public or media's right to attend trial. The public right of access to trials is well established and inherent in the nature of our democratic form of government. Globe Newspaper Co. v. Superior Court,

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457 U.S. 596, 604-05 (1982). Lilly has failed to demonstrate an overriding interest sufficient to overcome the public interest in public court proceedings.

DATED at Anchorage, Alaska, this 3rd day of March 2008.

MARK RINDNER
Superior Court Judge

I certify that on March 3, 2008 a copy was mailed to:
E. Sanders B. Jamieson
Administrative Assistant

A

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

ORDER

The State has requested clarification of this Court's Orders Excluding Evidence of Other Drugs Manufactured by Defendant and Defendant's Profits, Net Worth and the Price of Zyprexa. The motion is granted. The State may introduce such evidence for the limited purpose of demonstrating Lilly's motivation to act in the manner that is the subject of this litigation. Such evidence may not be introduced for any other purpose.

IF such evidence is introduced the Court will deal with objections to such evidence at trial. If Lilly wishes, it may draft and request an instruction be given to the jury explaining the limited purpose for which such evidence may be considered.

DATED at Anchorage, Alaska, this 3rd day of March 2008.

MARK RINDNER
Superior Court Judge

I certify that on March 3, 2008 a copy was mailed to:
E. Sanders B. Jamieson

Administrative Assistant

A

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

STATE OF ALASKA,

Plaintiff,

Case No. 3AN-06-05630 CI

ELI LILLY AND COMPANY,

Defendant.

DEFENDANT ELI LILLY AND COMPANY'S SUPPLEMENTAL EXHIBIT LIST

Defendant Eli Lilly and Company ("Lilly") hereby files its supplemental exhibit list to the Joint Exhibit List filed by the State. These supplemental exhibits, listed below, are merely larger font versions of the Zyprexa® warning label. Lilly has previously designated smaller font versions of these exhibits and they appear on the Joint Exhibit List. For ease of reference, Lilly has kept the same number for the exhibit but has added an "A" to the exhibit number to identify the larger font version. Lilly has served these exhibits on Plaintiff on March 3, 2008.

EL-2937-A	Zyprexa Label In Effect on 04/12/2000 – Large Font
EL-2953-A	Zyprexa Label In Effect on 09/16/2003 – Large Font
EL-2954-A	Zyprexa Label In Effect on 10/02/1996 – Large Font
EL-2945-A	Zyprexa Label In Effect on 01/14/2004 – Large Font

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A

DATED this 3rd day of March, 2008.

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

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

I certify that on March 3, 2008, a copy of the foregoing was served by hand on:

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Feldman Orlansky & Sanders
500 L Street, Suite 400
Anchorage, Alaska 99501-2911

_____

doc\607.0038\163720.1

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A

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

RESPONSE TO STATE'S SUBMISSION OF EXHIBITS TO BE PRE-ADMITTED FOR USE DURING OPENING STATEMENT

On February 29, 2008, the State of Alaska filed its Submission of Exhibits to be Pre-admitted for use During Opening Statements. In response defendant Eli Lilly and Company ("Lilly") submits this short response to supplement its previously filed Motion to Rule on Before-Trial Admission of the State's "Pre-Admit" List.

Set forth below are 1) Lilly's objections to the seven documents the State has just added to its Pre-Admit list and 2) the identity of the exhibits that the State has indicated it intends to use in its opening statement, but whose inadmissibility has already been determined by the Court's rulings on Lilly's *motions in limine*.

A. Objections to exhibits recently added to the State's pre-admit list

The following chart lists the State's seven 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 of Exhibit "A" delineates each of the bases for Lilly's objections to each document. The State submitted copies of these documents to the Court in its February 29 filing.

A

	Trialx#	Objections
1	1941	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal sales representative training material. Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
2	2133	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal document regarding proposed actions, M.I.L. regarding Foreign Regulatory Actions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
3	3238	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing plan Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Foundation (Alaska R. Evid. 901)
4	3278	Subsequent Remedial Measures (Alaska R. Evid. 407)
5	10003	Hearsay; agree to admit – notice
6	10035	M.I.L. regarding Profits and Price Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal communication related to potential line extensions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
7	10153	Hearsay; agree to admit – notice

B. Documents whose admissibility has already been decided by the Court's *Motion in Limine* rulings

On February 22, 2008, the Court granted several of Lilly's *Motions in Limine* excluding evidence relating to various discrete topics. Some of the documents the State has advised it intends to use in its opening statement are covered by these rulings. The documents whose inadmissibility has already been determined by the *Motions in Limine* rulings are set forth

below. The State has previously submitted these documents to the Court, and represented that it has highlighted the portions it intends to use in its opening statement.

Trialx#	*Motion in Limine*
3924	Covered by *Motion in Limine* ruling regarding profits and price.
5846	Covered by *Motion in Limine* ruling regarding profits and price.
6215	Covered by *Motion in Limine* ruling regarding profits and price.
7822	Covered by *Motion in Limine* ruling regarding profits and price.
8584	Covered by *Motion in Limine* ruling regarding profits and price.
10061	Covered by *Motion in Limine* ruling regarding profits and price.
10035	Covered by *Motion in Limine* ruling regarding profits and price.
320	Covered by *Motion in Limine* ruling regarding adverse events.
1169	Covered by *Motion in Limine* ruling regarding promotional activity outside of Alaska.

DATED this 3rd day of March, 2008.

Attorneys for Defendant

PEPPER HAMILTON LLP
Nina M. Gussack, admitted *pro hac* vice
George A. Lehner, admitted *pro hac* vice
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By: _____
Brewster H. Jamieson,
ASBA No. 8411122
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ASBA No. 0211044

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-5630 CI

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DATED this 3rd day of March, 2008.

Attorneys for Defendant

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

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

THE STATE OF ALASKA'S OBJECTIONS TO ELI LILLY AND COMPANY'S STATEMENT OF THE CASE

At the February 22, 2008 status conference in this matter, the Court indicated it wanted a short statement of the case from each of the parties which informed the jury what the case was about. The Court stressed that this was "not oral argument" and that what it was looking for was something "brief" and "neutral."[1] The Court further stressed that the statement is not intended to provide either party an "unfair advantage."[2] The Court explained what it was looking for in a hearing on February 27, indicating the statement should be delivered "in more neutral terms than you might in opening statement and in a short, concise fashion."[3] The Court admonished the parties to "avoid a

[1] Exhibit A, Transcript of Pretrial Hearing before the Honorable Mark Rindner, February 22, 2008, 13-14.
[2] *Id.*, 14.
[3] Exhibit B, Transcript of Pretrial Hearing before the Honorable Mark Rindner, February 27, 2008, 27.

A

lot of adjectives and adverbs in your description because those will end up making more objectionable."[4] Finally, the Court stressed that it did not want the parties' statements "to go too far in terms of advocacy of what is supposed to happen in your openings statements."[5]

On March 1, 2008, the State received Eli Lilly and Company's Statement of the Case. The statement submitted by Lilly is contrary to the Court's request in that it is lengthy, argumentative and clearly goes too far in terms of advocacy, potentially resulting in an unfair advantage to Lilly before the jury is even impaneled. From the outset, the statement is argumentative and filled with hyperbole. Moreover, Lilly's statement presents arguments on matters which may not even be presented to the jury as evidence. For example, the first paragraph states that Zyprexa can prevent patients from experiencing "a living hell that most people cannot imagine."[6] Lilly goes on in the statement to assert that in certain situations "someone from inside the office of the Attorney General will ask a judge in this building" to order the administration of Zyprexa against a patient's will.[7]

Instead of explaining in a short, concise fashion what the case is about so that questions can be asked in voir dire to determine bias of potential jurors, Lilly attempts to

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[4] *Id.*
[5] *Id.*, 28.
[6] Exhibit C, Eli Lilly and Company's Statement of the Case.
[7] *Id.*

cast aspersions on the State's actions and in doing so misrepresents what the evidence in this case will ultimately show. While the Court wanted the parties to avoid an opening statement, Lilly goes even further, turning its statement of the case into a closing argument based on material which may not be available for such argument at the close of the evidence. This is not what the Court directed the parties to provide for a brief explanation of the case prior to jury selection.

For the foregoing reasons, the State objects to Lilly's Statement of the Case.

Respectfully submitted this 3rd day of March, 2008.

FELDMAN, ORLANSKY & SANDERS

Counsel for Plaintiff

BY _____

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Counsel for Plaintiff

CERTIFICATE OF SERVICE

Plaintiff, State of Alaska, hereby certifies that it has caused to be served upon the individuals listed below a copy of Memorandum in Support of Plaintiff's Motion to Compel via hand delivery on March 31st, 2008.

Respectfully submitted,

Eric T. Sanders
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COUNSEL FOR PLAINTIFF

Defendant's Counsel

Brewster Jamieson
Lane Powell
301 West Northern Lights Blvd, Ste 301
Anchorage, AK 99503-2648

Dated: March 31st, 2008

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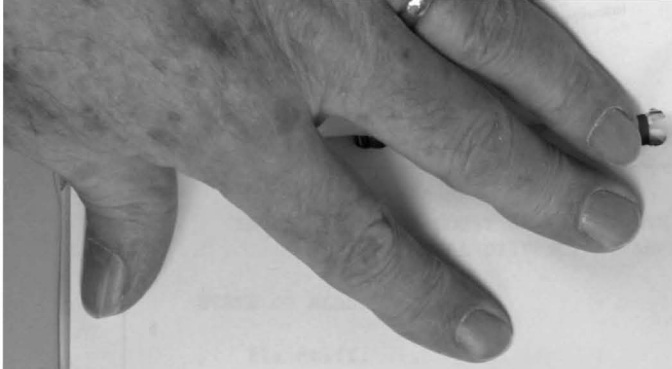

EXHIBIT A

A

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

STATE OF ALASKA,

Plaintiff,

vs.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

PRETRIAL HEARING
BEFORE THE HONORABLE MARK RINDNER

February 22, 2008

emergency so I can get an idea of what jurors aren't able to sit through a three-week trial without it becoming a hardship or emergency as that's defined. And I usually don't rule on those immediately. I just ask people to identify themselves and let you explore that further during the course -- at some point, during the proceedings and during the introduction to the jurors, the jurors need to be described what the nature of the case is so that they can answer questions down the road as to, you know, is there something about this kind of case that's going to make them not able to serve on a jury?

I used to do that by trying to do a very vanilla short thing that I would read, but I've tried to switch that to give you each sort of a minute or two minutes to describe your case because we found it engages the jurors a little bit more if you can describe your case in a way -- I don't want a lot of argument. This is not oral argument. But I want you to be able to tell them that, basically, this is a case about a drug that's being manufactured and what the claims are, and something about it just without getting into a lot of detail so they know what

the case is about. So if you each want to prepare something that's short that will just be a brief -- neutral is what I'm looking for -- description of the case that I can see and make sure that everybody's comfortable and nobody thinks somebody is getting some unfair advantage at that point, just so that the jurors can be told this is what the case is about and this is why we're going to ask you to spend time with us for the next three weeks that hopefully will excite them about that rather than discourage them from that.

MR. JAMIESON: Your Honor, would you envision that that's -- we submit you a blurb, submit them a blurb, you would look it over --

THE COURT: Right. Make sure everybody is okay with that. And that will then be the blurb that will -- when I go through what I do with the panel when they first come in --

MR. JAMIESON: Would you be reading that to the jury or would --

THE COURT: Well, I can do it either way. I don't care. Again, part of what I'm trying to do here and why I've sort of

EXHIBIT B

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

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

PRETRIAL HEARING
BEFORE THE HONORABLE MARK RINDNER

February 27, 2008

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

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

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

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

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

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

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

EXHIBIT C

ELI LILLY AND COMPANY'S STATEMENT OF THE CASE

You are here because the State of Alaska sued our client, Eli Lilly and Company, a pharmaceutical company. Lilly discovered Zyprexa, and it has sold this medication across the world for almost a dozen years. For the seriously mentally ill, it can restore life where, untreated, patients would experience a living hell that most people cannot even imagine. Since 1996, doctors in Alaska in private practice; doctors employed by hospitals; and doctors employed by the State at API have prescribed Zyprexa. In that time, the State of Alaska has, through its Medicaid program, paid for thousands of prescriptions for this medication. The medicine is so effective that when the State mental hospital here in Anchorage has a psychotic patient who needs the medication, but refuses to take it, someone from inside the office of the Attorney General of the State of Alaska will ask a judge in this building for permission to give this medicine to the patient against the patient's will.

Although to this day, the State continues to pay for the medication; and although to this day, the State has never told doctors not to prescribe it; and although to this day, the State has not restricted how or when doctors may prescribe Zyprexa, it claims that Lilly deceived the State about Zyprexa's side effects. You will have to resolve – either in favor of the State (if it proves its case), or in favor of Lilly (if the State fails to prove its case). The State claims that Lilly failed to adequately warn the State of Alaska and physicians in Alaska of these alleged side effects of Zyprexa.

Doctors, employees of the State, Lilly employees and expert witnesses will tell you how the federal government regulates the sale of medications across the country, and you will learn how the Medicaid program here regulates the availability of medications. Then, Judge Rindner will ask you to decide the issues here. When he explains the law to you, he will tell you

that the State cannot win this case unless it fulfills its responsibility to prove the truth of its claims to you. If it does not, then Judge Rindner will tell you to find in favor of Lilly.

Eski, Joey L. (Vol. 01) - 03/02/2008 1 CLIP (RUNNING 00:37:53.868)

RPWB Desig

ESKI 3 8 08 108 SEGMENTS (RUNNING 00:37:53.868)

1. PAGE 8:22 TO 9:15 (RUNNING 00:00:35.737)

JOEY L. ESKI,
having been sworn, testified as follows:
EXAMINATION
Q (BY MR. ALLEN) Good morning.
A Good morning.
Q How are you today?
A I'm fine. How are you?
Q Fine.
Can you tell the jury your name, please?
A Joey L. Eski. Joey L. Eski.
Q For whom do you work?
A Eli Lilly and Company.
Q And what is your current job for Eli Lilly and Company?
A I am currently an executive sales representative with the neuroscience division, and I am a specialty rep in the community mental health centers.

2. PAGE 10:08 TO 10:11 (RUNNING 00:00:09.678)

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.

3. PAGE 10:15 TO 10:23 (RUNNING 00:00:30.051)

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.

4. PAGE 12:18 TO 12:22 (RUNNING 00:00:11.834)

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?

5. PAGE 13:03 TO 13:08 (RUNNING 00:00:14.650)

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 --

6. PAGE 25:10 TO 25:17 (RUNNING 00:00:18.000)

What I was trying to get back to, let me explain to you about a deposition.
A Sure.
Q And you're doing great. You're doing fantastic. And I'm sure, like I said, if you have any problems, let me know and I'll try to help you out. Okay?
A Okay.

7. PAGE 27:02 TO 27:18 (RUNNING 00:00:37.000)

Q The other thing you're going to have to do and, again, it's just a little bit different than talking informally, is you're going to have to give yes or no answers or whatever explanation you feel is necessary, other than um-hms or uh-huhs. And a couple of times you've done that --
A Sure.
Q -- which is normal. That's normal conversation. But you're just going to have to give yeses or no's.
Do you understand that?
A I do.
Q And I hope you don't think it's rude that if I hear you say uh-hm or uh-huh, I will ask you if that was a yes or a no. Okay?
A That's fine. It's probably my nerves.

8. PAGE 29:20 TO 29:23 (RUNNING 00:00:05.841)

How long have you worked for Eli Lilly?
A This is my tenth year of service with Eli Lilly.

9. PAGE 36:03 TO 36:05 (RUNNING 00:00:04.098)

Q And you moved up here to Alaska in '97 or '98, in that period?
A Yes.

10. PAGE 36:11 TO 36:13 (RUNNING 00:00:06.912)

Q Okay. And what were you -- what was your job when you were hired in September of '98?
A Sales representative in neuroscience.

11. PAGE 40:23 TO 41:12 (RUNNING 00:00:23.000)

Q Would Ms. Cramer also detail the same doctors as you did?
A Exactly same doctors.
00041:01 Q And you all would make different visits at different times?
A That's correct. We had what we call a routing, yes.
Q And you both promoted Zyprexa?
A We did.
Q And that was your job as a sales rep, to promote Zyprexa, right?
A That's part of it, yes.
Q What was the other part?
A To be a resource to the physicians, a face for Eli Lilly.

12. PAGE 42:23 TO 43:10 (RUNNING 00:00:35.090)

Q (BY MR. ALLEN) Okay. When you walk in, you have detail pieces in hand, do you not?
A Not always.
00043:01 Q Okay. Not always. You often have detail pieces in hand?
A Probably not as much as you think I do. I mean, it's not -- it depends where I'm going, what physician I'm seeing.
Q Okay.
A A detail piece is something that I use as a guide. If someone has a question and there's an answer to their question in my detail piece, then I'll pull it out and use it.

13. PAGE 44:19 TO 44:23 (RUNNING 00:00:13.204)

So when new detail pieces come out or changes are made to detail pieces, Eli Lilly doesn't just leave it to you to try to figure it out. They provide you with training materials about how to talk about that detail piece, right?

14. PAGE 45:01 TO 45:01 (RUNNING 00:00:02.060)

00045:01 A Sure.

15. PAGE 45:02 TO 45:12 (RUNNING 00:00:18.283)

Q (BY MR. ALLEN) And they give you written material that instructs you as how you're supposed to speak about that detail piece, correct?
A It's a guide. It's a guide, an idea.
Q Right. They're called resource guides?
A Sometimes.
Q Or they're called implementation guides?
A Uh-huh.
Q Is that a yes?
A Yes.

16. PAGE 50:02 TO 50:09 (RUNNING 00:00:17.611)

Q Ma'am, I've handed you what's been marked as Exhibit 1. This is -- do you recognize this as LillyUSA Sales -- Sales Good Promotional Practice, Definition of a Sales Call and Call Notes, Eli Lilly and Company, February, 2001?
A Uh-huh.
Q Have you seen this before?
A I have.

17. PAGE 52:14 TO 53:11 (RUNNING 00:00:47.523)

Q (BY MR. ALLEN) Now, we go under the definitions. You see the definition of a call note?
A I do.
Q It's a business record documented within a call system that accurately reflects all aspects of a sales call.
Did I read that correctly?
A You did. Yes, you did.
Q In the Information and Procedures section I want to read you to -- the goal. Do you see the goal of a sales call?
00053:01 A Yes.
Q This is Eli Lilly's words, not Scott

Allen's: The goal of a sales call is to appropriately influence a health care professional using the approved Lilly product information to allow him or her to choose the best therapy for his or her patients and ultimately to increase the sales of Lilly's products.

Did I read that correctly?

A You did.

18. PAGE 56:13 TO 56:19 (RUNNING 00:00:12.429)

Q I apologize. It was previously marked as Noesges Exhibit No. 8. I'll hand one to you and one to your counsel. I appreciate your attention to that matter. This is also a Lilly Good Promotional Practices document.

Do you see that?

A I do.

19. PAGE 57:13 TO 57:24 (RUNNING 00:00:30.207)

Q All right. Off-label information. I'm going to read the definition given to you: Any information about a Lilly product that is not contained in or is not consistent with the package insert labeling approved by the FDA. Examples include, but are not limited to, indications, dosage forms, dosing schedules, combination therapy and safety information.

Do you see that?

A Uh-huh.

Q Is that a yes?

A That is a yes.

20. PAGE 59:02 TO 59:07 (RUNNING 00:00:15.872)

Q So whatever information you gave to the health care professionals concerning the safety profile and side effect information on Zyprexa was within the label, correct?

A Yes. I would have given whatever was available to me at the time.

21. PAGE 67:01 TO 67:03 (RUNNING 00:00:03.553)

00067:01 Q Do you remember the Alaska State Action Team?

A I do, uh-huh.

22. PAGE 71:07 TO 71:17 (RUNNING 00:00:23.917)

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.

23. PAGE 71:23 TO 72:09 (RUNNING 00:00:30.542)

Q Now, you understand -- I'm sure you do -- that the Medicaid system picks up the bill for Medicaid patients here in Alaska, right?

00072:01 A Sure.
02 Q And you understand that the State
03 obviously has an interest in trying to do that as
04 economically as possible; you understand that?
05 A I do.
06 Q And you understand that there have been
07 proposals at times to restrict the sale and
08 distribution of certain drugs in order to change
09 the formulary; do you understand that?

24. PAGE 72:14 TO 72:20 (RUNNING 00:00:15.793)

14 A The State of Alaska proposed a preferred
15 drug list, which is not a restriction --
16 Q That's right.
17 A -- and so physicians, no matter mental
18 health or what type of physician they are, they
19 can always write on a prescription "medically
20 necessary," if it's a preferred drug list.

25. PAGE 75:04 TO 75:07 (RUNNING 00:00:09.245)

04 Q Well, you had a concern or your bosses
05 had a concern about the State prior authorization
06 pending State legislation, did they not?
07 A I don't remember.

26. PAGE 75:11 TO 75:17 (RUNNING 00:00:10.555)

11 Q Exhibit 3.
12 A Sure.
13 Q There's an e-mail that you wrote in
14 April of 2003. Do you see that?
15 A Uh-huh.
16 Q Is that yes?
17 A Yes, yeah.

27. PAGE 76:06 TO 76:08 (RUNNING 00:00:06.209)

06 Q Where do these people work?
07 A The ones that I can identify are
08 psychiatrists.

28. PAGE 77:05 TO 77:19 (RUNNING 00:00:39.717)

05 Q Okay. Well, you're sending -- what are
06 you sending them?
07 A I am sending them -- I did not prepare
08 these documents, so the attachments are not mine.
09 I'm sending them letters that they can look at
10 as -- I think they were just like ideas of what
11 to write.
12 Q What to write who?
13 A To their -- Frank Murkowski or Joel
14 Gilbertson.
15 Q Right. Your e-mail and your carbon copy
16 to Jeff Hattori -- who is Mr. Hattori?
17 A Jeffrey Hattori is one of the public
18 health representatives, but he's actually -- his
19 focus is advocacy.

29. PAGE 81:16 TO 81:18 (RUNNING 00:00:06.000)

16 Q And this is signed Joey Eski, Eli Lilly
17 and Company, right?
18 A That's right.

30. PAGE 82:13 TO 83:02 (RUNNING 00:00:34.494)

13 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?

31. PAGE 83:05 TO 83:17 (RUNNING 00:00:22.969)

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.

32. PAGE 84:02 TO 84:18 (RUNNING 00:00:42.143)

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.

33. PAGE 85:01 TO 85:10 (RUNNING 00:00:24.908)

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.

34. PAGE 85:23 TO 86:11 (RUNNING 00:00:24.577)

Q You were trying to get no restrictions on any mental health drugs, according to you,

including but not limited to Zyprexa, correct?
00086:01 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.

35. PAGE 86:16 TO 86:18 (RUNNING 00:00:11.787)

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.

36. PAGE 88:06 TO 88:13 (RUNNING 00:00:11.143)

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.

37. PAGE 89:08 TO 89:11 (RUNNING 00:00:07.134)

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.

38. PAGE 90:16 TO 90:24 (RUNNING 00:00:24.177)

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.

39. PAGE 92:14 TO 92:23 (RUNNING 00:00:30.756)

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.

40. PAGE 93:05 TO 93:06 (RUNNING 00:00:04.024)

Q I'm sorry. And the P&T committees are located where? At the hospitals?

41. PAGE 93:11 TO 93:15 (RUNNING 00:00:11.227)

A This is -- it started out at the office

of the State Medicaid.
Q Excuse me. The State Medicaid office.
A And, then -- now they are in the Frontier Building.

42. PAGE 97:21 TO 98:24 (RUNNING 00:01:06.560)

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.

43. PAGE 99:09 TO 99:14 (RUNNING 00:00:13.381)

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.

44. PAGE 103:19 TO 104:07 (RUNNING 00:00:44.306)

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?

45. PAGE 104:10 TO 104:10 (RUNNING 00:00:01.236)

A You read it correctly.

46. PAGE 104:14 TO 104:16 (RUNNING 00:00:06.002)

Q And you were involved in the process of trying to influence the Alaska State legislature, were you not?

47. PAGE 104:19 TO 104:20 (RUNNING 00:00:02.125)

A I don't know how to answer your question. I'm sorry.

48. PAGE 107:04 TO 107:11 (RUNNING 00:00:19.620)

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?

49. PAGE 107:14 TO 107:23 (RUNNING 00:00:28.853)

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.

50. PAGE 112:24 TO 113:14 (RUNNING 00:00:45.579)

Q (BY MR. ALLEN) Okay. Exhibit 6. Subject line is all caps, Urgent, three
00113:01 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.

51. PAGE 115:22 TO 116:11 (RUNNING 00:00:38.000)

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.
00116:01 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.

52. PAGE 116:21 TO 117:02 (RUNNING 00:00:18.000)

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.
00117:01 Did I read that correctly?
A Yes.

53. PAGE 117:21 TO 117:24 (RUNNING 00:00:07.441)

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?

54. PAGE 118:02 TO 118:03 (RUNNING 00:00:02.000)

A Yes, I was part of the State Alaska Team.

55. PAGE 119:07 TO 119:12 (RUNNING 00:00:17.120)

Q Well, let me hand you just Exhibit No. 7. One for you and one for your counsel.
This is the Hattori Public Affairs Liaison Monthly Report in April and May of 2004.
Do you see that?
A I do.

56. PAGE 120:03 TO 120:16 (RUNNING 00:00:36.599)

Q Let me just read what it says into the record, and I'll have some questions for you. Working with PR -- that's public relations firm -- to implement PR efforts for Lilly and general mental health prescription drug issues, including supporting media efforts with product launches, issues including hyperglycemia and diabetes, importation, utilization, dissemination of, quote, library, closed quotes, materials, preparation to discuss new Medicare bill implications, and promote Lilly answers and other efforts.
Do you see that?
A I just read it with you, yes.

57. PAGE 122:17 TO 122:19 (RUNNING 00:00:08.597)

Q Back in April and May of 2004, were there issues involving hyperglycemia and diabetes surrounding Zyprexa?

58. PAGE 122:22 TO 123:09 (RUNNING 00:00:49.689)

A I don't know what you mean by issues. I mean, are you -- can you be more specific or not? I mean, there was a lot of things. There were media. There were, you know, physicians. There
00123:01 were all kinds of other communications from Lilly. I mean, there were a number of things. I don't know exactly what you're asking me, though. I mean -- am I answering? Is that what you're looking for? Yes or not? I'm asking for clarification. You said ask you for help, so --
Q Yeah. Were there concerns about

diabetes and hyperglycemia surrounding Zyprexa in April and May of 2004?

59. PAGE 123:12 TO 123:14 (RUNNING 00:00:14.099)

A There was lots of uncertainty around atypicals and diabetes and hyperglycemia and -- certainly.

60. PAGE 123:18 TO 123:22 (RUNNING 00:00:08.540)

Q My question is particularly directed at Zyprexa. Were there concerns --
A Sure.
Q -- or issues -- sure is the answer?
A Yes, yes.

61. PAGE 132:18 TO 132:21 (RUNNING 00:00:17.000)

Don't you remember giving doctors the comparable rates message in handouts? You remember that, don't you?
A Vaguely, yes.

62. PAGE 146:01 TO 146:05 (RUNNING 00:00:12.458)

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?

63. PAGE 146:08 TO 146:08 (RUNNING 00:00:04.907)

A Around diabetes, yes.

64. PAGE 150:16 TO 151:01 (RUNNING 00:00:18.377)

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.

65. PAGE 152:24 TO 153:15 (RUNNING 00:00:35.349)

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.

66. PAGE 154:22 TO 155:04 (RUNNING 00:00:40.917)

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.

67. PAGE 155:24 TO 156:07 (RUNNING 00:00:16.809)

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.

68. PAGE 166:06 TO 166:10 (RUNNING 00:00:15.995)

Q So you do agree that currently you must tell physicians and health care providers that Zyprexa carries a higher rate of hyperglycemia than Seroquel or Risperdal or Abilify or Geodon?
A Of hyperglycemia, yes.

69. PAGE 168:04 TO 168:08 (RUNNING 00:00:13.039)

Q (BY MR. ALLEN) When did they first tell you, being Eli Lilly, your superiors, that they knew that the risk of hyperglycemia in regard to second-generation antipsychotics fell on a continuum? When did they first tell you that?

70. PAGE 168:11 TO 168:14 (RUNNING 00:00:09.048)

A Same label change.
Q (BY MR. ALLEN) When was that?
A I think it was October of '07, but I can't remember exactly.

71. PAGE 168:17 TO 169:11 (RUNNING 00:00:57.439)

Q Okay. So the first time they told you there was a continuum and the first time they told you that Zyprexa had a higher rate of hyperglycemia was in October of 2007?
A That is the first time I'd ever seen that wording.
Q And prior to that time, you were told that there was comparable rates, correct?
A Of?
Q Of what?
A I'm asking you. Comparable rates of what?
Q Well, what were you told there were comparable rates of?
A We were told that there were comparable rates, I mean, of diabetes, but specifically -- I mean, it says it here for hyperglycemia, but I'm not sure. I need to think about what your question is. I'm sorry. Say it again. Prior to 2007 --

72. PAGE 169:15 TO 169:24 (RUNNING 00:00:33.737)

A What was I told there were comparable rates of, prior to 2007. Diabetes, and I guess we thought there were comparable rates of hyperglycemia, given the older data, so --
Q (BY MR. ALLEN) So prior to October of 2007, Eli Lilly informed you that there was comparable rates of diabetes and hyperglycemia between Zyprexa and the other second-generation antipsychotics?
A Yes. I mean --

73. PAGE 187:17 TO 188:06 (RUNNING 00:00:51.165)

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 --

74. PAGE 189:13 TO 189:23 (RUNNING 00:00:18.000)

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.

75. PAGE 210:20 TO 210:24 (RUNNING 00:00:14.140)

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.

76. PAGE 211:04 TO 211:05 (RUNNING 00:00:04.703)

Q A warning is a more severe rate of incidence and a more likelihood; is that correct?

77. PAGE 211:07 TO 212:03 (RUNNING 00:00:24.033)

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.

78. PAGE 212:08 TO 212:19 (RUNNING 00:00:23.499)

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.

79. PAGE 218:06 TO 219:04 (RUNNING 00:00:41.096)

Q (BY MR. ALLEN) Do you see in Exhibit 13, which is the 2007 label --
A Yes.
Q -- it says -- it's in the warning section, which you've told us the difference, right?
A Right.
Q This is the first time it's ever appeared in the warning section, correct?
A Yes, the hyperlipidemia, yes.
Q It says, Undesirable alterations in lipids --
A I'm behind you. I'm sorry.
Q Yes, ma'am. It's on page 9. I apologize.
A Okay.
Q It says, Undesirable alterations in lipids have been observed with olanzapine use. Did I read that correctly?
A Yes.
Q What is undesirable about these alterations in lipids that have been observed with olanzapine use?
A I can't answer that. I don't know.

80. PAGE 219:10 TO 220:02 (RUNNING 00:00:34.076)

Q Yes, ma'am. And you've told us within the first 30 minutes of this deposition or thereabouts that part of your job was to, as reflected in the policies, was to detail within the label on the risk of the product, correct?
A Uh-huh.
Q Is that yes?
A Yes.
Q And you're supposed to receive materials and information to train you to do that, to

answer questions accurately, correct?
A Yes.
Q And what does the sentence in the 2007 October label change where it says, Undesirable alterations in lipids have been observed with olanzapine use -- what does the undesirable portion of that mean?
A I don't know.

81. PAGE 226:07 TO 226:11 (RUNNING 00:00:12.168)

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.

82. PAGE 227:05 TO 227:18 (RUNNING 00:00:23.000)

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.

83. PAGE 243:17 TO 243:22 (RUNNING 00:00:17.667)

study. I'll just ask you this question: Did you know back in 1995 that Eli Lilly knew that there was a statistically significant elevation in cholesterol on the high side when Zyprexa was compared to haloperidol? Did you know that?
A No.

84. PAGE 243:24 TO 244:05 (RUNNING 00:00:14.052)

Q (BY MR. ALLEN) Ma'am?
A No.
Q Did anybody ever tell you in a clinical trial that Eli Lilly was in charge of that Zyprexa was shown back in the mid-'90s to have increased levels of cholesterol over and above that of haloperidol?

85. PAGE 244:07 TO 244:07 (RUNNING 00:00:02.366)

A No, I don't have that information.

86. PAGE 247:12 TO 247:19 (RUNNING 00:00:17.074)

Q Was weight gain in the warning section of the label right away?
A No.
Q Was it in the warning section of the label before October of 2007?
A As a warning?
Q That's what I asked.
A No.

87. PAGE 249:12 TO 250:08 (RUNNING 00:00:54.013)

was looking for. I've marked as Exhibit 16 the 2003 PDR reference, adverse reactions, and I'm going to highlight it for you so we can find it together. I think I have one for your counsel. I do. I think I gave away my last one, so you're going to have to share it with your counsel.

Exhibit 16, adverse reaction section. Do you see that?

A I do.

Q Do you see -- the adverse reaction section on page 4, right?

A Uh-huh.

Q Is that a yes?

A Yes.

00250:01 Q Do you see the highlighted language that says, It is important to emphasize that although the events occurred during treatment with olanzapine, they were not necessarily caused by it. The entire label should be read to gain a complete understanding of the safety profile of olanzapine. Is that true?

A Does it say that? Yes.

88. PAGE 256:01 TO 256:19 (RUNNING 00:00:33.000)

00256:01 Q Okay. You see a listing of other adverse events observed during clinical trial?

A Yes.

Q And do you see body as a whole?

A Yes.

Q Let me just read body as a whole. Frequent dental pain and flu syndrome.

Did I read that correctly?

A Yes.

Q Frequent, under cardiovascular systems, hypotension.

Did I read that correctly?

A Yes.

Q Frequent, under digestive system, is flatulence. That's gas, is it not?

A I believe so.

Q Increased salivation and thirst.

Did I read that correctly?

A Yes.

89. PAGE 258:12 TO 259:04 (RUNNING 00:00:41.823)

Q Okay. Are all those frequent adverse reactions to Zyprexa?

A Are they all related to Zyprexa?

Q Yes, ma'am.

A I can't say.

Q Why can't you say?

A Because of the nature of the reporting in a clinical trial.

Q Tell me about that. Explain that to me. I don't understand what you're saying.

A As I understand it, the participants in the clinical trial are required to report every single thing that happens to them, and then it should be reported, and whether it makes sense to

00259:01 be attributed to the drug or not, it's still reported.

Q And it's stuck in the adverse reaction section; is that right?

90. PAGE 259:07 TO 259:07 (RUNNING 00:00:05.595)

07 A Well, this is the other adverse events.

91. PAGE 259:12 TO 259:19 (RUNNING 00:00:22.516)

12 Q So what you're saying is, based on what
13 you've been trained, anything that happened at
14 clinical trial the patient is supposed to report
15 and it's put in the other adverse events section,
16 right?
17 A Anything -- I mean, they also look at
18 the occurrence of it versus placebo or the
19 control group or whatever.

92. PAGE 263:07 TO 264:19 (RUNNING 00:00:58.000)

07 Q Okay. Well, let's go down to just
08 digestive -- excuse me -- infrequent under
09 digestive system includes fecal impaction. And
10 you said you just don't know about that either,
11 do you?
12 A No, I don't.
13 Q Okay. Let's go down to hemic and
14 lymphatic system. Infrequent is listed anemia.
15 Do you see that?
16 A Yes.
17 Q How is that related to Zyprexa?
18 A I don't know.
19 Q Well, let's go down to musculoskeletal
20 system. It says infrequent, arthritis. How is
21 that related to Zyprexa?
22 A I do not know.
23 Q Is it related to Zyprexa? Arthritis.
24 A I don't know.
25 Q Is the abdomen being enlarged related to
00264:01 Zyprexa?
02 A I can't say.
03 Q Is atrial fibrillation related to
04 Zyprexa?
05 A I do not know.
06 Q Well, all those are infrequent reactions
07 under the other adverse reactions, right?
08 A Yes.
09 Q Well, I found another one. Look at the
10 endocrine system. Do you see it?
11 A I do.
12 Q Diabetes mellitus.
13 A Uh-huh.
14 Q Doesn't it say infrequent?
15 A Uh-huh.
16 Q Ma'am?
17 A Yes, it says infrequent.
18 Q Is that related to Zyprexa?
19 A I have no -- I don't know.

93. PAGE 266:14 TO 266:15 (RUNNING 00:00:05.060)

14 Q The other adverse events section is not
15 a warning to anybody, is it?

94. PAGE 266:17 TO 267:14 (RUNNING 00:00:05.475)

17 A I can't answer that. I mean, to me,
18 yes.
19 Q (BY MR. ALLEN) Oh.
20 A I mean, it's not a warning, it's a --
21 sorry.
22 Q It's not a warning, it's a what?

A It's an awareness.
Q Okay. It's not a warning; it's an awareness, right?
A Uh-huh.
Q Is that a yes?
A Yes.
Q Okay. Because you're not warning -- you didn't go around warning doctors of dental pain, did you?
A No, I did not.
Q Okay. You didn't go around warning them of increased salivation and gas, did you?
A No, I did not.
Q Okay. And they're listed in there -- in the other adverse events section more frequently than diabetes, right?
A Yes.

95. PAGE 270:17 TO 270:19 (RUNNING 00:00:03.655)

Q If the warning is different, as you've told us, that's significant, isn't it?
A Uh-huh.

96. PAGE 270:21 TO 271:14 (RUNNING 00:00:36.262)

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. I want them to know that it changed.
Q Right. You said it's an agenda if it changes, right?
A I said that it's -- we're directed to do that, yes.
Q Yeah. You have a warning change that just occurred within the last five months on weight gain, right?
A The whole label changed, yes.
Q And the weight gain was included for the first time ever in the warning section, right?
A Uh-huh.
Q Is that yes?
A Yes.

97. PAGE 272:15 TO 272:16 (RUNNING 00:00:03.098)

Q So it's a big difference when something's in the warning section, right?

98. PAGE 272:18 TO 272:24 (RUNNING 00:00:13.574)

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.

99. PAGE 276:20 TO 277:06 (RUNNING 00:00:42.991)

Q And in the warning section there's a whole warning on tardive dyskinesia, is there not?
A Yes.
Q Okay. Can you hand that back to me, please? I'm looking for a particular sentence.

00277:01 And in the warning section in the 2003 PDR
02 concerning tardive dyskinesia it states, Whether
03 antipsychotic drug products differ in their
04 potential to cause tardive dyskinesia is unknown.
05 Do you see that?
06 A Yes.

100. PAGE 281:04 TO 281:08 (RUNNING 00:00:09.150)

04 Q Just so the record is clear, since the
05 very dawn of Zyprexa being on the market, it has
06 always carried a risk of tardive dyskinesia, has
07 it not?
08 A Yes.

101. PAGE 284:12 TO 284:22 (RUNNING 00:00:21.408)

12 Q So just so the record's clear, Zyprexa
13 is not indicated for bipolar depression, is it?
14 A No, it is not. Zyprexa -- olanzapine is
15 not.
16 Q Is it indicated for children?
17 A No, it is not indicated for children.
18 Q Why did I see in your call notes that
19 you went and saw a child psychiatrist?
20 A There's a lot of child psychiatrists in
21 the community that service children, adolescents
22 and adults.

102. PAGE 285:15 TO 285:25 (RUNNING 00:00:27.757)

15 Q Does the label support any superior
16 efficacy of Zyprexa over the first-generation
17 antipsychotics?
18 A I would have to look through.
19 Q Yes, ma'am. Well, go ahead and look
20 through. Take your time. We'll go off the
21 record and then we'll -- the question on the
22 table is whether or not the label that is current
23 supports superior efficacy of Zyprexa over the
24 first-generation antipsychotics. And we'll go
25 off the record and let you look.

103. PAGE 287:08 TO 287:12 (RUNNING 00:00:12.469)

08 Q Okay. In the label, as we sit here
09 today, is there any data or information in the
10 label that supports the fact that Zyprexa is
11 superior to any first-generation antipsychotic?
12 A In the package insert, no.

104. PAGE 288:04 TO 288:09 (RUNNING 00:00:12.142)

04 Q Okay. Now, next question: Is there
05 anything within the label, as we sit here today,
06 that supports the fact that Zyprexa is superior
07 in efficacy to any second-generation
08 antipsychotic?
09 A No.

105. PAGE 301:13 TO 301:22 (RUNNING 00:00:21.404)

13 Q Is there anything in the current label
14 that supports a superior safety profile of
15 Zyprexa over any other antipsychotic, other than
16 Clozaril?
17 A Just in this label?
18 Q Yes, ma'am.
19 A No.

Q Okay. So in the label there's no superior efficacy and there's no superior safety, correct?

106. PAGE 301:25 TO 301:25 (RUNNING 00:00:01.243)

A Yes.

107. PAGE 304:06 TO 304:22 (RUNNING 00:00:41.000)

Q Okay. Now, not only is there an increased risk of hyperlipidemia and hyperglycemia in the Zyprexa label, there's an increased risk of weight gain in the warning section of the current label, correct?
A Yes.
Q I'm trying to figure out what in the label of Zyprexa gives it an advantage over any other antipsychotic in safety or efficacy. Is there anything in the label that you can find?
MR. BRENNER: Objection.
A In the label? In this -- in the package insert?
Q (BY MR. ALLEN) Yes, ma'am.
A No.
Q There's not, is there? Ma'am?
A No.

108. PAGE 362:19 TO 363:02 (RUNNING 00:00:18.422)

Q In the last ten years since you started working as a detail representative, have you ever detailed any other products besides Zyprexa and Symbyax?
A Yes.
Q What other products?
A Prozac and Strattera.
00363:01 Q When did you quit detailing Prozac?
02 A The year when it went off patent.

TOTAL: 1 CLIP FROM 1 DEPOSITION (RUNNING 00:37:53.868)

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 PRECLUDE TESTIMONY OF JOEY ESKI FROM TRIAL PHASE ONE OR PROTECTIVE ORDER REGARDING HER TRIAL TESTIMONY

1. The jury in phase one of trial will decide one issue: whether Zyprexa's label appropriately warned prescribing physicians. The Court confirmed this during the February 28, 2008, hearing when it explained, "[t]he jury is going to be instructed on the UTPA . . . based on evidence of the product labels, which I left in, and the jury is going to be instructed on common-law warning claims . . . . those claims are in . . . ."[1]

2. Despite the Court's summary judgment ruling, the State of Alaska ("the State") has subpoenaed Eli Lilly and Company ("Lilly") sales representative Joey Eski for trial.[2] Ms. Eski's testimony, which revolved around her federally regulated, and UTPCPA exempted, promotional activity, is irrelevant to the remaining issue during phase one of trial.

[1] Hr'g Tran. 13:21 to 14:5, Feb. 28, 2008.

[2] *See* Subpoena to Joey Eski, Feb. 29, 2008 (Exh. A).

3. To the extent that the State claims that Lilly overpromoted Zyprexa—a claim that the State has not made to date and has not proffered in its proposed jury instructions—Alaska courts have not adopted overpromotion as relevant to a failure-to-warn cause of action.[3]

4. Even if the Court concludes that overpromotion should be considered, the issue is typically rooted in negligence causes of action,[4] a claim that the State has dismissed.

5. Even if the Court allows the State to pursue overpromotion, the issue is relevant only to phase two of trial. Courts throughout the country that have considered the question of overpromotion have found that the central inquiry to an overpromotion allegation is whether promotional activity *caused* a physician to prescribe a medication when, in light of an adequate product label, the physician otherwise would not have prescribed.[5] Thus the critical testimony in resolving an overpromotion allegation lies not with the sales representative, but with the physician. The parties will not develop physician testimony until phase two of this case, and Ms. Eski's testimony should not be considered until that time. Lilly, therefore, requests that the Court enter an order precluding the State's use of Ms. Eski's testimony during phase one of trial.

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[3] *See In re: Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 814 (N.D. Ohio 2004) (noting that the cases heralded as overpromotion cases are "at least thirty years old and only sparsely cited since they were decided. . . . [and] so stale that their legitimacy as legal authority is questionable).

[4] *See Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363-64 (4th Cir. 1975); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973); *Incollingo v. Parke, Davis & Co.*, 282 A.2d 206 (Pa. 1971); *Whitley v. Cubberly*, 210 S.E.2d 289 (N.C. App. 1974).

[5] *See, e.g., Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1377-78 (S.D. Fla. 2007) (noting that the key issue is evidence that marketing materials induced physicians to inappropriately select patients for use of a medical device); *Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1121–23 (D. Kan. 2002) (finding that allegations of "subliminal marketing influences" were insufficient to survive summary judgment because the prescribing physician testified that he did not rely on sales representatives for information); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 662 (Cal. 1973) (noting that the relevant inquiry is whether overpromotion caused physicians to prescribe the medication); *Incollingo v. Parke, Davis & Co.*, 282 A.2d 206 (Pa. 1971); *Love v. Wolf*, 226 Cal. App. 2d 378, 399-400 (Cal. Ct. App. 1964).

6. Even if the Court determines that Ms. Eski's testimony may be offered during the first phase of trial, Ms. Eski has had long-standing, prepaid vacation plans, and she will be in Hawaii with her family from March 10 through March 22.[6] Lilly requests that the Court enter a protective order, excusing Ms. Eski from appearing for testimony during this phase of the trial.

DATED this 3rd day of March, 2008.

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[6] *See* Affidavit of Joey Eski (March 3, 2008).

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-06-05630 CI

AFFIDAVIT OF JOEY ESKI

STATE OF ALASKA)
) ss.
THIRD JUDICIAL DISTRICT)

I, Joey Eski, being first duly sworn, states as follows:

1. I am an executive sales representative with Eli Lilly and Company. I live in Anchorage, Alaska.

2. I will be out of state from March 10th through March 22nd of 2008 on a family vacation in Hawaii. My family and I have planned this vacation since January 2008. On January 14-15, 2008, I purchased four round-trip tickets from Anchorage to Hawaii, for myself, my friend, and my children, leaving Anchorage on March 10th and returning on March 22nd. Confirmations of these tickets are attached as Exhibits 1 and 2. On February 5, 2008, I purchased an additional four round-trip tickets from the island of Hawaii to the island of Maui. Confirmations are attached as Exhibit 3.

Further affiant sayeth naught.

Joey Eski

SUBSCRIBED AND SWORN TO this 2nd day of March, 2008.

JERI ANN JENSON NOTARY PUBLIC STATE OF ALASKA My Commission Expires March 9, 2011

Notary in and for the State of Alaska
My commission expires: 03-09-11

009867.0038/163707.1

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

From: Alaska/Horizon Airlines <Alaska.IT@AlaskaAir.com>
Date: Mon, 14 Jan 2008 11:19:30 -0800
To: jeski@gci.net
Subject: Alaska Airlines/Horizon Air Confirmation Letter for 3/10/08

Thank you for choosing Alaska Airlines / Horizon Air!

For questions, changes or cancellations on an Alaska Airlines or Horizon Air purchased ticket, please visit alaskaair.com -- you'll save money too! Changes made on alaskaair.com will save $25.00 per ticket over calling reservations.

Confirmation Code: GPLATF

Name: ESKI/IVY
Ticket Number: 027-2115906036
Base Fare: 0.00
Tax: 5.00
Total: 5.00
Mileage Plan: None

REMINDERS AND RESTRICTIONS

This electronic ticket is not transferable and may include non-refundable segments. If you choose to change your itinerary, any fare increases and a change fee will be collected at the time the change is made.

PAYMENT INFORMATION

The amount of $5.00 (USD) was charged to the Visa Card **********1343 held by JOEY ESKI on 1/14/2008, using electronic ticket number 027-2115906036. This document is your receipt.

Name: ESKI/ETHAN
Ticket Number: 027-2115906037
Base Fare: 0.00
Tax: 5.00
Total: 5.00

EXHIBIT 1
PAGE 1 OF 3

Mileage Plan: None

REMINDERS AND RESTRICTIONS

This electronic ticket is not transferable and may include non-refundable segments. If you choose to change your itinerary, any fare increases and a change fee will be collected at the time the change is made.

PAYMENT INFORMATION

The amount of $5.00 (USD) was charged to the Visa Card **********1343 held by JOEY ESKI on 1/14/2008, using electronic ticket number 027-2115906037. This document is your receipt.

ITINERARY

March 10 2008
Alaska Airlines 870
Depart: Anchorage, AK at 3:20 PM
Arrive: Honolulu, HI at 7:40 PM
Seats: 23B, 23A, Y Class
Meal: Available for purchase

March 22 2008
Alaska Airlines 871
Depart: Honolulu, HI at 9:10 PM
Arrive: Anchorage, AK at 5:30 AM
Seats: 19F, 18F, Y Class

INFLIGHT FOOD SERVICE

On some of your flights, in addition to our usual beverage service, you also have the option to purchase a meal for $5.00(USD or CAD) cash. Please check the details section of your itinerary to determine which flights offer food for purchase. You can find more information on Alaska's Northern Bites meal service at http://www.alaskaair.com/www2/help/faqs/MealService.asp

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Each ticketed passenger is allowed, free of charge, two checked bags and one carry-on bag plus one personal item, such as a purse, briefcase, or laptop computer. The carry-on bag can measure up to 10" high, 17" wide, and 24" long (25 x 43 x 60 cm). We recommend you put identification on both the outside and inside of all baggage. At least one of your carry-on items should be stowed under the seat in front of you. The free weight allowance is 50 pounds per piece of checked baggage. Unfortunately, Alaska Airlines can not assume liability for loss, damage or delay in the delivery of fragile or perishable articles or other valuables, including but not limited to cameras and electronic equipment, medication or keys, whether with or without the knowledge of the carrier.
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EXHIBIT 1
PAGE 2 OF 3

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Refund and change options are available online at alaskaair.com for most purchased reservations. For information, see the View/Change a Reservation page located under the reservations tab at alaskaair.com.
https://www.alaskaair.com/booking/ssl/viewpnrstart.aspx

For further assistance with refunds or changes on all other reservations, including Mileage Plan Awards, contact 1-800-ALASKAAIR (1-800-252-7522) for Alaska Airlines or 1-800-547-9308 for Horizon Air. Please have your confirmation code ready for the Reservations Agent. Note: If calling from Mexico, precede these telephone numbers with 001.

For questions, changes, and cancellations on a Partner Award itinerary, Air France, American Airlines, British Airways, Continental Airlines, Delta Air Lines, KLM, LAN, Northwest Airlines, Qantas or Cathay Pacific Airways please call the Partner Desk at 1-800-307-6912.

Refunds for qualifying tickets may be obtained by calling the appropriate toll-free number listed above or by applying at any ticket counter location.

Please review U.S. Department of Transportation Consumer Notices regarding your consumer rights and limitations of liability at:
www.alaskaair.com/www2/help/faqs/ConsumerNotices.asp or simply obtain a copy when checking in.

EXHIBIT 1
PAGE 3 OF 3

From: Alaska/Horizon Airlines <Alaska.IT@AlaskaAir.com>
Date: Tue, 15 Jan 2008 11:04:58 -0800
To: jeski@gci.net
Subject: Alaska Airlines/Horizon Air Confirmation Letter for 3/10/08

Thank you for choosing Alaska Airlines / Horizon Air!

For questions, changes or cancellations on an Alaska Airlines or Horizon Air purchased ticket, please visit alaskaair.com -- you'll save money too! Changes made on alaskaair.com will save $25.00 per ticket over calling reservations.

Confirmation Code: KLATWL

Name: ESKI/JOEY
Ticket Number: 027-2115956038
Base Fare: 1166.69
Tax: 37.71
Total: 1204.40
Mileage Plan: Alaska Airlines #*****631 Gold

REMINDERS AND RESTRICTIONS

This electronic ticket is not transferable and may include non-refundable segments. If you choose to change your itinerary, any fare increases and a change fee will be collected at the time the change is made.

PAYMENT INFORMATION

The amount of $1204.40 (USD) was charged to the Visa Card **********1343 held by JOEY ESKI on 1/15/2008, using electronic ticket number 027-2115956038. This document is your receipt.

Name: SCHWENN/MICHELLE
Ticket Number: 027-2115956040
Base Fare: 50.00
Tax: 33.58

EXHIBIT 2
PAGE 1 OF 3

Total: 83.58
Mileage Plan: Alaska Airlines #*****686

REMINDERS AND RESTRICTIONS

This electronic ticket is not transferable and may include non-refundable segments. If you choose to change your itinerary, any fare increases and a change fee will be collected at the time the change is made.

PAYMENT INFORMATION

The amount of $83.58 (USD) was charged to the Visa Card **********1343 held by JOEY ESKI on 1/15/2008, using electronic ticket number 027-2115956040. This document is your receipt.

ITINERARY

March 10 2008
Alaska Airlines 870
Depart: Anchorage, AK at 3:20 PM
Arrive: Honolulu, HI at 7:40 PM
Seats: 23C, 23F, Y Class
Meal: Available for purchase

March 22 2008
Alaska Airlines 871
Depart: Honolulu, HI at 9:10 PM
Arrive: Anchorage, AK at 5:30 AM
Seats: 19E, 18E, Y Class

INFLIGHT FOOD SERVICE

On some of your flights, in addition to our usual beverage service, you also have the option to purchase a meal for $5.00(USD or CAD) cash. Please check the details section of your itinerary to determine which flights offer food for purchase. You can find more information on Alaska's Northern Bites meal service at http://www.alaskaair.com/www2/help/faqs/MealService.asp

BAGGAGE

Each ticketed passenger is allowed, free of charge, two checked bags and one carry-on bag plus one personal item, such as a purse, briefcase, or laptop computer. The carry-on bag can measure up to 10" high, 17" wide, and 24" long (25 x 43 x 60 cm). We recommend you put identification on both the outside and inside of all baggage. At least one of your carry-on items should be stowed under the seat in front of you. The free weight allowance is 50 pounds per piece of checked baggage. Unfortunately, Alaska Airlines can not assume liability for loss, damage or delay in the delivery of fragile or perishable articles or other valuables, including but not limited to cameras and electronic equipment, medication or keys, whether with or without the knowledge of the carrier.
Visit http://www.alaskaair.com/www2/help/faqs/CheckedBaggage.asp to read our full baggage policy.

CHECK-IN INFORMATION

Check out our fast and easy Check-In Options
(http://www.alaskaair.com/as/www2/flights/Check-In-Options.asp). Save time

EXHIBIT 2
PAGE 2 OF 3

when you check in online at www.alaskaair.com. You may also check in at an airport kiosk or ticket counter. Baggage may be checked at the ticket counter, or, where available, via a Check-In Kiosk. Please have this document or your confirmation code available.

To accommodate everyone wishing to travel on your flight, you must be checked-in and available to board at the designated boarding gate at least 30 minutes before scheduled departure for domestic or international flights, except on 2000 series flights between Seattle/Portland, which require only 20 minutes. Failure to do so may cause the cancellation of reserved seats and cancellation of the entire reservation.

Picture identification, such as a driver's license or passport, is required to board the aircraft. For international travel, anyone crossing an international border is required by the country of entry to produce evidence of citizenship. For more information please visit www.alaskaair.com/www2/help/faqs/Travel_Documents.asp or call 1-800-252-7522 for details.

Save time at the airport and simplify the check in process by providing the required International Travel Information online at https://www.alaskaair.com/booking/ssl/viewpnrstart.aspx

If unaccompanied minors are traveling on this itinerary, please review this important information:
http://www.alaskaair.com/as/www2/help/faqs/ChildrenTravelingAlone.asp

CHANGE OF PLANS

Save money -- You can make your reservation changes on alaskaair.com versus calling 1-800-ALASKAAIR (1-800-252-7522) and you will save $25.00 per ticket on change fees.

Refund and change options are available online at alaskaair.com for most purchased reservations. For information, see the View/Change a Reservation page located under the reservations tab at alaskaair.com.
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EXHIBIT 2
PAGE 3 OF 3

From: GO <customercare@iflygo.com>
Date: Tue, 05 Feb 2008 18:12:37 -0600 (CST)
To: jeski@gci.net
Subject: Travel Reservation March 10 for ESKI

This email confirms receipt of your reservation made on www.iflygo.com <http://www.iflygo.com> .

You may print out the itinerary and bring it to the airport as a receipt, as all transactions are ticketless.

Click here to access your reservation on the web or a mobile device.
<https://www.virtuallythere.com/new/reservationsChron.html?
host=YV&pnr=N20GENH0MR1O&name=ESKI&language=0&email=2>

Click here to view and print e-ticket receipt 5332102807254
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pnr=N20GENH0MR1O&pcc=GVY&language=0&name=ESKI&host=YV&ETNBR1=5332102807254&ETDTE

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****

JOEY ESKI, IVY ESKI, ETHAN ESKI, MICHELLE SCHWENN

EXHIBIT 3
PAGE 1 OF 2

Reservation code: HWFWIP

Mon, Mar 10
Flights: MESA AIRLINES, YV 1019
Operated by: MESA AIRLINES DBA GO!
From: HONOLULU, HI (HNL) Departs: 10:00pm
To: KAHULUI MAUI, HI (OGG) Arrives: 10:35pm
Class: Economy Seat(s): Check-In Required
Status: Confirmed
Meal: Smoking: No
Aircraft: CRJ-CANADAIR REGIONAL JET Mileage: 101
Duration: 35 minute(s)
Please verify flight times prior to departure

Sat, Mar 22
Flights: MESA AIRLINES, YV 1007
Operated by: MESA AIRLINES DBA GO!
From: KAHULUI MAUI, HI (OGG) Departs: 6:30pm
To: HONOLULU, HI (HNL) Arrives: 7:02pm
Class: Economy Seat(s): Check-In Required
Status: Confirmed
Meal: Smoking: No
Aircraft: CRJ-CANADAIR REGIONAL JET Mileage: 101
Duration: 32 minute(s)
Please verify flight times prior to departure

****

Please print a copy of this information and put it in a safe place so that you may refer to your itinerary and Sabre Record Locator (confirmation number) for your trip.

Due to increased security measures, please have a valid picture ID available at the ticket counter. You should plan to arrive at the airport at least an hour before scheduled departure time.

If you need to make changes to or cancel your reservation, please contact go! Reservations at 1-888 IFLYGO2 (1 888-435-9462). Reservation changes may result in additional fees and penalties. Please refer to the FAQ tab on www.iflygo.com <http://www.iflygo.com> for ticketing change fees.

All tickets are non-transferable. When making a change to a non-refundable ticket, there is a $20 change fee as well as a possible change in the fare if original booking class is not available. The upgrade fee is the difference between the fare you paid and the current fare available.

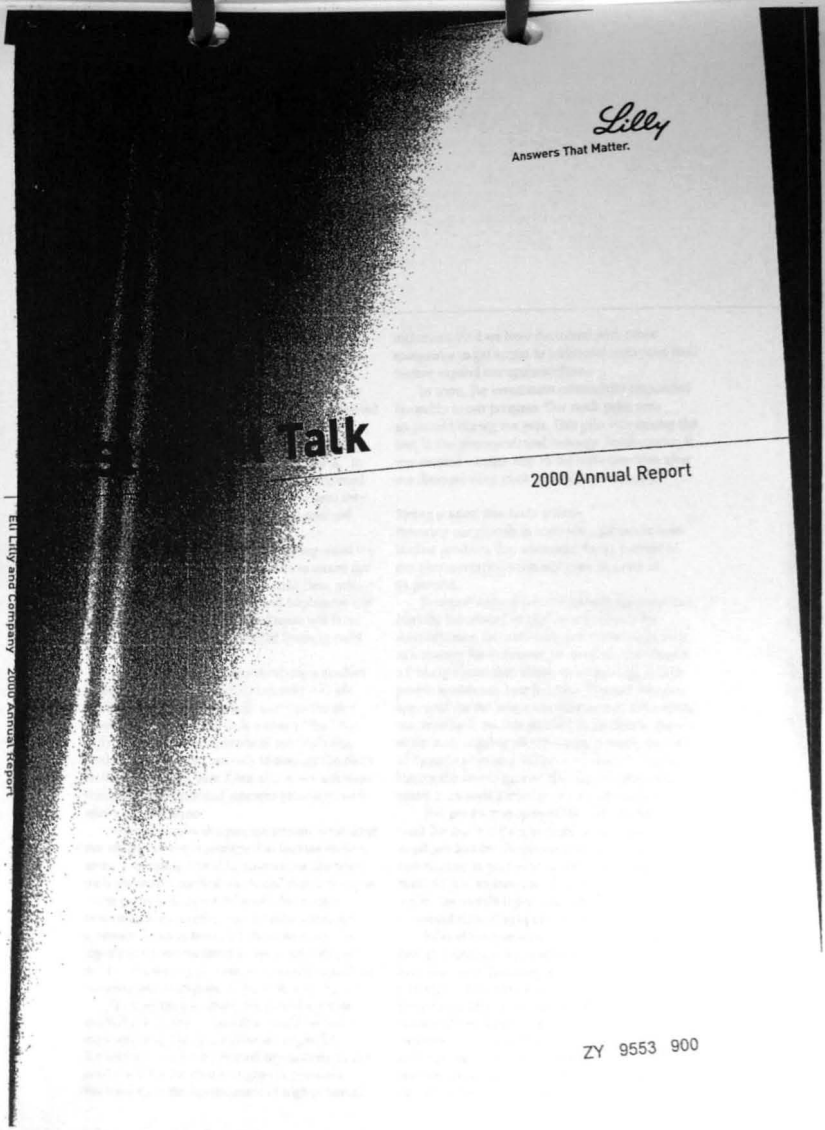
If you booked a car or hotel and they did not come back with a confirmation number, please call the car or hotel company directly to verify the booking.

All go! flights are operated by Mesa Airlines.

Click here to opt out of receiving future e-mails from Virtually There.
<http://www.virtuallythere.com/new/emOptOut.html?host=YV&language=0&email=2&pcc=GVY>

GO
1-888-IFLYGO2 (1-888-435-9462) Email: customercare@iflygo.com
...the island's airline

EXHIBIT 3
PAGE 2 OF 2


Lilly
Answers That Matter.
Talk
2000 Annual Report
Eli Lilly and Company 2000 Annual Report

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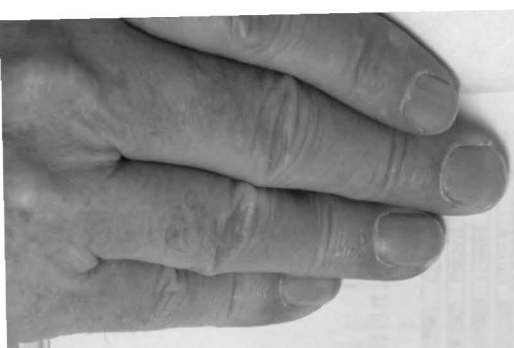

To Our Shareholders

In keeping with our pledge to answer important questions, I want to address one that I am sure is on your minds.

For several years, we have been preparing for the expiration of the U.S. patents that have protected our exclusive rights to our top-selling product, Prozac®. Due to uncertainty over the exact timing of this event, we have referred to it as "Year X." In January 1999, a federal district court had affirmed our 2003 Prozac patent. Last August, we were very surprised when a federal appeals court reversed that ruling.

We strongly disagree with the ruling—and we are making every effort in the courts to secure our rights to the 2003 patent. At the same time, prudence dictates that we prepare and implement our plans with the assumption that Prozac will face generic competition in the United States in early August 2001.

Given this turn of events involving a product with U.S. sales of $2.2 billion, you may well ask whether Lilly can successfully navigate the next several years. My response is a strong "Yes." We fully recognize the magnitude of our challenge. And we are prepared not only to manage the short-term challenges of Year X but also to embark soon thereafter on a period of renewed growth. Here is why I am confident.

We continue to sharpen the implementation of our simple, clear-cut strategy that focuses on two areas: generating scientific innovations that meet patients' unmet medical needs and then helping as many patients as possible benefit from those innovations. As a result, our net sales increased 9 percent in 2000, to $10.9 billion. Adjusted for significant one-time items in 1999 and 2000, our net income rose 15 percent, to $2.9 billion, and our earnings per share grew 16 percent, to $2.65.

For a number of years, we have also implemented contingency plans that would help us overcome any Year X outcome we might face. For instance, we have invested aggressively in our products with the strongest growth potential. We have sped the development of high-potential molecules. And we have partnered with other companies to get access to additional molecules that further expand our opportunities.

In 2000, the investment community responded favorably to our progress. Our stock price rose 40 percent during the year. This gain was among the best in the pharmaceutical industry. Furthermore, it represented a major step in the right direction after our disappointing stock performance in 1999.

Strong product line fuels growth

Powering our growth in 2000 were six newer best-in-class products that accounted for 41 percent of our pharmaceutical sales and grew at a rate of 31 percent.

Zyprexa® exemplifies our growth opportunities. Initially introduced in 1996 as a treatment for schizophrenia, this molecule was approved in 2000 as a therapy for the manic phase of bipolar disease, a lifelong illness that affects as many as 34 million people worldwide. Late last year, Zyprexa was also approved for the long-term treatment of schizophrenia, making it the first product in its class to demonstrate such ongoing effectiveness. In 2000, our sales of Zyprexa were $2.3 billion, a 25 percent increase. During the fourth quarter, this neuroscience blockbuster surpassed Prozac as our top-selling product.

Two products surpassed the $500 million sales mark for the first time in 2000. Sales of Evista®, our novel product for the prevention and treatment of osteoporosis in postmenopausal women, were $522 million, an increase of 60 percent. Gemzar®, one of the world's top-selling anticancer agents, generated sales of $559 million, up 23 percent.

Sales of the human insulin analog, Humalog®, rose 56 percent, to $350 million. As more patients used Humalog, Humalog mixtures, and our pen-cartridge delivery systems, our total insulin sales grew 10 percent, to $1.5 billion. We also continued to expand our diabetes care presence through the copromotion of Actos®, an oral treatment for type 2 diabetes discovered by our partner, Takeda. Our revenue from Actos was $223 million during 2000—its first full year on the market.

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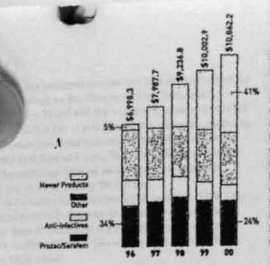


Net Sales
($ millions)

Net sales during 2000 reflect the strong growth of Lilly's newer products and a consistent lessening of the company's reliance on the sales of Prozac. The company's newer products—Zyprexa, Evista, Actos, Humalog, Gemzar, and ReoPro—grew by a combined 31 percent over 1999, representing 41 percent of total net sales compared with 34 percent in 1999. Prozac sales accounted for 24 percent of total net sales in 2000, down from 34 percent in 1996.

The growth of those five products more than offset sales decreases for two other important products. The sales of our sixth newer product, the cardiovascular agent ReoPro® discovered by the Centocor unit of Johnson & Johnson, fell 7 percent, to $418 million. The worldwide sales of Prozac declined 2 percent, to $2.6 billion, largely due to the initial impact of generic competition in the United Kingdom.

Intense competition is a fact of life throughout the pharmaceutical industry. To meet that competition, we significantly elevated our marketing investments in 2000 with the goal of making our growth products available to more patients throughout the world. More specifically, we added some 2,000 sales representatives worldwide, an increase of more than 20 percent. We recruited scores of experienced marketing professionals to support our growing product line. And we pursued clinical studies supporting new indications and formulations for key products that will further expand our growth opportunities.

Outstanding pipeline adds further growth potential

Even as we capitalize on our current generation of products, we are speeding our next generation of new-product candidates to the global marketplace. As you will see later in this report, we could introduce as many as 10 more medicines by the end of 2004. Several of those candidates are potential first-in-class products that could address medical problems for which there are no current treatments. All are potential best-in-class products that could provide superior results for patients.

In the near term, we are immersed in our preparations for the launches of two unique biotech products. Clinical data indicate that drotrecogin alfa (activated), also known by the proposed trade name Zovant, may be the first therapy that effectively treats patients with sepsis, a condition that kills an estimated half million people worldwide annually. Fortéo™ is an innovative molecule that appears in clinical trials to rapidly rebuild bone diminished by osteoporosis. We filed regulatory submissions for Fortéo in late 2000 and for Zovant in early 2001. We expect to launch both in 2001.

Beyond Zovant and Fortéo, we hit the development targets last year for nearly all the molecules in our near-term pipeline. Two exceptions were the anticancer agent oxaliplatin, which was not approved by the FDA, and the antidepressant candidate R-fluoxetine, which did not meet its clinical-trial goals. We returned both potential products to partners.

While Lilly scientists have discovered most of the molecules in our pipeline, we continue to work with other companies to add more opportunities. For example, Cialis™ is a promising near-term drug candidate from ICOS Corporation for the treatment of male erectile dysfunction that Lilly and ICOS are working together to develop. During 2000, we announced agreements with three other companies—Ono, Sankyo, and Mitsubishi-Tokyo—that each added a molecule to our pipeline.

We currently have well over 100 scientific collaborations. Those cooperative efforts not only help us enhance our pipeline with additional drug candidates but also give us access to more biological targets for drug discovery and important new R&D technologies. Because collaborations are an essential part of our strategy, we created an Office of Alliance Management with the mission of helping Lilly become the pharmaceutical industry's best business partner. We are making good progress in that pursuit.

In 2000, we strengthened our internal research capabilities by recruiting nearly 700 scientists and expanding our "innovation engine," Lilly Research Laboratories, to 6,900 people at 11 sites worldwide. We also increased our global R&D investment by 13 percent, to $2 billion. This represented 19 percent of our sales.

Those actions are paying off. Last year was one of the best ever for Lilly Research Laboratories. Our scientists met or exceeded virtually all our rising research-productivity targets for identifying high-potential molecules and initiating early-stage clinical trials of drug candidates. A key factor in those productivity gains is the early impact of the biotech revolution about which we hear so much.

Last October, the company marked the 30th anniversary of the listing of Lilly stock on the New York Stock Exchange. Chairman Sidney Taurel and the board of directors celebrated the occasion with a day of activities at the exchange, hosted by NYSE Chairman and Chief Executive Officer Richard Grasso. Capping the activities at 4 p.m., Taurel struck the ceremonial gavel at the exchange podium as the final bell sounded, signaling the close of trading for the day.

Prior to its initial listing on the NYSE on July 9, 1970, Lilly stock had been sold in the over-the-counter market. During those first days of trading on the New York exchange, the company's market capitalization was about $3 billion. Today, it's nearly $100 billion.

Technology revolutions create new opportunities

Over time, the biomedical revolution will transform all areas of pharmaceutical R&D. In the near term, however, we believe the greatest potential involves the use of new research tools to identify previously undiscovered genes that trigger the production of natural proteins in the body involved in major diseases. Those natural proteins, or modified versions, sometimes prove to be outstanding biotech drug candidates.

This trend plays directly into our strengths. We are established leaders in the discovery, development, and production of protein medicines. The upcoming launches of Fortéo and Zovant will expand our protein portfolio to seven products. And we have a number of additional protein candidates in various stages of development.

We are also using revolutionary new R&D capabilities to expedite our searches for so-called "small-molecule" medicines similar to Prozac and Zyprexa that constitute the majority of our drug candidates. Our scientists are committed to helping patients benefit from this unfolding biotech revolution as soon as possible.

Additionally, we are exploiting the power of the e-business revolution on behalf of patients. In 2000, we created a new organization, e.Lilly, that is generating, attracting, and testing scores of new approaches based on information technology. These concepts have the potential to accelerate improvement in virtually every aspect of our business, from the earliest stages of research to providing information for patients.

Ready for the future

In 2000, we enthusiastically welcomed two outstanding leaders to our board of directors. Sir Winfried "Win" Bischoff is chairman of Citigroup Europe and former chairman and CEO of Schroders, plc. George M. C. Fisher recently retired as chairman and CEO of Eastman Kodak Company and previously served as chairman and CEO of Motorola, Inc. Together, these men reinforce the leadership experience and global perspective of our board that will be great assets during this challenging period.

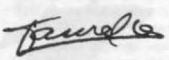
I also wish great success to Mitchell E. Daniels, Jr., who recently became director of the U.S. Office of Management and Budget for President George W. Bush. This cabinet-level appointment is a great honor for Mitch, who served most recently as our senior vice president for corporate strategy and policy. Among his many contributions to the company during the past 11 years, Mitch built an outstanding team in public affairs and communications and played a pivotal role in our preparations for Year X. We will long benefit from his legacy.

As I look ahead, our strategy is on target and our implementation is getting better and better. We are not only applying traditional R&D and sales-and-marketing capabilities but also capitalizing on the revolutions in biotechnology and information technology. Our ongoing progress throughout the company reflects the achievements and the aspirations of 35,700 Lilly colleagues in whom I take great pride.

Later this year, we will celebrate the 125th anniversary of Lilly's founding. Over these many years, our company has made history with medical breakthroughs—from the first insulin product and major antibiotic advances to Prozac and Zyprexa. So, we are very thankful for the Lilly family and Lilly retirees who created the heritage that we are working to extend into the twenty-first century.

As we face Year X, we intend to make history again with the greatest outpouring of innovation in Lilly history—beginning with Zovant and Fortéo. We plan to emerge from Year X a stronger company that is ready for a new growth era. We are prepared to write the next great chapters in the Lilly story.

For the board of directors,



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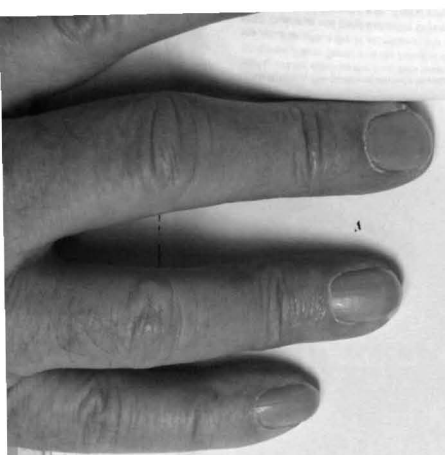
Sidney Taurel
Chairman of the Board, President, and Chief Executive Officer



No company would relish losing the patent on its biggest product three years early. We certainly don't.

We were very surprised and disappointed by the judicial ruling that invalidated our 2003 U.S. patent on Prozac. We strongly disagree with the court's decision, and we are doing everything we can through the judicial process to reestablish our rights.

In the meantime, the U.S. Food and Drug Administration has granted us market exclusivity until August 2, 2001, under a federal statute encouraging pediatric studies of certain medicines.

We intend to focus on Prozac in the United States right up to the last day of its exclusivity. And we'll pursue related opportunities. One is our patented once-weekly formulation aimed at preventing the recurrence of depression. A second is Sarafem™, a newly introduced brand for women

What happened with Prozac?

who suffer from premenstrual dysphoric disorder, the severe mood and physical symptoms associated with their menstrual cycle that interfere with their daily activity and relationships.

We won't miss any opportunities for Prozac—or the rest of our business. For the last four years, we've been preparing to bridge the gap that would be created by generic competition for Prozac. We're ready.

We've invested aggressively in our next generation of innovative drugs and shortened their timelines to launch. We've accelerated development of additional indications and formulations for our newer products. And we've intensified our efforts to partner with other companies on their high-potential compounds in later stages of development.

We've significantly increased the size of our global sales force and will continue to do so in order to have the "firepower" we need to successfully launch and sell the next wave of products from our pipeline. We've also been sharpening our marketing and selling skills to help us realize the full potential of all our products worldwide.

In short, faced with the enormous challenge presented by the Prozac patent expiration, we've positioned ourselves to produce earnings growth through the immediate postexpiration period and resume fast growth following that.

Millions of people worldwide have benefited from Prozac. This remarkable product has revolutionized the way mental illness is viewed and treated. The success of Prozac has helped make possible the outstanding accomplishments of Lilly

research over the last decade and has provided us with the ability to pursue the breakthroughs we expect to introduce in this new decade. It's a wonderful story—for medical science, for patients, and for us. We are proud of Prozac.

And yet, as important as Prozac has been for patients and to our business, it's not the future. For patients, the future is the next generation of medicines with the ability to treat and cure difficult diseases in ways now only hoped for. For us, the future is our newer products already driving our growth and our pipeline of innovative products yet to come. Our focus is on the next Prozac—and the one after that.

So, what now?

Gemzar Gemzar has been described as a "pipeline within a molecule." It's being used to treat the vast majority of pancreatic-cancer patients in both Europe and the United States, and it's become the standard of care for non-small-cell lung cancer in several countries. We're evaluating Gemzar in several types of solid tumors. Our goal is to make it a cornerstone of treatment for lung, pancreatic, bladder, breast, and ovarian cancers.

Our newer products will stand as our front line against inevitable generic competition from Prozac. Introduced throughout the last half of the 1990s, they'll be the key to our ability to produce earnings growth during that time and resume our strong performance thereafter.

Zyprexa Zyprexa is a genuine blockbuster, surpassing the $2 billion sales mark in 2000 and becoming Lilly's number-one-selling product in the fourth quarter. Just as Prozac changed the treatment of depression, Zyprexa has redefined the standard of care for schizophrenia, a devastating disease that ravages the mind and has been called the "cancer of mental illness."

Introduced as a therapy for schizophrenia in 1996, Zyprexa was approved in the U.S. last year for the additional indications of acute mania associated with bipolar disorder and the maintenance of treatment response in schizophrenia. We're exploring broader uses for Zyprexa in schizophrenia and other key segments of the antipsychotic market, including bipolar depression and the psychotic or behavioral disturbances that accompany dementia.

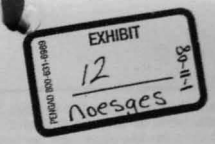
Evista Evista is a blockbuster in the making. The growth of our product for the prevention and treatment of osteoporosis in postmenopausal women continues to be outstanding. Evista has been shown to significantly reduce a woman's risk of clinical spinal fracture within one year of treatment and increase bone mineral density as early as six months.

We continue to investigate the potential of Evista beyond osteoporosis—including its potential effect on heart disease and the reduction of risk of breast cancer in postmenopausal women. Given the breadth of Evista's efficacy potential and its favorable tolerability, we believe it will ultimately set a new standard for women's health products.

Insulins In 1999, the world's first insulin company established itself as the world's leading insulin company, becoming number one worldwide in market share. This leadership was strengthened in 2000. We've achieved this success through the introduction of the Humalog family of insulins and the launch of world-class pen delivery devices. Patients are switching to our Humalog and Humalog mixture formulations and pen delivery devices from their earlier-generation insulin products and their vials and syringes.

Actos The quick uptake of Actos, the oral diabetes agent we launched with our copromotion partner Takeda in the United States during 1999, marked our successful expansion in diabetes care beyond insulins. Actos provides an excellent complement to our insulin business as an oral agent for type 2 diabetes, the most prevalent form of the disease. Our newest product, it is recognized as therapy for reducing insulin resistance, an underlying cause of type 2 diabetes.

New Submissions In addition, we expect 2001 launches for two new products currently under review by regulatory agencies. Drotrecogin alfa (activated), known by the proposed trade name Zovant, targets sepsis, a disease that kills approximately 1,400 people per day worldwide and for which there currently is no approved treatment. Results of a study indicated a nearly 20 percent reduction in the risk of death in patients who were given Zovant. And clinical trials of Fortéo, our novel bone-formation agent for osteoporosis, have demonstrated that it strengthens overall skeletal architecture very rapidly. In addition, the trials showed it can significantly reduce fractures caused by thinning bones at both the spine and nonspine sites.



NAME = Williams, Marga
CALLDATE = 05/17/2002
CALLID = 68130738
PRESCRIBERLN = Flores
PRESCRIBERFN = Kathryn
CITY = Soldotna
STATE = AK
ACTION : **********R**********Also got in a decent ZYP recap, reminded doc that ZYP is a great mood stabilizer, esp for pats whose symptoms were aggravated by an SSRI... Dr. Anderson just stabilized a bipolar pat earlier this week on 15 mg. Went over Lilly Answers Program with Anderson, Sheridan, and Flores and their nurses. Dr. Deede and Lori the PA were off, so no one was over on that side of the clinic. Still need to go over Lilly Answers Program w/them.
REACTION : Excellent, see above! Also visited personally with Sheridan and Flores.
FOLLOWUP : Review Hirschfeld Scales for ZYP recap*****R*****. Dr. Deede and Lori the PA were off, so no one was over on that side of the clinic. Still need to go over Lilly Answers Program w/them.
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1500

NAME = Williams, Margaret
CALLDATE = 05/17/2002
CALLID = 68130741
PRESCRIBERLN = McIntosh
PRESCRIBERFN = Marguerite
CITY = Soldotna
STATE = AK
ACTION : **********R**********. ZYP mention only.
REACTION : Great with staff, good with doc.
FOLLOWUP : Really work ZYP via pat whose symptoms are aggravated by an SSRI, emphasize ZYP as a mood stabilizer.
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1501

NAME = Williams, Margaret
CALLDATE = 06/06/2002
CALLID = 68698813
PRESCRIBERLN = Dahms
PRESCRIBERFN = Laurie
CITY = Palmer
STATE = AK
ACTION : Actually got in a decent ZYP detail for pats with unresolved symptoms, pats who fail on an SSRI, patients could be suffering from complicated mood disorder, perhaps bipolar, ZYP is an excellent mood stabilizer, very safe, easy to dose. Got in part of this with Moser too, and he was even agreeable, says he does treat bipolar patients... Just quick product mentions with Dr. Werner.
REACTION : Good, actually! Gee whiz, perhaps Moser is finally opening up to ZYP...
FOLLOWUP : Keep working ZYP, but softly...
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1565

NAME = Kristen Clouthier
CALLDATE = 06/27/2002
CALLID = 69271199
PRESCRIBERLN = Grant
PRESCRIBERFN = Madeleine
CITY = Anchorage
STATE = AK
ACTION : office luncheon, zyprexa dvd, cathy and donna. **********R**********
REACTION : **********R**********

********** ********** Zyprexa dvd was successful - it enerate many questions and conversation regarding the proper pt type. Julie Wilson, a new md there (was a resident at Prov) is interested to find out what the injectible zyprexa is used for. Pam engle was concerned about weight gain for those zyprexa pts but we discussed proper diet and the fact that if pts are feeling better perhaps they will be able to actually excercise. Also discussed the mechanism of zyprexa and that the drug does not cause weight gain, but it does increase the pts appetite. Suggested that when she prescribe zyprexa she discuss with her pts to let her know if they feel they are eating more. Dr. Hunt gave the example of using zyprexa most commonly for pts who have failed 2 ssri's and also for wont spanish ts in need that wont see psychs due to langueage barriers. He often manages those pts. Very important - anh is hiring two new psych nurse practicioners on staff within the next few months - so zyprexa pts may be handled in house in the future. One nurse on 10th and one on Mtn View.

FOLLOWUP : perhaps the two new nurses could pull charts of failing ssri pts and provide zyprexa opportunity. see what hunt thinks.
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1632

NAME = Kristen Clouthier
CALLDATE = 06/27/2002
CALLID = 69271200
PRESCRIBERLN = Engle
PRESCRIBERFN = Pam
CITY = Anchorage
STATE = AK
ACTION : office luncheon, zyprexa dvd, cathy and donna, **********R**********
REACTION : ********** ********** ********** Zyprexa dvd was successful - it enerate many questions and conversation regarding the proper pt type. Julie Wilson, a new md there (was a resident at Prov) is interested to find out what the injectible zyprexa is used for. Pam engle was concerned about weight gain for those zyprexa pts but we discussed proper diet and the fact that if pts are feeling better perhaps they will be able to actually excercise. Also discussed the mechanism of zyprexa and that the drug does not cause weight gain, but it does increase the pts appetite. Suggested that when she prescribe zyprexa she discuss with her pts to let her know if they feel they are eating more. Dr. Hunt gave the example of using zyprexa most commonly for pts who have failed 2 ssri's and also for wont spanish ts in need that wont see psychs due to langueage barriers. He often manages those pts. Very important - anh is hiring two new psych nurse practicioners on staff within the next few months - so zyprexa pts may be handled in house in the future. One nurse on 10th and one on Mtn View.

FOLLOWUP : perhaps the two new nurses could pull charts of failing ssri pts and provide zyprexa opportunity. see what hunt thinks.
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1633

NAME = Kristen Clouthier
CALLDATE = 06/27/2002
CALLID = 69271206
PRESCRIBERLN = Mackie
PRESCRIBERFN = Scott
CITY = Anchorage
STATE = AK
ACTION : office call - brought ****R*****zyprexa bag of goodies, chocolates, cherries, dried fruit. showed fishing pictures. Invite to both zyprexa ****R**** programs
REACTION : **********R********** dr. mackie graduated cum laude also and was in the top 10% of his medical class - very impressive - discussed zyprexa and ssri failure as his pt type but also alot of elderly. he is very aware of zyprexa and its uses. sharp man! He said he may attend the zyprexa program , give reminder.
FOLLOWUP : dvd, ***R*** zyprexa
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1635

NAME = Kristen Clouthier
CALLDATE = 07/10/2002
CALLID = 69529152

PRESCRIBERLN = Nolte
PRESCRIBERFN = Miriam
CITY = Anchorage
STATE = AK
ACTION : office call - reminders, zyp water bottles, digfast hascale, donna pt, **********R**********
REACTION : busy, quick reminders dosing and pt types **********R********** zyp donna and ssri failure dosing- invites to programs - are attending july 16th
FOLLOWUP : na
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1663

NAME = Kristen Clouthier
CALLDATE = 07/11/2002
CALLID = 69495263
PRESCRIBERLN = Flores
PRESCRIBERFN = Kathryn
CITY = Soldotna
STATE = AK
ACTION : **********R********** zyp desk reference and digfast - chocolate chip cookies of course for dr. anderson.
REACTION : he was leaving for a surgery in a minute so only reminders, but had some good time with kathy - discussed elderly and ssri failure pts , digfast tool and she was interested in the h questionaire - said it was good to have on hand for coding work and determining proper pt - reminded her about the program marvin.
FOLLOWUP : na
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1666

NAME = Kristen Clouthier
CALLDATE = 07/11/2002
CALLID = 69495268
PRESCRIBERLN = Davidhizar
PRESCRIBERFN = Lavern
CITY = Soldotna
STATE = AK
ACTION : intro of self and products again - left idc chart, **********R********** zyp desk ref and digfast
REACTION : was very nice, discussed marvin program - said he would be in town for it - would callif can make it - probably needs a reminder that morning so he will come. discussed zyp pt type - elderly and ssri pt, also angered or agitated, cant keep a job,marraige pt and dosing.- he said he has seen many people come through the door like that.
FOLLOWUP : reminder for program
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1667

NAME = Kristen Clouthier
CALLDATE = 07/11/2002
CALLID = 69495269
PRESCRIBERLN = Sanders
PRESCRIBERFN = Jim
CITY = Soldotna
STATE = AK
ACTION : ********R******** pens, pads, zyp desk reference, digfast, bag of goodies
REACTION : **********R**********quickly zyp digfast and proper dosing for elderly, ssri pt, donna t and the extreme mood disrder. invite to program.
FOLLOWUP : more on zyp
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1668

NAME = Kristen Clouthier
CALLDATE = 07/12/2002
CALLID = 69529146
PRESCRIBERLN = White, Jr.
PRESCRIBERFN = Roy Matison
CITY = Anchorage

STATE = AK
ACTION : lunch w/michele - **********R**********
********** zyprexa h scale, digfast cards, preper pt focus - invites to programs
REACTION : complaints from lanza, jones, taylor, schultes, coalwell if cant bring wife wont come to programs anymore.
**********R**********
********** zyprexa pt type - elderly, multiple ssri, dosing digfast cheat sheet and key and h scale information - all found scale useful and discussed safety of zyp. vs other agents - scheultes asked about zyp and diabetes - was able to respond according and discuss moa of zyprexa- increase in appetitie which may lead to obesity but no causal relationship established between zyp and diabetes - also compared to other agents there is no increased incidence with zyp - high risk rate in this population anyway - he would like medical letter- but was satified with answer.
**********R**********
FOLLOWUP : **********R**********
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1678

NAME = Kristen Clouthier
CALLDATE = 07/12/2002
CALLID = 69529148
PRESCRIBERLN = Coalwell
PRESCRIBERFN = Timothy
CITY = Anchorage
STATE = AK
ACTION : lunch w/michele - **********R**********
********** zyprexa h scale, digfast cards, preper pt focus - invites to programs
REACTION : complaints from lanza, jones, taylor, schultes, coalwell if cant bring wife wont come to programs anymore.
**********R**********
********** zyprexa pt type - elderly, multiple ssri, dosing digfast cheat sheet and key and h scale information - all found scale useful and discussed safety of zyp. vs other agents - scheultes asked about zyp and diabetes - was able to respond according and discuss moa of zyprexa- increase in appetitie which may lead to obesity but no causal relationship established between zyp and diabetes - also compared to other agents there is no increased incidence with zyp - high risk rate in this population anyway - he would like medical letter- but was satified with answer.
**********R**********
FOLLOWUP : **********R**********
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1679

NAME = Kristen Clouthier
CALLDATE = 07/15/2002
CALLID = 69571711
PRESCRIBERLN = Hagen
PRESCRIBERFN = Derek
CITY = Anchorage
STATE = AK
ACTION : office luncheon - **********R**********
********** zyprexa reminder of ssri pt, elderly pt and thick chart donna pt, indications, dosing appropriate startting dose, digfast cards - h scale questionnaire.
REACTION : maples just started here, oberstad and maples covering out of town docs pts - alot of elderly from smith

whenever he is out - perfect zyp pt - they all took the digfast - found it useful and will use - especially foland - **********R**********R**********R**********

FOLLOWUP : **********R********** zyp dvd again for different pt population **********R**********

LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1687

NAME = Kristen Clouthier
CALLDATE = 09/11/2002
CALLID = 71297363
PRESCRIBERLN = Bosveld
PRESCRIBERFN = Robert
CITY = Anchorage
STATE = AK
ACTION : office call - **********R********** book for dr farr from marvan - cme for dr farr.

REACTION : dr little will be golfing this next weekend - in ak with steer - hasnt diagnose anyone for zyp yet but looking. bosveld said he looked up zyp in tthe drug manual and it was classified as a psychotic - i discussed the indication of zyp and that the original studies were done for schizo pts - and that fda changed our pi to be a novel psychotropic - which encompasses modd stabilization. he asked if can use it as an ssri - said no it is not indicated as an antideppressant or for mood depressant but it does have stabilization for both negative and positive symptoms - he was satisfied with that. ******R******

FOLLOWUP : reminders reminders reminders - dr farr - cme?applebaum
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1950

NAME = Williams, Margaret
CALLDATE = 09/13/2002
CALLID = 71335378
PRESCRIBERLN = Bartling
PRESCRIBERFN = Victor
CITY = Fairbanks
STATE = AK
ACTION : Took in my usual muffins, got brief but decent detail time with each key doc, focused on Maguire recap, focused on bipolar patients and how ZYP is an efficacious, safe, and easy to dose mood stabilizer... The mood stabilizer light bulb seemed to finally "turn on" for Dr. Steiner, he did not remember that ZYP is a mood stabilizer, agreed that 1 of 3 pats depressed are bipolar depressed, has had patients get manic on an SSRI, so was all of a sudden rather interested in ZYP and was surprised ZYP is indicated for bipolar mania, his issue with ZYP is wt gain, send med letter on ZYP being used for bipolar disorder in general and strategies to manage potential weight gain. Dr. Judkins stated that he thinks primary care physicians will start to treat more and more bipolar pats since the medication (ZYP) is easy to dose, very safe, and actually works! Dr. Bartling declined being trained as a speaker (did really consider this and was complimented) as he has a very busy schedule at TVC, he's also the director of the Denali Nursing Home at the FBKS Memorial Hospital, and has several children. He and I discussed ZYP use in the elderly in more detail, but bipolar as well. Bartling wants more info on using ZYP in the elderly... All 4 docs just loved my Girdwood Forest Fair parade baby float photos, I knew they would! **********R**********

REACTION : Really friendly, actually. Even Dr. Steiner thanked me for kind of "interrupting" him and impressing upon him that ZYP IS indicated for bipolar mania and is a mood stabilizer...
FOLLOWUP : ZYP via handheld DVD...
LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER : ZYAKAG3 1960

NAME = Kristen Clouthier
CALLDATE = 09/13/2002
CALLID = 71468519
PRESCRIBERLN = Brock
PRESCRIBERFN = Heather
CITY = Anchorage
STATE = AK
ACTION : office call - samples, ****R***** pt education, goody bags, zyp pt education, cme opportunities- follow up with

hunt and heather for speaking times

REACTION : Heather - got the message about need ing dates- she is taking boards monday so very proccupied at the moment - will discuss wiht hunt mid next week and call. hunt - still interested yes - chld is sick so going home to work - will call me fter he and heather talk. grant - thank yous for the samples - **********R********** sharon smith - having great success with zyp on her most dificult pts too - realizes weight can be managed but has a cuople pts ballooned up - she says she cant get these pts here to fill out any forms - discussed 5 minute sit down for behavioral and weight watchers.. Jill johnson - always nice as can be - asked about using zyp as add on therapy to ssri - said not indicated there but third partied marvan and mcguire - it has been used in that instance - discusses quick efect. - **********R**********

FOLLOWUP : follow up with spanish zyp pt education, spanish weight mgmt guides, water bottles for office and heather hunt talks.

LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order

BATESNUMBER : ZYAKAG3 1963

NAME = Kristen Clouthier
CALLDATE = 09/13/2002
CALLID = 71468521
PRESCRIBERLN = Johnson
PRESCRIBERFN = Jill
CITY = Anchorage
STATE = AK

ACTION : office call - samples, ****R***** pt education, goody bags, zyp pt education, cme opportunities- follow up with hunt and heather for speaking times

REACTION : Heather - got the message about need ing dates- she is taking boards monday so very proccupied at the moment - will discuss wiht hunt mid next week and call. hunt - still interested yes - chld is sick so going home to work - will call me fter he and heather talk. grant - thank yous for the samples - **********R********** is interested in the cme - sharon smith - having great success with zyp on her most dificult pts too - realizes weight can be managed but has a cuople pts ballooned up - she says she cant get these pts here to fill out any forms - discussed 5 minute sit down for behavioral and weight watchers.. Jill johnson - always nice as can be - asked about using zyp as add on therapy to ssri - said not indicated there but third partied marvan and mcguire - it has been used in that instance - discusses quick efect. - **********R**********

FOLLOWUP : follow up with spanish zyp pt education, spanish weight mgmt guides, water bottles for office and heather hunt talks.

LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order

BATESNUMBER : ZYAKAG3 1964

NAME = Kristen Clouthier
CALLDATE = 10/22/2002
CALLID = 72417917
PRESCRIBERLN = Judkins
PRESCRIBERFN = Hunter
CITY = Fairbanks
STATE = AK

ACTION : office call - zyp slim jim, cme, digfast card

REACTION : he has tried zyp sucessfully- reminded him of the apa - he said he has used it for a couple of pts that have been previously treated with ssri and they became agitated or irritable. - no concerns at the moment - provided cme op to him - **********R**********

FOLLOWUP : **********R********** also elaborate on how to diagnose more pts - broader pt profile - compared vs risperdol and indications

LEGEND : State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order

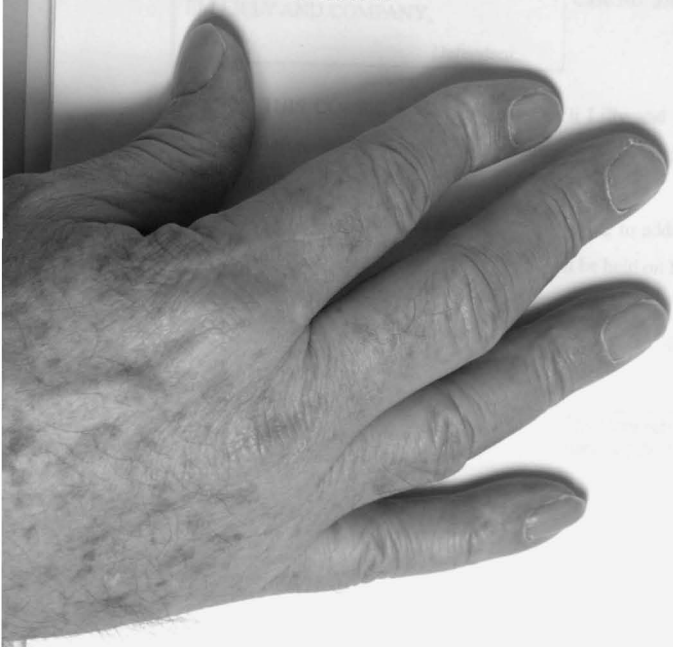
BATESNUMBER : ZYAKAG3 2106

NAME = Warren, John K
CALLDATE = 08/18/2003
CALLID = 80158589
PRESCRIBERLN = Steer
PRESCRIBERFN = Paul
CITY = Anchorage
STATE = AK

ACTION : met Dr. S. but he was in a rush so only had a minute to talk. asked him what he uses seroquel for?

REACTION : for patients not responding to ssri. rep sold him on it.

FOLLOWUP	:	follow up and spend time of quality of Zyp. vs. Seroquel.
LEGEND	:	State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER	:	ZYAKAG3 2939
NAME	=	Warren, John K
CALLDATE	=	10/14/2003
CALLID	=	81807470
PRESCRIBERLN	=	Farr
PRESCRIBERFN	=	Ilona
CITY	=	Anchorage
STATE	=	AK
ACTION	:	quick visit to see Dr. Farr - also saw Dr Trujillo. brieflyasked about depression pts.and success with SSRI treatment. set up a lunch wirth office and also may need to take Dr. Farr out for lunch to avoid interruptions. Need to remember to hammmer Zyp. safety versus Risperdal.
LEGEND	:	State of Alaska v. Eli Lilly and Company: Confidential - Subject to Protective Order
BATESNUMBER	:	ZYAKAG3 3133



IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered Eli Lilly and Company's ("Lilly") Motion to Rule on Before-Trial Admission of the State's "Pre-Admit" List, all responses thereto, as well as applicable law:

IT IS HEREBY ORDERED that a hearing to address the before-trial admissibility of the State's proposed "pre-admit" exhibits will be held on March __, at _____a.m./p.m.

ORDERED this _____ day of February/March, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 29, 2008, a copy of the foregoing was served by hand on:

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

009867/0038/163697.1

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

2.29.08

Not used 3.3.08

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

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant Eli Lilly and Company's Opposition to Plaintiff's Requests for Clarification of the Court's Orders Excluding Evidence of Other Drugs Manufactured by Defendant and Defendant's Profits, Net Worth and the Price of Zyprexa®:

IT IS HEREBY ORDERED that plaintiff's two requests for clarification are DENIED.

IT IS FURTHER ORDERED that this Court's original Orders regarding these Motions in Limine remain in effect with no modification.

ORDERED this _____ day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 27, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 406
Anchorage, Alaska 99501-5911

0098670038/163630.1

FEB 27 2008

LANE POWELL LLC
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered defendant Eli Lilly and Company's Motion Requesting Confidential Protections of Regulatory Communications Not Subject to Public Disclosure, any response thereto, as well as applicable law:

IT IS HEREBY ORDERED that Lilly's motion is GRANTED.

IT IS FURTHER ORDERED that the Court and the parties shall protect from disclosure Lilly's 2007 confidential submissions to the FDA and the related communications between Lilly and the FDA. This protection encompasses the documents as well as references to the same through testimony or briefing.

ORDERED this _____ day of February, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

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

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

009867/0038/163641.1

LANE POWELL LLC
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Anchorage, Alaska 99503-2648
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Returned 3/3/08

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ELI LILLY AND COMPANY'S MOTION TO RULE ON BEFORE-TRIAL ADMISSION OF THE STATE'S "PRE-ADMIT" LIST

During the February 22, 2008 pretrial conference, the State of Alaska ("the State") noted an interest in having a subset of the documents identified in its exhibit list admitted into evidence before the start of trial.[1] Eli Lilly and Company ("Lilly") has identified for the State the documents that it agrees to pre-admit into evidence, but many of the State's proposed exhibits are objectionable because the documents are subject to one or more of Lilly's motions in limine or proscribed by one or more of Alaska's Rules of Evidence.[2]

Additionally, on February 27, 2008, the Court granted, in part, Lilly's supplemental motion seeking dismissal of the State's claims pursuant to the UTPCPA exemption and federal preemption, dismissing the State's UTPCPA claims concerning Lilly's alleged marketing activity, but denying the motion as it related to Zyprexa's® labeling. Lilly

[1] Transcript of Pretrial Hearing, February 22, 2008, at 45:22 to 46:8.

[2] Specifically, the State's documents are inadmissible under Alaska Rules of Evidence 401-404, 701, 801-802, and/or 901-902.

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understood the Court's ruling, and filed a motion for clarification to confirm its understanding, to eliminate all of the State's claims that Lilly improperly promoted Zyprexa, leaving as the only question to be resolved during the first phase of trial whether Zyprexa's labeling adequately described the risks of the medication. Lilly argued that the very terms of the Court's ruling, the rationale that the Court applied in reaching its ruling by relying on the *Zeneca* decision, and the federal regulatory framework concerning pharmaceutical advertising required this conclusion. The Court confirmed Lilly's position during yesterday's hearing, noting that "[t]he jury is going to be instructed on the UTPA . . . based on evidence of the product labels, which I left in, and the jury is going to be instructed on common-law warning claims . . . . those claims are in . . . ."[3]

In light of the Court's ruling on summary judgment, many of the documents on the State's exhibit list are not relevant to the labeling claims remaining in the case because they are promotion-based documents that relate to:

- internal sales representative training material;
- promotional material, including safety information dictated by "fair balance" required by federal law;
- internal promotional-planning, market research, and market perceptions documents;
- internal communication related to potential line extensions for Zyprexa;

[3] Transcript of Pretrial Hearing, February 28, 2008, at 13:21 to 14:5.

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- internal information provided to Lilly's marketing department concerning responses to the media;
- information disseminated to the public and physicians unrelated to Zyprexa's labeling;
- information disseminated to physicians and the public unrelated to Zyprexa's safety; and
- internal information unrelated to Zyprexa's labeling.

For example, the State's exhibit number 00019, which is entitled, Zyprexa Primary Care Q3 Implementation Guide, is not only prejudicial and lacking foundation, but it is also an internal Lilly document related solely to sales-representative training. The document discusses Lilly's presence in the primary care field, sales messages and strategies based on market segmentation, training for sales representatives related to their interaction with physicians, and discussions of promotional material for use with physicians. This information was relevant only to the State's promotion-based UTPCPA claims and has no bearing on the State's remaining, label-based claims.

Lilly has attached as Exhibit "A," a complete list of the State's proposed "pre-admit" exhibits. The first column of Exhibit A, titled "Trialx#," is a list of the State's "pre-admit" list, sorted in numerical order. The second column of Exhibit "A" delineates each of the bases for Lilly's objections to each document. Lilly has also provided courtesy copies of the State's "pre-admit" documents for the Court's review.

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As the Court suggested during the pretrial hearing, Lilly requests that the Court set a hearing to rule as to the before-trial admissibility of the State's proposed "pre-admit" exhibits, and Lilly can describe its objections more specifically at that time.

DATED this 29th day of February, 2008.

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

By _____
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I certify that on February 29, 2008, a copy of the foregoing was served by hand on:

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_____

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Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
1	Zyprexa MDL Plaintiffs' Exhibit No 00019	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal Lilly training material; Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
2	Zyprexa MDL Plaintiffs' Exhibit No 00195	Hearsay; agree to admit - notice
3	Zyprexa MDL Plaintiffs' Exhibit No 00284	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)
4	Zyprexa MDL Plaintiffs' Exhibit No 00320	M.I.L. regarding Foreign Regulatory Actions M.I.L. regarding adverse events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)
5	Zyprexa MDL Plaintiffs' Exhibit No 00439	Hearsay; agree to admit - notice
6	Zyprexa MDL Plaintiffs' Exhibit No 00775	Hearsay; agree to admit - notice
7	Zyprexa MDL Plaintiffs' Exhibit No 00778	Hearsay; agree to admit - notice
8	Zyprexa MDL Plaintiffs' Exhibit No 00918	Agree to admit
9	Zyprexa MDL Plaintiffs' Exhibit No 00942	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Promotional material (any included safety information is included pursuant to federal regulation)
10	Zyprexa MDL Plaintiffs' Exhibit No 00946	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing plan Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802) Foundation (Alaska R. Evid. 901)
11	Zyprexa MDL Plaintiffs' Exhibit No 00985	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: glossary of marketing terms Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
12	Zyprexa MDL Plaintiffs' Exhibit No 00988	M.I.L. regarding adverse events Compound Exhibit
13	Zyprexa MDL Plaintiffs' Exhibit No 00990	Agree to admit

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Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
14	Zyprexa MDL Plaintiffs' Exhibit No 00995	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: information concerning marketplace; Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
15	Zyprexa MDL Plaintiffs' Exhibit No 01077	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document over one year before promotion to primary care market Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
16	Zyprexa MDL Plaintiffs' Exhibit No 01079	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: communications to primary care sales force M.I.L. regarding Profits and Price; Other Lilly Drugs; Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
17	Zyprexa MDL Plaintiffs' Exhibit No 01110	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document regarding internal market research, marketplace perceptions, and planning for proposed sales representative communications Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
18	Zyprexa MDL Plaintiffs' Exhibit No 01111	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document regarding internal market research, marketplace perceptions, and planning for proposed sales representative communications Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
19	Zyprexa MDL Plaintiffs' Exhibit No 01145	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing strategy document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
20	Zyprexa MDL Plaintiffs' Exhibit No 01169	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Character Evidence (Alaska R. Evid. 404) No allegation statements made in Alaska
21	Zyprexa MDL Plaintiffs' Exhibit No 01215	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal document concerning responses to anticipated questions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document

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Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
22	Zyprexa MDL Plaintiffs' Exhibit No 01301	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
23	Zyprexa MDL Plaintiffs' Exhibit No 01345	Hearsay; agree to admit - notice
24	Zyprexa MDL Plaintiffs' Exhibit No 01349	Agree to admit
25	Zyprexa MDL Plaintiffs' Exhibit No 01408	M.I.L. regarding adverse events M.I.L. regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802) Not a Complete Document Compound Exhibit
26	Zyprexa MDL Plaintiffs' Exhibit No 01419	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document concerning opportunities for line extensions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
27	Zyprexa MDL Plaintiffs' Exhibit No 01440	Hearsay; agree to admit - notice
28	Zyprexa MDL Plaintiffs' Exhibit No 01449	Hearsay; agree to admit - notice
29	Zyprexa MDL Plaintiffs' Exhibit No 01452	Hearsay; agree to admit - notice
30	Zyprexa MDL Plaintiffs' Exhibit No 01453	Hearsay; agree to admit - notice
31	Zyprexa MDL Plaintiffs' Exhibit No 01456	Hearsay; agree to admit - notice
32	Zyprexa MDL Plaintiffs' Exhibit No 01480	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal draft meeting agenda and notes of marketing employee Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
33	Zyprexa MDL Plaintiffs' Exhibit No 01586	Agree to admit
34	Zyprexa MDL Plaintiffs' Exhibit No 01602	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
35	Zyprexa MDL Plaintiffs' Exhibit No 01603	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document
36	Zyprexa MDL Plaintiffs' Exhibit No 01604	Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901) Compound Exhibit
37	Zyprexa MDL Plaintiffs' Exhibit No 01605	Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901)
38	Zyprexa MDL Plaintiffs' Exhibit No 01857	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: training and compliance with internal policy and law not at all connected to label
39	Zyprexa MDL Plaintiffs' Exhibit No 01926	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal Lilly training material Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
40	Zyprexa MDL Plaintiffs' Exhibit No 01962	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal Lilly training material Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
41	Zyprexa MDL Plaintiffs' Exhibit No 02197	Agree to admit
42	Zyprexa MDL Plaintiffs' Exhibit No 02368	Hearsay; agree to admit - notice
43	Zyprexa MDL Plaintiffs' Exhibit No 02588	M.I.L. regarding Profits and Price Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)
44	Zyprexa MDL Plaintiffs' Exhibit No 03109	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Internal discussions regarding proposed actions, unrelated to labeling
45	Zyprexa MDL Plaintiffs' Exhibit No 03211	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal communications re: potential sales representative communications

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Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
46	Zyprexa MDL Plaintiffs' Exhibit No 03223	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal document discussing strategy M.I.L. regarding Call Notes, Sales Reps Outside Alaska, Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Character Evidence (Alaska R. Evid. 404) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)
47	Zyprexa MDL Plaintiffs' Exhibit No 03567	Agree to admit
48	Zyprexa MDL Plaintiffs' Exhibit No 03680	Hearsay; agree to admit - notice
49	Zyprexa MDL Plaintiffs' Exhibit No 03816	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims M.I.L. regarding adverse events M.I.L. regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
50	Zyprexa MDL Plaintiffs' Exhibit No 03872	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)
51	Zyprexa MDL Plaintiffs' Exhibit No 03909	M.I.L. regarding Other Lilly Litigation Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
52	Zyprexa MDL Plaintiffs' Exhibit No 03924	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing plan 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)
53	Zyprexa MDL Plaintiffs' Exhibit No 03927	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Draft internal marketing slide regarding marketplace perceptions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Lay Witness Opinion (Alaska R. Evid. 701) Not a Complete Document Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
54	Zyprexa MDL Plaintiffs' Exhibit No 04007	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing video not shown to physicians or sales reps has nothing to do with labeling Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
55	Zyprexa MDL Plaintiffs' Exhibit No 04051	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal briefing, labeling not discussed Foundation (Alaska R. Evid. 901)
56	Zyprexa MDL Plaintiffs' Exhibit No 04176	Agree to admit
57	Zyprexa MDL Plaintiffs' Exhibit No 04365	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Marketing and planning document M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
58	Zyprexa MDL Plaintiffs' Exhibit No 04436	Not Relevant (Alaska R. Evid. 401, 402) M.I.L. regarding Foreign Regulatory Actions, Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
59	Zyprexa MDL Plaintiffs' Exhibit No 04532	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)
60	Zyprexa MDL Plaintiffs' Exhibit No 04784	Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Draft months before document was made final
61	Zyprexa MDL Plaintiffs' Exhibit No 04815	Hearsay; agree to admit - notice
62	Zyprexa MDL Plaintiffs' Exhibit No 04858	Agree to admit subject to M.I.L. regarding adverse events (hearsay - notice)
63	Zyprexa MDL Plaintiffs' Exhibit No 04864	M.I.L. regarding adverse events M.I.L. regarding Foreign Regulatory Actions Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
64	Zyprexa MDL Plaintiffs' Exhibit No 04871	Hearsay; agree to admit - notice

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Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
65	Zyprexa MDL Plaintiffs' Exhibit No 04968	Not Relevant (Alaska R. Evid. 401, 402): internal marketing planning document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Brief references to labeling are admissible from other sources
66	Zyprexa MDL Plaintiffs' Exhibit No 05073	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing strategy document
67	Zyprexa MDL Plaintiffs' Exhibit No 05078	Not Relevant (Alaska R. Evid. 401, 402) M.I.L. regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
68	Zyprexa MDL Plaintiffs' Exhibit No 05522	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)
69	Zyprexa MDL Plaintiffs' Exhibit No 05565	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal communication regarding proposed responses to anticipated questions in Germany. MIL re: Foreign Regulatory Actions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
70	Zyprexa MDL Plaintiffs' Exhibit No 05846	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document regarding sales force communications M.I.L. regarding Profits and Price
71	Zyprexa MDL Plaintiffs' Exhibit No 05913	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: MIL regarding Other Lilly Litigation; Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
72	Zyprexa MDL Plaintiffs' Exhibit No 06128	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: discussion regarding how to position marketing outside of the United States in reaction to referenced study is not in the case Hearsay
73	Zyprexa MDL Plaintiffs' Exhibit No 06215	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
74	Zyprexa MDL Plaintiffs' Exhibit No 06360	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
75	Zyprexa MDL Plaintiffs' Exhibit No 06890	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Lay Witness Opinion (Alaska R. Evid. 701)
76	Zyprexa MDL Plaintiffs' Exhibit No 06998	Hearsay; agree to admit - notice
77	Zyprexa MDL Plaintiffs' Exhibit No 06999	Hearsay; agree to admit - notice
78	Zyprexa MDL Plaintiffs' Exhibit No 07028	Agree to admit
79	Zyprexa MDL Plaintiffs' Exhibit No 07731	M.I.L. regarding adverse events Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901)
80	Zyprexa MDL Plaintiffs' Exhibit No 07802	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
81	Zyprexa MDL Plaintiffs' Exhibit No 07804	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
82	Zyprexa MDL Plaintiffs' Exhibit No 07822	M.I.L. 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)
83	Zyprexa MDL Plaintiffs' Exhibit No 07971	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal Lilly training material
84	Zyprexa MDL Plaintiffs' Exhibit No 08042	Agree to admit as to pp. 1-2. No foundation as to p. 3 (Alaska R. Evid. 901).
85	Zyprexa MDL Plaintiffs' Exhibit No 08141	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Draft internal planning strategy document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

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Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
86	Zyprexa MDL Plaintiffs' Exhibit No 08262	Agree to admit
87	Zyprexa MDL Plaintiffs' Exhibit No 08479	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document relating to primary care M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
88	Zyprexa MDL Plaintiffs' Exhibit No 08562	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document describing the structure of a team that is not relevant to any labeling claims Waste of Time (Alaska R. Evid. 403)
89	Zyprexa MDL Plaintiffs' Exhibit No 08564	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing planning document M.I.L. regarding Profits and Price Foundation (Alaska R. Evid. 901)
90	Zyprexa MDL Plaintiffs' Exhibit No 08584	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal planning document M.I.L. 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)
91	Zyprexa MDL Plaintiffs' Exhibit No 08632	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing sales representative interaction with physicians
92	Zyprexa MDL Plaintiffs' Exhibit No 08666	Agree to admit
93	Zyprexa MDL Plaintiffs' Exhibit No 08911	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document concerning sales representative interaction with physicians Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Character Evidence (Alaska R. Evid. 404) Foundation (Alaska R. Evid. 901)
94	Zyprexa MDL Plaintiffs' Exhibit No 08960	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal training document for sales representatives
95	Zyprexa MDL Plaintiffs' Exhibit No 08997	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document not relevant to labeling claims Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
96	Zyprexa MDL Plaintiffs' Exhibit No 09054	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document concerning planning M.I.L. regarding Profits and Price M.I.L. regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802)
97	Zyprexa MDL Plaintiffs' Exhibit No 09070	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Document discussing the pharmaceutical industry generally, the general corporate structure of Lilly M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Lay Witness Opinion (Alaska R. Evid. 701) Hearsay (Alaska R. Evid. 801, 802)
98	Zyprexa MDL Plaintiffs' Exhibit No 09073	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Document discussing Lilly's corporate structure M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802) Foundation (Alaska R. Evid. 901)
99	Zyprexa MDL Plaintiffs' Exhibit No 09165	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal planning correspondence regarding perceptions of the market Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
100	Zyprexa MDL Plaintiffs' Exhibit No 09201	Hearsay; agree to admit - notice
101	Zyprexa MDL Plaintiffs' Exhibit No 09281	Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
102	Zyprexa MDL Plaintiffs' Exhibit No 09624	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing and planning document M.I.L. regarding Profits and Price Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
103	Zyprexa MDL Plaintiffs' Exhibit No 09722	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document related to interactions with physicians
104	Zyprexa MDL Plaintiffs' Exhibit No 09739	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal planning document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
105	Zyprexa MDL Plaintiffs' Exhibit No 09807	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
106	Zyprexa MDL Plaintiffs' Exhibit No 09808	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing available programs. Foundation (Alaska R. Evid. 901) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
107	Zyprexa Plaintiff's Exhibit 10017	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing Lilly's foreign sales force M.I.L. regarding Foreign Regulatory Actions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
108	Zyprexa Plaintiff's Exhibit 10025	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document from Marketing to the sales force M.I.L. regarding Other Lilly drugs Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902) M.I.L. regarding Other Lilly drugs
109	Zyprexa Plaintiff's Exhibit 10026	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal company material related to sales force communications Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
110	Zyprexa Plaintiff's Exhibit 10027	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal company material related to sales force commission Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
111	Zyprexa Plaintiff's Exhibit 10029	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing training of sales representatives to interact with physicians
112	Zyprexa Plaintiff's Exhibit 10030	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: promotional material in its final form, as subjected to federal law and regulation Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

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Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
113	Zyprexa Plaintiff's Exhibit 10031	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document among marketing team M.I.L. regarding Other Lilly Litigation Hearsay (Alaska R. Evid. 801, 802)
114	Zyprexa Plaintiff's Exhibit 10038	Not Relevant (Alaska R. Evid. 401, 402) M.I.L. regarding Other Lilly Litigation; Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Compromise or Offer to Compromise (Alaska R. Evid. 408) Insurance (Alaska R. Evid. 411)
115	Zyprexa Plaintiff's Exhibit 10041	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)
116	Zyprexa Plaintiff's Exhibit 10061	Not Relevant (Alaska R. Evid. 401, 402) to labeling M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)
117	Zyprexa Plaintiff's Exhibit 10064	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal planning document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
118	Zyprexa Plaintiff's Exhibit 10066	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing marketplace perceptions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
119	Zyprexa Plaintiff's Exhibit 10068	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)
120	Zyprexa Plaintiff's Exhibit 10094	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)

EXHIBIT A
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Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
121	Zyprexa Plaintiff's Exhibit 10095	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407)
122	Zyprexa Plaintiff's Exhibit 10097	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document concerning sales-representive interactions with physicians.
123	Zyprexa Plaintiff's Exhibit 10104	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407
124	Zyprexa Plaintiff's Exhibit 10105	M.I.L. regarding Foreign Regulatory Actions M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407)
125	Zyprexa Plaintiff's Exhibit 10107	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407)
126	Zyprexa Plaintiff's Exhibit 10108	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)
127	Zyprexa Plaintiff's Exhibit 10109	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)
128	Zyprexa Plaintiff's Exhibit 10110	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
129	Zyprexa Plaintiff's Exhibit 10111	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)

EXHIBIT A
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

PLAINTIFF'S SUBMISSION OF EXHIBITS TO BE PRE-ADMITTED FOR USE DURING OPENING STATEMENT

Plaintiff hereby submits certain of Plaintiff's Exhibits for review by the Court to determine their admissibility in advance of Opening Statements. See Attachment A hereto. Each of these exhibits is objected to by Defendant as indicated in Lilly's Response to Plaintiff's Pre-Admit Exhibit List. See Attachment B. The Plaintiff's Exhibits being submitted for the Court's review for use in Opening Statement are only a subset of the exhibits listed in Lilly's Response and for the Court's convenience, Plaintiff has highlighted Lilly's Response to indicate which of the exhibits are included in this submission to which Lilly objects.

Plaintiff is also submitting seven additional documents for review by the Court which were not previously included on Plaintiff's Pre-Admit Exhibit List and thus Lilly has not yet had an opportunity to indicate its objections to those particular exhibits. See Attachment C. Plaintiff assumes that Defendant will object to them all.

With respect to certain exhibits, particularly lengthy exhibits, the Plaintiff has for the Court's convenience highlighted particularly pertinent sections. In addition, Plaintiff attaches a letter from Scott Allen regarding the admissibility of certain exhibits and categories of exhibits. See Attachment D. Plaintiff requests that the Court read Mr. Allen's letter before reviewing the Exhibits attached hereto as it may assist the Court in understanding Plaintiff's positions regarding the admissibility of these documents.

Respectfully submitted this 29th day of February, 2008.

FELDMAN, ORLANSKY & SANDERS

Counsel for Plaintiff

BY Eric Sanders by

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(843) 727-6500
Counsel for Plaintiff

CERTIFICATE OF SERVICE

Plaintiff, State of Alaska, hereby certifies that it has caused to be served upon the individuals listed below a copy of Memorandum in Support of Plaintiff's Motion to Compel via hand delivery on February _____, 2008.

Respectfully submitted,

Eric T. Sanders
Feldman, Orlansky & Sanders
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Anchorage, AK 99501
(907) 272-3538

COUNSEL FOR PLAINTIFF

Defendant's Counsel

George Lehner, Esq.
The Hotel Captain Cook

Dated: February _____, 2008

ATTACHMENT B

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
1	Zyprexa MDL Plaintiffs' Exhibit No 00019	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal Lilly training material; Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
2	Zyprexa MDL Plaintiffs' Exhibit No 00195	Hearsay; agree to admit - notice
3	Zyprexa MDL Plaintiffs' Exhibit No 00284	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)
4	Zyprexa MDL Plaintiffs' Exhibit No 00320	M.I.L. regarding Foreign Regulatory Actions M.I.L. regarding adverse events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)
5	Zyprexa MDL Plaintiffs' Exhibit No 00439	Hearsay; agree to admit - notice
6	Zyprexa MDL Plaintiffs' Exhibit No 00775	Hearsay; agree to admit - notice
7	Zyprexa MDL Plaintiffs' Exhibit No 00778	Hearsay; agree to admit - notice
8	Zyprexa MDL Plaintiffs' Exhibit No 00918	Agree to admit
9	Zyprexa MDL Plaintiffs' Exhibit No 00918	Agree to admit
10	Zyprexa MDL Plaintiffs' Exhibit No 00942	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Promotional material (any included safety information is included pursuant to federal regulation)
11	Zyprexa MDL Plaintiffs' Exhibit No 00946	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing plan Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802) Foundation (Alaska R. Evid. 901)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
12	Zyprexa MDL Plaintiffs' Exhibit No 00985	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: glossary of marketing terms Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
13	Zyprexa MDL Plaintiffs' Exhibit No 00988	M.I.L. regarding adverse events Compound Exhibit
14	Zyprexa MDL Plaintiffs' Exhibit No 00990	Agree to admit
15	Zyprexa MDL Plaintiffs' Exhibit No 00995	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: information concerning marketplace; Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
16	Zyprexa MDL Plaintiffs' Exhibit No 01077	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document over one year before promotion to primary care market Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
17	Zyprexa MDL Plaintiffs' Exhibit No 01079	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: communications to primary care sales force M.I.L. regarding Profits and Price; Other Lilly Drugs; Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
18	Zyprexa MDL Plaintiffs' Exhibit No 01110	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document regarding internal market research, marketplace perceptions, and planning for proposed sales representative communications Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
19	Zyprexa MDL Plaintiffs' Exhibit No 01111	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document regarding internal market research, marketplace perceptions, and planning for proposed sales representative communications Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
20	Zyprexa MDL Plaintiffs' Exhibit No 01145	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing strategy document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
21	Zyprexa MDL Plaintiffs' Exhibit No 01169	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Character Evidence (Alaska R. Evid. 404) No allegation statements made in Alaska
22	Zyprexa MDL Plaintiffs' Exhibit No 01215	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal document concerning responses to anticipated questions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document
23	Zyprexa MDL Plaintiffs' Exhibit No 01301	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
24	Zyprexa MDL Plaintiffs' Exhibit No 01345	Hearsay; agree to admit - notice
25	Zyprexa MDL Plaintiffs' Exhibit No 01349	Agree to admit
26	Zyprexa MDL Plaintiffs' Exhibit No 01408	M.I.L. regarding adverse events M.I.L. regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802) Not a Complete Document Compound Exhibit
27	Zyprexa MDL Plaintiffs' Exhibit No 01419	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal planning document concerning opportunities for line extensions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
28	Zyprexa MDL Plaintiffs' Exhibit No 01440	Hearsay; agree to admit - notice
29	Zyprexa MDL Plaintiffs' Exhibit No 01449	Hearsay; agree to admit - notice

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
30	Zyprexa MDL Plaintiffs' Exhibit No 01452	Hearsay; agree to admit - notice
31	Zyprexa MDL Plaintiffs' Exhibit No 01453	Hearsay; agree to admit - notice
32	Zyprexa MDL Plaintiffs' Exhibit No 01456	Hearsay; agree to admit - notice
33	Zyprexa MDL Plaintiffs' Exhibit No 01480	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal draft meeting agenda and notes of marketing employee Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
34	Zyprexa MDL Plaintiffs' Exhibit No 01586	Agree to admit
35	Zyprexa MDL Plaintiffs' Exhibit No 01602	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901)
36	Zyprexa MDL Plaintiffs' Exhibit No 01603	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document
37	Zyprexa MDL Plaintiffs' Exhibit No 01604	Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901) Compound Exhibit
38	Zyprexa MDL Plaintiffs' Exhibit No 01605	Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901)
39	Zyprexa MDL Plaintiffs' Exhibit No 01857	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: training and compliance with internal policy and law not at all connected to label

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
40	Zyprexa MDL Plaintiffs' Exhibit No 01926	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal Lilly training material Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
41	Zyprexa MDL Plaintiffs' Exhibit No 01962	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal Lilly training material Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
42	Zyprexa MDL Plaintiffs' Exhibit No 02197	Agree to admit
43	Zyprexa MDL Plaintiffs' Exhibit No 02368	Hearsay; agree to admit - notice
44	Zyprexa MDL Plaintiffs' Exhibit No 02588	M.I.L. regarding Profits and Price Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)
45	Zyprexa MDL Plaintiffs' Exhibit No 03109	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Internal discussions regarding proposed actions, unrelated to labeling
46	Zyprexa MDL Plaintiffs' Exhibit No 03211	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal communications re: potential sales representative communications
47	Zyprexa MDL Plaintiffs' Exhibit No 03223	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal document discussing strategy M.I.L. regarding Call Notes, Sales Reps Outside Alaska, Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Character Evidence (Alaska R. Evid. 404) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)
48	Zyprexa MDL Plaintiffs' Exhibit No 03567	Agree to admit
49	Zyprexa MDL Plaintiffs' Exhibit No 03680	Hearsay; agree to admit - notice

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
50	Zyprexa MDL Plaintiffs' Exhibit No 03816	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims M.I.L. regarding adverse events M.I.L. regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
51	Zyprexa MDL Plaintiffs' Exhibit No 03872	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)
52	Zyprexa MDL Plaintiffs' Exhibit No 03909	M.I.L. regarding Other Lilly Litigation Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
53	Zyprexa MDL Plaintiffs' Exhibit No 03924	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing plan 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)
54	Zyprexa MDL Plaintiffs' Exhibit No 03927	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Draft internal marketing slide regarding marketplace perceptions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Lay Witness Opinion (Alaska R. Evid. 701) Not a Complete Document Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
55	Zyprexa MDL Plaintiffs' Exhibit No 04007	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing video not shown to physicians or sales reps has nothing to do with labeling Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
56	Zyprexa MDL Plaintiffs' Exhibit No 04051	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal briefing, labeling not discussed Foundation (Alaska R. Evid. 901)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
57	Zyprexa MDL Plaintiffs' Exhibit No 04176	Agree to admit
58	Zyprexa MDL Plaintiffs' Exhibit No 04365	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Marketing and planning document M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
59	Zyprexa MDL Plaintiffs' Exhibit No 04436	Not Relevant (Alaska R. Evid. 401, 402) M.I.L. regarding Foreign Regulatory Actions, Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
60	Zyprexa MDL Plaintiffs' Exhibit No 04532	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)
61	Zyprexa MDL Plaintiffs' Exhibit No 04784	Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Draft months before document was made final
62	Zyprexa MDL Plaintiffs' Exhibit No 04815	Hearsay; agree to admit - notice
63	Zyprexa MDL Plaintiffs' Exhibit No 04858	Agree to admit subject to M.I.L. regarding adverse events (hearsay - notice)
64	Zyprexa MDL Plaintiffs' Exhibit No 04864	M.I.L. regarding adverse events M.I.L. regarding Foreign Regulatory Actions Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
65	Zyprexa MDL Plaintiffs' Exhibit No 04871	Hearsay; agree to admit - notice
66	Zyprexa MDL Plaintiffs' Exhibit No 04968	Not Relevant (Alaska R. Evid. 401, 402): internal marketing planning document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Brief references to labeling are admissible from other sources

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
67	Zyprexa MDL Plaintiffs' Exhibit No 05073	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: internal marketing strategy document
68	Zyprexa MDL Plaintiffs' Exhibit No 05078	Not Relevant (Alaska R. Evid. 401, 402) M.I.L. regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
69	Zyprexa MDL Plaintiffs' Exhibit No 05522	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)
70	Zyprexa MDL Plaintiffs' Exhibit No 05565	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal communication regarding proposed responses to anticipated questions in Germany. MIL re: Foreign Regulatory Actions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
71	Zyprexa MDL Plaintiffs' Exhibit No 05846	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document regarding sales force communications M.I.L. regarding Profits and Price
72	Zyprexa MDL Plaintiffs' Exhibit No 05913	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: MIL regarding Other Lilly Litigation; Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
73	Zyprexa MDL Plaintiffs' Exhibit No 06128	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: discussion regarding how to position marketing outside of the United States in reaction to referenced study is not in the case Hearsay
74	Zyprexa MDL Plaintiffs' Exhibit No 06215	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
75	Zyprexa MDL Plaintiffs' Exhibit No 06360	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
76	Zyprexa MDL Plaintiffs' Exhibit No 06890	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Lay Witness Opinion (Alaska R. Evid. 701)
77	Zyprexa MDL Plaintiffs' Exhibit No 06998	Hearsay; agree to admit - notice
78	Zyprexa MDL Plaintiffs' Exhibit No 06999	Hearsay; agree to admit - notice
79	Zyprexa MDL Plaintiffs' Exhibit No 07028	Agree to admit
80	Zyprexa MDL Plaintiffs' Exhibit No 07731	M.I.L. regarding adverse events Not Relevant (Alaska R. Evid. 401, 402) Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901)
81	Zyprexa MDL Plaintiffs' Exhibit No 07802	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
82	Zyprexa MDL Plaintiffs' Exhibit No 07804	Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
83	Zyprexa MDL Plaintiffs' Exhibit No 07822	M.I.L. 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)
84	Zyprexa MDL Plaintiffs' Exhibit No 07971	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal Lilly training material

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
85	Zyprexa MDL Plaintiffs' Exhibit No 08042	Agree to admit as to pp. 1-2. No foundation as to p. 3 (Alaska R. Evid. 901).
86	Zyprexa MDL Plaintiffs' Exhibit No 08141	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Draft internal planning strategy document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
87	Zyprexa MDL Plaintiffs' Exhibit No 08262	Agree to admit
88	Zyprexa MDL Plaintiffs' Exhibit No 08479	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document relating to primary care M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
89	Zyprexa MDL Plaintiffs' Exhibit No 08562	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document describing the structure of a team that is not relevant to any labeling claims Waste of Time (Alaska R. Evid. 403)
90	Zyprexa MDL Plaintiffs' Exhibit No 08564	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing planning document M.I.L. regarding Profits and Price Foundation (Alaska R. Evid. 901)
91	Zyprexa MDL Plaintiffs' Exhibit No 08584	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal planning document M.I.L. 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)
92	Zyprexa MDL Plaintiffs' Exhibit No 08632	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing sales representative interaction with physicians
93	Zyprexa MDL Plaintiffs' Exhibit No 08666	Agree to admit

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
94	Zyprexa MDL Plaintiffs' Exhibit No 08911	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document concerning sales representative interaction with physicians Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Character Evidence (Alaska R. Evid. 404) Foundation (Alaska R. Evid. 901)
95	Zyprexa MDL Plaintiffs' Exhibit No 08960	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal training document for sales representatives
96	Zyprexa MDL Plaintiffs' Exhibit No 08997	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document not relevant to labeling claims Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Not a Complete Document
97	Zyprexa MDL Plaintiffs' Exhibit No 09054	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal strategy document concerning planning M.I.L. regarding Profits and Price M.I.L. regarding Foreign Regulatory Actions Hearsay (Alaska R. Evid. 801, 802)
98	Zyprexa MDL Plaintiffs' Exhibit No 09070	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Document discussing the pharmaceutical industry generally, the general corporate structure of Lilly M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Lay Witness Opinion (Alaska R. Evid. 701) Hearsay (Alaska R. Evid. 801, 802)
99	Zyprexa MDL Plaintiffs' Exhibit No 09073	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Document discussing Lilly's corporate structure M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802) Foundation (Alaska R. Evid. 901)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
100	Zyprexa MDL Plaintiffs' Exhibit No 09165	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal planning correspondence regarding perceptions of the market Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902)
101	Zyprexa MDL Plaintiffs' Exhibit No 09201	Hearsay; agree to admit - notice
102	Zyprexa MDL Plaintiffs' Exhibit No 09281	Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
103	Zyprexa MDL Plaintiffs' Exhibit No 09624	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal marketing and planning document M.I.L. regarding Profits and Price Hearsay (Alaska R. Evid. 801, 802) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
104	Zyprexa MDL Plaintiffs' Exhibit No 09722	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document related to interactions with physicians
105	Zyprexa MDL Plaintiffs' Exhibit No 09739	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal planning document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
106	Zyprexa MDL Plaintiffs' Exhibit No 09807	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
107	Zyprexa MDL Plaintiffs' Exhibit No 09808	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing available programs. Foundation (Alaska R. Evid. 901) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
108	Zyprexa Plaintiff's Exhibit 10017	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing Lilly's foreign sales force M.I.L. regarding Foreign Regulatory Actions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
109	Zyprexa Plaintiff's Exhibit 10025	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document from Marketing to the sales force M.I.L. regarding Other Lilly drugs Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901) Not Authenticated (Alaska R. Evid. 901, 902) M.I.L. regarding Other Lilly drugs
110	Zyprexa Plaintiff's Exhibit 10026	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal company material related to sales force communications Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
111	Zyprexa Plaintiff's Exhibit 10027	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal company material related to sales force commission Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
112	Zyprexa Plaintiff's Exhibit 10029	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing training of sales representatives to interact with physicians
113	Zyprexa Plaintiff's Exhibit 10030	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: promotional material in its final form, as subjected to federal law and regulation Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
114	Zyprexa Plaintiff's Exhibit 10031	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document among marketing team M.I.L. regarding Other Lilly Litigation Hearsay (Alaska R. Evid. 801, 802)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
115	Zyprexa Plaintiff's Exhibit 10038	Not Relevant (Alaska R. Evid. 401, 402) M.I.L. regarding Other Lilly Litigation; Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Compromise or Offer to Compromise (Alaska R. Evid. 408) Insurance (Alaska R. Evid. 411)
116	Zyprexa Plaintiff's Exhibit 10041	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)
117	Zyprexa Plaintiff's Exhibit 10061	Not Relevant (Alaska R. Evid. 401, 402) to labeling M.I.L. regarding Profits and Price Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Hearsay (Alaska R. Evid. 801, 802)
118	Zyprexa Plaintiff's Exhibit 10064	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal planning document Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Foundation (Alaska R. Evid. 901)
119	Zyprexa Plaintiff's Exhibit 10066	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document discussing marketplace perceptions Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403)
120	Zyprexa Plaintiff's Exhibit 10068	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)
121	Zyprexa Plaintiff's Exhibit 10094	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
122	Zyprexa Plaintiff's Exhibit 10095	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407)
123	Zyprexa Plaintiff's Exhibit 10097	Not Relevant (Alaska R. Evid. 401, 402) to Labeling Claims: Internal document concerning sales-representive interactions with physicians.
124	Zyprexa Plaintiff's Exhibit 10104	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407
125	Zyprexa Plaintiff's Exhibit 10105	M.I.L. regarding Foreign Regulatory Actions M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407)
126	Zyprexa Plaintiff's Exhibit 10107	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407)
127	Zyprexa Plaintiff's Exhibit 10108	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)
128	Zyprexa Plaintiff's Exhibit 10109	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)

Lilly's Responses to the State's Pre-Admission List

	Trialx#	Subject
129	Zyprexa Plaintiff's Exhibit 10110	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)
130	Zyprexa Plaintiff's Exhibit 10111	M.I.L. regarding Recent Regulatory Events Not Relevant (Alaska R. Evid. 401, 402) Prejudicial, Confusing, Waste of Time (Alaska R. Evid. 403) Subsequent Remedial Measures (Alaska R. Evid. 407) Hearsay (Alaska R. Evid. 801, 802)

A

ATTACHMENT D

CRUSE, SCOTT, HENDERSON & ALLEN, L.L.P.

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February 29, 2008

VIA HAND DELIVERY

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

Dear Judge Rindner:

I am forwarding to Your Honor the documents the State intends to use in opening next week. There is no way possible to use each of these documents in its entirety in opening, and only a foolish lawyer would attempt to do so. However, there are sentences within each, and/or a word or two within some, that I will discuss with the jury. For example, in Document #08479, I intend to discuss the language about Lilly's expansion of the Zyprexa market in 2000 (and thus the expansion of the lack of a warning) to a broader market including PCPs (primary care physicians).This market is described within the document as "huge."

Further, Lilly's stated "position" within the document is listed as: "Zyprexa: the safe proven solution...we will emphasize safety..." Jack Jordan, Lilly's U.S. Marketing Director, defines the term product "position" in his testimony as "what we want our customers to think about a product."

While I will not see Lilly's "objection" to this document or others as I write this correspondence (I am taking the deposition of Ms. Eski and did not receive the objections of Lilly before I left for today's deposition), I can imagine that they will contend it is "objectionable" because it relates to the "off-label" claim. This document is not offered for that purpose; it is offered as proof of erosion of the printed warning, lack of warning and deceptive trade practices under the UTPA.

This is but one example of how/why a document is relevant and material for more than one purpose.

Sincerely, while I cannot anticipate all of Lilly's "objections" here in the dark, it may be that Lilly will not object or that they will make broad objections that are based on false assumptions about the claim of admissibility, particularly on the VIVA Zyprexa PCP campaign. One thing should be kept in mind about this PCP effort. Such documents will not be offered for "off-label" purposes (in fact Lilly has always contended that it did not market off-label and thus any contention by them that these documents will be presented to the jury for such purposes is both contrary to their claim that they did not off-label market and more importantly mistakenly states our reason for the introduction of same). Another example is Document #5846, the power point presented at the VIVA "launch party" in Orlando, Florida in October 2000. Slide #68 asks the question "why are we entering this market?" and is answered by Lilly, in part, "Zyprexa's success is crucial to corporate performance; PCPs represent last major untapped segment." Slide #79 sets forth "key message elements" identifying "safety" and "ease of use...no blood monitoring" (the only way to obtain a diagnosis of hyperglycemia/diabetes is by blood monitoring which is featured as unnecessary by Lilly). Same for Slide #83, etc...

Therefore, I ask the Court to recognize that Lilly's "objections" may mistakenly direct the Court's attention to a claimed purpose of the State that is not accurate. I, for one, believe this is likely to occur. I can give two more brief examples, Exhibits #1926 and #284 involving "detailing" pieces given to doctors and sales force training. These pieces mention "Donna" etc... who now must be accepted as an on-label promotion per multiple Lilly marketing executives' testimony (a fact with which we disagree but off-label is no longer a cause of action). Still, the detailing pieces demonstrate that Lilly continued to "position" Zyprexa as "favorable safety profile" for which "blood monitoring" (the method to diagnose diabetes) was not required.

In sum, Your Honor, I am writing this letter "in the dark" inasmuch as I have not seen the objections and am now in deposition. But, I want the Court to know that I am aware of the Court's rulings, am experienced counsel and can assure the Court that all of my reasons for the documents submitted are within the Court's rulings and the remaining causes of action. If I am later proven wrong, it will be my client who suffers – but I do not want the State's purpose to be misstated without the opportunity to be heard. Thus, I ask for a hearing on Monday to the extent I need to explain the need to present this evidence in opening.

In closing, I sincerely appreciate the Court's time, energy and effort and will be available by phone at the Captain Cook Hotel, or by cell (713) 907-8319 to

answer any questions and would like the opportunity to do so if you have inquiries.

Sincerely yours,

Scott Allen by

On Behalf of the State of Alaska
T. Scott Allen, Jr.

TSA/jrm

P.S. I apologize for any poor sentence structure and misspellings as I am dictating this "on the run" to the deposition of Ms. Eski.

cc: Mr. George A. Lehner
Mr. Brewster Jamieson

In the Supreme Court of the State of Alaska

Eli Lilly and Company,	)	
	)	Supreme Court No. **S-13026**
Petitioner,	)	
v.	)	**Notice of Filing**
	)	Appellate Rule 402, 403
State of Alaska,	)	Trial Court Interlocutory Order
	)	
Respondent.	)	Date of Notice: **2/29/08**
	)	

Trial Court Case # **3AN-06-05630CI**

A petition for review of Judge Rindner's order distributed on **2/27/08** was filed on **2/29/08**. The response to the petition is due on or before **3/13/08**.

Clerk of the Appellate Courts

cc: Judge Rindner
Trial Court Clerk/Anchorage

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

STATE OF ALASKA,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 3AN-06-05630 CI

ORDER

THIS COURT, having considered Eli Lilly and Company's ("Lilly") Opposition to the State's Objections to Defendant's Exhibits, as well as applicable law:

IT IS HEREBY ORDERED that the State's Objections are OVERRULED.

IT IS FURTHER ORDERED that Lilly's exhibits, to wit, the internal FDA documents are ADMITTED.

ORDERED this _____ day of February/March, 2008.

The Honorable Mark Rindner
Judge of the Superior Court

I certify that on February 29, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L. Street, Suite 400
Anchorage, Alaska 99501-3911

009867 0038/163702.1

2-29-08

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

ELI LILLY AND COMPANY'S OPPOSITION TO THE STATE'S OBJECTIONS TO DEFENDANT'S EXHIBITS

The Court has required the State of Alaska ("the State") to serve its objections to exhibits that Eli Lilly and Company ("Lilly") may refer to or show the jury in its opening statement. In response, the State served on Lilly its prior objections to Lilly's exhibits, which had been previously served on February 19, 2008.[1] Pursuant to the Court's instructions, and without waiving its right to respond to all of the State's objections, Lilly responds in this pleading only to those objections that pertain to exhibits it may introduce during its opening statement, all of which are documents produced by the FDA. The State's objections to these exhibits should be overruled and the Court should admit these exhibits prior to Lilly's opening statement because these FDA reports are not hearsay, or fall within an exception to the hearsay rule, and are relevant to its defenses to the State's claims.

[1] *See* Exhibit A, Plaintiff's Objections to Defendant's Exhibits.

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I. LILLY'S INTERNAL FDA DOCUMENTS ARE NOT HEARSAY, AND FALL WITHIN THE PUBLIC RECORDS AND REPORTS EXCEPTION TO ALASKA RULE OF EVIDENCE 803(8).

Lilly may refer to internal FDA documents, identified in the State's Exhibit C to their objections, during its opening statement. Contrary to the State's objections, these documents are admissible because they are not hearsay, and even if they were hearsay, they fall within an exception to the hearsay rule under the Alaska Rules of Evidence.

In its brief, the State argues that these documents are inadmissible hearsay that are "riddled with hearsay within hearsay." *See* State's Br. at p. 9. However, these documents are not hearsay under the Alaska Rules of Evidence to the extent they are introduced for the fact that the FDA prepared internal reviews and memoranda that reflect evaluations of the available clinical trial and adverse event report data submitted to the FDA at the time, independent of what the FDA concluded. *See* Alaska R. Evid. 801 (defining hearsay); *see also Zeneca Inc. v. Barr Laboratories, Inc.*, 1999 WL 509471, at *3 (S.D.N.Y. July 19, 1999) (finding that FDA documents were admissible as "not hearsay" because they were not introduced for their truth).[2]

Furthermore, to the extent admitted for the truth, the FDA documents fall within the public records exception to the hearsay rule. *See* Alaska R. Evid. 803(8). Under Rule 803(8):

[2] Lilly is not contending that it received the FDA documents contemporaneously with their creation, or prior to the litigation, such that it fulfills the notice exception to the hearsay rule. Accordingly, this objection by the State is not pertinent to admissibility.

> [R]ecords, reports, statements, or data compilations *in any form* of a public office or agency setting forth its regularly conducted and regularly recorded activities, or matters observed pursuant to duty imposed by law and as to which there was a duty to report, or factual findings from an investigation made pursuant to authority granted by law.

Id. (emphasis added). Lilly's internal FDA exhibits are reports from a public office or agency setting forth factual findings made pursuant to federal law, and thus, fall within this exception to the hearsay rule. Moreover, Lilly has complied with the requirement of Alaska Evidence Rule 803(8)(b) that it "deliver a copy of it" to the adverse party within "a reasonable time before the trial . . . ." Lilly has produced its exhibits electronically on February 4, 2008, in accordance with this Court's Routine Pretrial Order, and thus there is no unfair surprise on the State.[3]

While no court in Alaska has addressed this precise evidentiary issue, several federal courts, applying the same exception under the Federal Rules of Evidence, have found that a report or statement of the FDA, or similar agencies, falls within the public records exception to the hearsay rule. *See Figueroa v. Boston Scientific Corporation*, 2003 WL 21488012, at *3 (S.D.N.Y. June 27, 2003) (finding that a letter prepared by the FDA was a "report" under Federal Rule of Evidence 803(8) and was admissible under the public records exception); *Kennedy v. Baxter Healthcare Corporation*, 66 Fed. Appx. 662, 663 (8th Cir. 2003) (finding that "informal FDA pronouncements were probative of whether [a

[3] In fact, the documents were actually produced by the FDA to the Plaintiffs' Steering Committee in the Multi-District Litigation, including attorneys for the State in this case.

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manufacturer] acted reasonably in designing, labeling, and selling"). *In re Agent Orange Product Liability*, 611 F. Supp. 1223, 1240 (E.D.N.Y. 1985) (Weinstein, J.) (finding that the public records exception to the Federal Rules of Evidence "is based upon our experience that public officials who are scientists generally perform their duties accurately and faithfully") (*citing* Grant, The Trustworthiness Standard for the Public Records and Reports Hearsay Exception, 12 W. State U.L. Rev. 53, 56 (1984)).

II. LILLY'S INTERNAL FDA EXHIBITS ARE RELEVANT

Lilly's internal FDA exhibits are relevant to its defenses to the State's common law failure to warn and UTPCPA claims, as they establish that the contents of the Zyprexa label were the result of continuous interactions with, and scrutiny by, the FDA. The FDA's status as a national, expert scientific authority makes its analyses and opinions relevant to the determination of whether Lilly adequately warned of Zyprexa's risks. *Carlin v. Superior Court*, 920 P.2d 1347, 1352-53 (Cal. 1996) ("[E]vidence of compliance with FDA requirements is admissible as relevant evidence in a strict tort liability case on the issue whether a pharmaceutical manufacturer failed to provide adequate warnings.") (*citing Hatfield v. Sandoz-Wander, Inc.*, 464 N.E.2d 1105, 1109 (Ill. App. 1 Dist. 1984); *see In re Ephedra Products Liability Litigation*, 393 F. Supp. 2d 181, 195-96 (S.D.N.Y. 2005) (admitting into evidence a statement in a Federal Register to bolster expert testimony because the statement showed "the FDA makes the same inferences from good but inconclusive science as [the party's] experts."). The trier of fact may assess the FDA's view of a

pharmaceutical warning and accord it "the weight it deserves." *Toner v. Lederle Laboratories*, 732 P.2d 297, 311 n.12 (Idaho 1987).

Lilly Exhibit EL-2119 is a "Review and Evaluation of Clinical Data re: Antipsychotics association with DM," which shows that the FDA had continuously analyzed clinical data of antipsychotics, including Zyprexa. Similarly, Lilly Exhibit EL-2131 is a "Review of Clinical Data by Gerard Boehm re: Lilly's re- analysis of data pertaining to blood glucose," demonstrating FDA review of the safety aspects of the Lilly label being challenged by the State.

Accordingly, for the reasons stated above, the State's objections should be overruled and the Court should admit these exhibits prior to Lilly's opening statement.

DATED this 29th day of February, 2008.

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

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

I certify that on February 29, 2008, a copy of the foregoing was served by hand on:

Eric T. Sanders, Esq.
Feldman Orlansky & Sanders
500 L Street, Suite 400
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_____

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

PLAINTIFF'S OBJECTIONS TO DEFENDANT'S EXHIBITS

Plaintiff hereby objects to the Defendant's exhibits listed and described below.

I. EXHIBITS RELATING TO THE ADMINISTRATION OF ALASKA'S MEDICAID PROGRAM AND MEDICAID CLAIMS DATABASE

These exhibits, copies of some of which accompany these objections in Exhibit A hereto, include:

EL-2080	Alaska Drug Utilization Review Committee Memorandum - DUR Committee Meeting Minutes from 11/19/04 meeting	ZYP-AK-03344 to 03347

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EL-2081	Alaska Drug Utilization Review Committee Memorandum - DUR Committee Meeting Minutes from 10/22/04 meeting	ZYP-AK-03348 to 03353
EL-2082	Email, From: Gloria Black, re: Peer Consultation component of the Behavioral Pharmacy Management System BPMS	ZYP-AK-03526
EL-2083	Email, From: Ann Swink, re: Edits to May BPMS Letter	ZYP-AK-05256 to 05257
EL-2084	Email, From: Ann Swink, re: Final PowerPoint Presentation - CNS Presentation to Alaska BPMS Stakeholder's Committee, 12/07/06	ZYP-AK-05276 to 05294
EL-2085	Email, From: Ann Swink, re: Reminder of Alaska Behavioral Pharmacy Management (BPMS) Steering Committee Meeting scheduled 12/15/06 with meeting minutes	ZYP-AK-05314 to 05324
EL-2086	Alaska Medicaid Preferred Drug List PDL, Revised 05/19/04	ZYP-AK-00008 – 00166
EL-2138	Campana - Deposition Exhibit 10 - 9.18.2007 (Alaska)	
EL-2139	Campana - Deposition Exhibit 11 - 9.18.2007 (Alaska)	

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EL-2140	Campana - Deposition Exhibit 12 - 9.18.2007 (Alaska)	
EL-2141	Campana - Deposition Exhibit 13 - 9.19.2007 (Alaska)	
EL-2142	Campana - Deposition Exhibit 14 - 9.19.2007 (Alaska)	
EL-2145	Campana - Deposition Exhibit 3 - 9.18.2007 (Alaska)	
EL-2147	Campana - Deposition Exhibit 5 - 9.18.2007 (Alaska)	
EL-2148	Campana - Deposition Exhibit 6 - 9.18.2007 (Alaska)	
EL-2149	Campana - Deposition Exhibit 7 - 9.18.2007 (Alaska)	
EL-2150	Campana - Deposition Exhibit 9 - 9.18.2007 (Alaska)	
EL-3807 to 3889	These exhibits are in electronic form and it is not practicable to include them in Exhibit A.	

Exhibits relating to the administration of Alaska's Medicaid program, the listing of drugs on the program's preferred drug list and Medicaid claims data are simply irrelevant to the issues in this trial which are only whether Defendant is liable for failure to

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adequately warn of the risks of Zyprexa and violating Alaska's UTCPA. In addition, the Plaintiff objects to Defendants' exhibits EL-3807 to 3889 on the grounds that Defendant has not produced a copy of those exhibits to Plaintiff and the Plaintiff is therefore unable to determine whether the electronic files are true and correct copies or whether they have been altered in any way.

II. COURT PLEADINGS AND PAPERS OTHER THAN ANSWERS TO INTERROGATORIES

These exhibits, copies of which accompany these objections in Exhibit B hereto, include:

EL-2144	Campana - Deposition Exhibit 2 - 9.18.2007 (Alaska)	
EL-3055	Stipulation for Partial Dismissal - 2nd Claim - Design Defect	
EL-3057	3-1-07, Plaintiff's Memo Describing its Claims and Proofs	
EL-3058	5-7-07, Defendant's Response to Plaintiff's Motion Concerning Claims and Proofs	
EL-3059	5-25-07, Plaintiff's Reply to Defendant's Response to Plaintiff's Motion Concerning Claims and Proofs	

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EL-3060	10-31-07, Memo in Support of Bifurcation	
EL-3061	11-9-07, Opposition in Response to Plaintiff's Memo in Support of Bifurcation	
EL-3062	1-8-08, Plaintiff's Opposition to Defendant's Motion for Summary Judgment	
EL-3063	12-10-07, Defendant's Motion for Summary Judgment and Memo in Support	
EL-3064	1-17-08, Lilly's Reply to Plaintiff's Opposition to Defendant's Motion for Summary Judgment with Exhibits	

Defense Exhibit EL-2144 is a copy of the Complaint in this action and EL-3055 is a copy of the stipulation between the parties to dismiss the Second Claim for Relief (Strict Product Liability: Design Defect). Plaintiff submits that the appropriate way to inform the jury about the nature of the legal claims and defenses in this bifurcated trial are through the Court's instructions. Admission of the Complaint and the stipulation dismissing the design defect claim may result in confusion, prejudice or misunderstanding by the jury. Therefore, they should be excluded. Alaska R. Evid. 403;

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EXHIBIT A
PAGE 5 OF 11

Brock v. Rogers & Babler, Inc., 536 P.2d 778, 783 (Alaska 1975) (stating unsworn assertions of fact in pleadings are not admissible evidence).

Defense Exhibits EL-3057 through EL-3064 comprise various motions and briefs by both parties – i.e., the parties' briefing regarding the nature of the claims and proofs, the briefing regarding bifurcation and the briefing regarding Lilly's motion for summary judgment. These exhibits should be excluded because they are not evidence; they are the parties' hearsay statements of what they think the law and facts are and their respective arguments about the facts and the law. Alaska Civil Pattern Jury Instruction 1.05. Introduction of those exhibits would constitute not only inadmissible hearsay but would also invade the province of the Court in instructing the jury as to the applicable law. Moreover, to the extent one party or the other might claim that some statement about the facts in a brief is some judicial admission, admission of the brief could result in the necessity of calling a party's lawyer as a witness to explain what was meant in the brief (thereby raising the specter of disqualification of counsel during the course of trial) or result in unnecessary confusion or prejudice. Alaska R. Evid. 403. What the jury finds as fact regarding the issue of Lilly's liability should be determined by reference to the evidence in contemporaneous documents and sworn testimony, not by the reading the briefs of counsel.

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III. INTERNAL FDA DOCUMENTS

These exhibits, copies of which accompany these objections in Exhibit C hereto, include:

EL-2112	Letter from Katherine Bennett, Pharm,D, Division of Drug Risk Evaluation re: Two-year Post-Marketing Review of Olanzapine	FDACDER001147 - FDACDER001170
EL-2119	Review and Evaluation of Clinical Data re: Antipsychotics association with DM	FDACDER001771 - FDACDER001784
EL-2120	Review and Evaluation of Clinical Data Completed by Gerard Boehm re: Zyprexa and other Antipsychotics association with DM - Relying on two epidemiological studies, re-analysis of blood glucose data	FDACDER002154 - FDACDER002168
EL-2121	Review and Evaluation of Clinical Data Completed by Gerard Boehm re: Zyprexa association with DM	FDACDER002169 - FDACDER002182
EL-2130	Review and Evaluation of Clinical Data re: Antipsychotics association with DM	FDACDER002189 - FDACDER002201
EL-2131	Review of Clinical Data by Gerard Boehm re: Lilly re-analysis of data pertaining to blood glucose	FDACDER002506 - FDACDER002508

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EL-2132	Review of Clinical Data by Gerard Boehm re: review of spontaneous reports glucose dysregulation	FDACDER002509 - FDACDER002517
EL-2133	INDA Review re: Published studies of the relationship between atypical antipsychotics and diabetes/hyperglycemia	FDACDER003158 - FDACDER003170
EL-2731	Paul Andreason Review and Evaluation of clinical data recommending approval of Zyprexa for schizophrenia	FDACDER000247 - FDACDER000449
EL-2732	Gerard Boehm's review of Dr. Mosholder's 06/25/03 Literature Review on the relationship between atypicals and glucose abnormalities	FDACDER002701 - FDACDER002705
EL-2737	Memo, From: Andrew Mosholder, To: Russel Katz, Subject: Consult-Literature review concerning the issue of diabetes mellitus/hyperglycemia associated with the atypical antipsychotic drugs	FDACDER002534 - FDACDER002551
EL-3068	Gerard Boehm, FDA review of Clinical Data regarding antitypical antipsychotics and diabetes/hyperglycemia	FDACDER003158 - FDACDER003170

These documents comprise various internal FDA memos bearing what appear to be FDA bates stamps and were purportedly obtained by Lilly through a Freedom of

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EXHIBIT A
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Information Act request. The memos review and evaluate clinical data provided to FDA by Lilly and other drug manufacturers, adverse event reports to the agency by Lilly and other third parties and published medical literature regarding Zyprexa and other atypical antipsychotic drugs. Even assuming that the documents are authentic they are clearly inadmissible as hearsay and since they purport to describe and evaluate other documents, they are riddled with hearsay within hearsay. Alaska R. Evid. 805; *Snyder v. Foote*, 822 P.2d 1353, 1360 (Alaska 1991). Moreover, there is nothing on the face of these documents nor any other evidence the State is aware of demonstrating that these internal FDA documents were provided by the agency to Lilly prior to this litigation and thus they would not be admissible as notice to Lilly or evidence of its state of mind.

IV. FDA CORRESPONDENCE WITH JANSSEN PHARMACEUTICAL

These exhibits, copies of which accompany these objections in Exhibit D hereto, include:

EL-2113	04/19/04 Letter from FDA re: Risperdal 11/10/03 Dear Healthcare Provider (HCP) Letter (letter attached)	ZYMSC000290 - ZYMSC000297
EL-3795	FDA 4/19/04 Warning Letter to Janssen Pharmaceutica, Inc., at http://www.fda.gov/Cder/warn/2004/12195Risperdal.pdf	Publicly available document

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These exhibits are both copies of an April 19, 2004 letter from FDA to Janssen Pharmaceutica asserting that a November 10, 2003 letter from Janssen to Healthcare Providers made false or misleading statements in that it claimed that Risperdal, another atypical antipsychotic drug, was not associated with an increased risk of diabetes when compared to patients treated with conventional antipsychotics and that Risperdal was associated with a lower risk of diabetes than some other atypical antipsychotics. The State submits that evidence purporting to demonstrate that another drug company made false or misleading statements about the safety of its drug is not relevant or admissible on the issues relating to whether Lilly is liable for its conduct regarding Zyprexa.

For the foregoing reasons, the Plaintiff objects to the Defendant's Exhibits listed above.

DATED this 19 day of February, 2008.

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Counsel for Plaintiff

BY _____
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Certificate of Service
I hereby certify that a true and correct copy of
Plaintiff's Objections to Defendant's Exhibits
was served by messenger on:

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

By Peggy S Crowe
Date 2/19/08

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

IN RE ZYPREXA PRODUCTS LIABILITY LITIGATION	)	MDL DOCKET No.
THIS DOCUMENT RELATES TO:	)	
ALL ACTIONS	)	

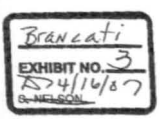
EXPERT WITNESS REPORT AND DECLARATION OF FREDERICK BRANCATI, MD, MHS

I, Frederick Brancati, MD, MHS, hereby state as follows:

BACKGROUND AND QUALIFICATIONS

1. I am a Professor of Medicine at the Johns Hopkins University School of Medicine, the Director of the Division of General Internal Medicine and hold a joint appointment in Epidemiology in the Johns Hopkins University Bloomberg School of Public Health in Baltimore, Maryland. My business address is Welch Center for Prevention, Epidemiology, and Clinical Research Johns Hopkins Medical Institutions 2024 East Monument Street, Suite 2-619, Baltimore, Maryland 21205.

2. **Education & Training** – In 1981 I was awarded a B.A., in Biochemical Sciences from Harvard University, Cambridge, MA, graduating *Magna cum laude*. In 1985 I was awarded my M.D. from the Columbia University College of Physicians & Surgeons, New York, NY. From 1985 to 1989 I was an Intern, Junior Resident, Senior Resident, then Chief Resident in Internal Medicine at the University of Pittsburgh Medical Center, Pittsburgh, PA. From 1989 until 1992 I served as a Post-doctoral Fellow in General



Internal Medicine, at the Johns Hopkins University School of Medicine in Baltimore, MD. I received my MHS in Epidemiology from the Johns Hopkins University Bloomberg School of Hygiene & Public Health 1992.

3. **Academic Appointments** – In 1992 I joined the Core Faculty, at the Welch Center for Prevention, Epidemiology, and Clinical Research at the Johns Hopkins University School of Medicine. From 1992 until 1993 I was an Instructor of Medicine at the Johns Hopkins University School of Medicine and from 1993 until 1998 I was an Assistant Professor of Medicine & Epidemiology. From 1998 until 2003 I was an Associate Professor of Medicine & Epidemiology and the Johns Hopkins University and in 2003 I became a full Professor of Medicine & Epidemiology at the Johns Hopkins University. In 2004 was became Director of the Division of General Internal Medicine at the Johns Hopkins University, Baltimore.

4. **Board Certification** – In 1989 I became board certified by the American Board of Internal Medicine,

5. **Society Memberships** – I am a member of the American College of Physicians, the Society of General Internal Medicine, the American Diabetes Association--Council on Epidemiology & Biostatistics, and I am a Fellow of the North American Association for the Study of Obesity

6. **Editorial Boards/Peer Reviewer for scientific journals** - In 2001 I was selected to join the editorial boards of *Disease Management* and *Obesity Research*. I am currently a peer reviewer for the following medical journals: *American Journal of Epidemiology, JAMA, Diabetes Care, Journal of General Internal Medicine, Diabetes, Kidney International, Medicine, Annals of Internal Medicine, New England Journal of Medicine,*

Circulation, Journal of Investigative Medicine and *Medical Care.*

7. **National Advisory Committees & Review Groups** - A selective listing of some of the pertinent National Advisory Committees and Review Groups of which I am, or was, a member includes the following:

   A. 1994-96: Co-Chair, Screening and Eligibility Committee, Diabetes Prevention Program, National Institute of Diabetes and Digestive and Kidney (NIDDK)

   B. 1997-2000: Chair, Screening and Eligibility Committee, Diabetes Prevention Program, (NIDDK).

   C. 1998: Special Reviewer, NIDDK Subcommittee B

   D. 1999-2001: Chair, Pharmacologic Intervention Committee, Look AHEAD Trial, NIDDK

   E. 1999-present: Member, Cardiovascular and Sleep Epidemiology (CASE, formerly EDC1 and ECD), NIH.

   F. 2000 Member, National Panel on Vitamin E and Diabetes Complications, NIDDK

   G. 2001-03 Chair, Protocol Oversight Committee, Look AHEAD Trial, NIDDK

   H. 2002-04 Member, National Practice Guidelines Panel, American Diabetes Association

   I. 2006 Co-Chair, Symposium on Public Health Approaches to Preventing Type 2 Diabetes, CDC

   J. 2006 Member, Planning Committee, Symposium on Prevention of Type 2 Diabetes, NIDDK

8. **CONSULTANTSHIPS** – I have been, or am, a consultant to the following projects/entities:

   A. 1993 *Guide to Clinical Preventive Services,* U.S. Preventive Services Task Force

B. 1996	U.S. Department of Defense, Gulf War Syndrome Project
C. 1996-97	Consultant on Outcomes Research in Diabetes, MEDTAP International
D. 1997-98	Consultant on Pharmacoepidemiology, Hoechst Marion Roussel.
E. 2000	Consultant on Diabetes Epidemiology, Novartis
F. 2001	Consultant on Diabetes Epidemiology, Pfizer
G. 2003-present	Consultant on Disease Management, Healthways

9. Selected Abstracts, Lectures and Presentations -

1992	*Epidemiology of diabetic end-stage renal disease* Clinical Epidemiology Seminar, University of Pennsylvania, Philadelphia, PA. Sponsored by the University of Pennsylvania
1993	*Epidemiology of type 2 diabetes* Medical Grand Rounds, The Williamsport Hospital, Williamsport, PA. Sponsored by the Williamsport Hospital
1995	*Methodologic issues in the epidemiology of diabetic nephropathy* American Diabetes Association, Councils on Epidemiology & Biostatistics and on Complications, Joint Symposium on Diabetic Nephropathy, Atlanta, GA. Sponsored by the American Diabetes Association
1997	*Novel risk factors for type 2 diabetes* Grand Rounds, Division of Endocrinology, U of Maryland, Baltimore, MD Sponsored by the University of Maryland
1998	*Epidemiology and prevention of type 2 diabetes: An update* Medical Grand Rounds, Hopkins-Bayview Medical Center, Baltimore, MD Sponsored by Hopkins-Bayview Department of Medicine
1999	*Genetic epidemiology of type 2 diabetes and related conditions*

Diabetes Research Symposium, University of Maryland, Baltimore, MD.
Sponsored by the University of Maryland

2000 *Emerging risk factors for type 2 diabetes*
Medical Grand Rounds, Marshall University School of Medicine, Huntington, WV.
Sponsored by the Marshall University School of Medicine

2000 *Adiposity and related conditions as risk factors for type 2 diabetes*
Obesity and Diabetes Research Symposium, University of Pittsburgh, PA.
Sponsored by the University of Pittsburgh

2001 *Recent advances in the epidemiology of type 2 diabetes*
Inter-Urban Club Speaker, Baltimore, MD
Sponsored by the Inter-Urban Club

2002 *Diabetes Prevention Program: Main Results*
Symposium on Diabetes Prevention, Society for Behavioral Medicine, Washington, DC
Sponsored by the Society for Behavioral Medicine

2002 *Diabetes Prevention Program: Implications for Older Adults*
Symposium on Diabetes in Older Adults, Baltimore, MD
Sponsored by the Geriatric Research & Educational Center, University of Maryland

2002 *Diabetes Prevention: Past, Present, and Future*
Medical Grand Rounds, University of Pittsburgh, Pittsburgh, PA
Sponsored by the University of Pittsburgh, Div of Endocrinology

10. Current Scientific Interests – The morbidity, mortality and epidemiology of diabetes mellitus

11. Selected Publications

A. **Brancati FL**, Whittle JC, Whelton PK, Seidler AJ, Klag MJ. The excess incidence of diabetic end-stage renal disease among blacks: a population-based study of potential explanatory factors. *JAMA* 1992; 268:3079-3084.

B. **Brancati FL**, Whelton PK, Whittle JC, Klag MJ. Epidemiologic analysis of existing data to investigate hypertensive renal disease: an example from the Maryland End-stage renal disease registry. *Amer J Kid Dis* 1993; 21(Suppl

1):15-24.

C. **Brancati FL**, Whelton PK, Kuller LH, Klag MJ. Diabetes, race, and socioeconomic status: a population-based study. *Ann Epidemiol* 1996; 6:67-73.

D. Diabetes Prevention Program Research Group. The Diabetes Prevention Program: Design and methods for a clinical trial in the prevention of type 2 diabetes. *Diabetes Care* 1999; 22(4):623-634.

E. **Brancati FL**, Kao WHL, Folsom AR, Watson RL, Szklo M. Incident type 2 diabetes mellitus in African American and white adults: The Atherosclerosis Risk In Communities Study. *JAMA* 2000; 283(17):2253-2259.

F. Saito I, Folsom AR, **Brancati FL**, Duncan BB, Chambless LE, McGovern PG. Nontraditional risk factors for coronary heart disease incidence among persons with diabetes: The Atherosclerosis Risk in Communities (ARIC) Study. *Ann Intern Med* 2000; 133(2) 81-91.

G. The Diabetes Prevention Program Research Group. The Diabetes Prevention Program: Baseline characteristics of the randomized cohort. *Diabetes Care* 2000; 23(11):1619-1629.

H. Barzilay JI, Spickerman CF, Kuller LH, Burke GL, Bittner V, Gottdiener JS, **Brancati FL**, Orchard TJ, O'Leary DH, Savage PJ. Prevalence of clinical and isolated subclinical cardiovascular disease in older adults with glucose disorders. *Diabetes Care* 2001; 24:1233-39.

I. Bertoni AG, Anderson GF, Krop JS, **Brancati FL**. Diabetes-related morbidity and mortality in a national sample of U. S. elders. *Diabetes Care* 2002; 25:471-475.

J. Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002 Feb 7; 346(6):393-403.

K. Gary TL, Genkinger JM, Guallar E, Peyrot M, **Brancati FL**. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *Diabetes Educ.* 2003; 29(3):488-501.

L. Selvin E, Coresh J, Golden SH, Boland LL, **Brancati FL**, Steffes MW; Atherosclerosis risk in communities study. Glycemic control, atherosclerosis, and risk factors for cardiovascular disease in individuals with diabetes: the atherosclerosis risk in communities study. *Diabetes Care.* 2005 Aug;28(8):1965-73.

M. Selvin E, Coresh J, Golden SH, **Brancati FL**, Folsom AR, Steffes MW. Glycemic control and coronary heart disease risk in persons with and without diabetes: the atherosclerosis risk in communities study. Arch Intern Med. 2005 Sep 12;165(16):1910-6.

N. **Brancati FL**, Cusumano AM. Epidemiology and prevention of diabetic nephropathy. (Review) Curr Opin Nephrol Hyper 1995; 4:223-239.

O. Corti MC, Williamson JD, Phillips CL, Rautaharju F, Rautaharju PM, Ferrucci L, **Brancati FL**, Fried LP. Cardiovascular diseases and diabetes. In: Guralnick JM, Simonsick EM, Kasper JD, Lafferty ME, eds. The Women's Health and Aging Study: Health and Social Characteristics of Older Women with Disability. Bethesda, MD: National Institute on Aging, 1995; NIH Pub. 95-4009.

12. The bases for my opinions derive from my education, training, experience, my knowledge and review of published scientific and medical literature.

13. My opinions are subject to further refinement in light of the continuing medical and scientific study, and the continuing review of discovery produced in on-going litigation.

14. **The objective** of this Rule26 report is to provide an opinion on the epidemiology of diabetes mellitus, especially as it relates to the incidence and prevalence of diabetes mellitus in the population of patients using the atypical antipsychotic agents and, specifically, olanzapine.

    A. **Method:** The methods utilized in the review are those typically used in the preparation, drafting and writing of a review article to be submitted for peer review.

    B. **Opinion:** It is my opinion, held to a reasonable degree of medical certainty, that exposure to olanzapine exposes patients to an increased risk of the development of diabetes mellitus; over and above the risk inherent in both the general population and in the population of patients prescribed the atypical

antipsychotics as a class.

INTRODUCTION

15. I hold the following opinions to a reasonable degree of medical certainty:

A. The available peer-reviewed scientific evidence demonstrates that Zyprexa and a number of other antipsychotic medications are associated with an increased risk of type 2 diabetes.

B. The propensity of individual atypical antipsychotic agents to cause weight gain (clozapine, olanzapine > risperidone, quetiapine > aripiprazole, ziprasidone) appears to mirror their risk for glucose dysregulation and type 2 diabetes.

Diabetes Mellitus

16. Diabetes mellitus (to be referred to as "diabetes" in this document) encompasses a number of disease processes that result in hyperglycemia along with many other complications. Insulin is the primary hormone responsible of glucose uptake in the tissues of the body; as a result of normal insulin secretion and normal action of insulin at tissues, normal glucose levels are maintained. The criteria for the diagnosis of diabetes from the National Diabetes Data Group and the World Health Organization are as follows: a fasting plasma glucose of $\geq$ 126 mg/dL, symptoms of diabetes with a random plasma glucose of $\geq$ 200 mg/dL, or a two-hour plasma glucose of $\geq$ 200 mg/dL during a glucose tolerance test. In general, the diagnosis should be confirmed on another occasion. There are a variety of types of diabetes, and broadly, the two categories usually considered are type 1 and type 2 diabetes. Type 1 diabetes, usually diagnosed in children, is caused by the autoimmune destruction of beta cells (the cells that make insulin) of the pancreas which leads to a lack of insulin. Type 2 diabetes, usually seen in

adults, encompasses a group of diseases which share in common a mixture of insulin resistance (the inability of insulin to function in the body's tissues), beta cell dysfunction, and increased glucose production[1]. Type 2 diabetes is the type of diabetes primarily discussed in this document.

Prevalence and Incidence of Diabetes

17. **Historic Trends** - The prevalence of type 2 diabetes has only been increasing since the 1950s as seen from the National Health Interview Survey[2]. This increase has been born out repeatedly. For exampled, data from the Behavioral Risk Factor Surveillance System, a self-report telephone survey, the prevalence of diabetes in the United States in 2000 was 7.3%[3], and by 2001, the prevalence of diabetes in the United States was 7.9%[4] There is a large burden of diabetes globally as well with estimates that the worldwide prevalence of diabetes will increase from 2.8% in 2000 to 4.4% by 2030 with 366 million people suffering from diabetes.[5]

18. **Differences by age, sex, race/ethnicity** - As evidenced by data from the Third National Health and Nutrition Examination Survey, 1988-1994, the prevalence of diabetes increases with age and is higher in non-Hispanic blacks and Mexican-Americans when compared to that of non-Hispanic whites[6]. These findings were echoed by analysis of data from the National Health and Nutrition Examination Survey, 1999-2002[7]. The trend of increasing prevalence of diabetes over time was seen on comparing the data collection from 1988-1994 to that of 1999-2002. Study of the National Health Interview Survey (1984-2000) revealed a higher lifetime risk of diabetes among women and Hispanics[8]. The Atherosclerosis Risk in Communities study of middle-aged subjects without diabetes found an increased incidence of diabetes in African American versus white

participants with 9 years of follow-up; in particular, African American women seemed to be at higher risk for the development of diabetes when compared to white women[9]. Finally, recent estimates from the Centers for Disease Control estimate that 9.6% of those older than 20 years of age have diabetes while 20.9% of those greater than 60 years of age have diabetes. In addition, the prevalence of diabetes is approximately 2% higher in men. The prevalence of diabetes in those over 20 years of age was again shown to vary by race/ethnicity: 15.1% in American Indians/Alaska Natives, 13.3% in non-Hispanic blacks, 9.5% in Hispanic/Latino Americans, and 8.7% in non-Hispanic whites[10].

Complications of Diabetes/Public Health Burden

19. Excess mortality and morbidity and as a result, excess cost are associated with diabetes. Analysis of data from National Health and Nutrition Examination Survey II (1970-1978) revealed a population attributable risk of death in the setting of a diagnosis of diabetes of 3.6%[11]. A retrospective analysis of Medicare claims over a 5-year period (1994-1999) estimated the mortality rate of seniors with diabetes to be 100.2/1000 person years versus 60.6/1000 person years in seniors without diabetes[12]. Additionally, a population-based longitudinal study from 1970-1994 revealed that although all-cause mortality rates have decreased overall, patients with diabetes have not experienced the same magnitude of decrease in mortality, and the mortality burden associated with diabetes has actually increased[12]. In the year 2002, it was estimated that per capita medical expenditures were $13,243 for people with diabetes versus $2,560 for people without diabetes; after adjustment, medical expenditures for diabetics were ~2.4 times that of nondiabetics[13].

20. Diabetes is associated with a multitude of macrovascular and microvascular

complications which contribute to excess morbidity. Macrovascular complications comprise the complications characterized by atherosclerosis of medium and large arteries; the clinical entities seen are coronary heart disease which can lead to myocardial infarction, ischemic stroke, and peripheral arterial disease which can contribute to gangrene. Microvascular complications consist of disease and dysfunction of smaller vessels of the arterial circulation, arterioles and capillaries, and related structures. Clinical entities include diabetic retinopathy which can lead to blindness, diabetic nephropathy which can be complicated by end-stage renal disease, and diabetic neuropathy which can contribute to gangrene. The significance of these complications was illustrated by report of diabetes-related complications (Figure 1) in 1996 of 131,595 diabetic Medicare beneficiaries[15].

Ischemic Heart Disease

21. It is well-established that diabetes is a strong risk factor for ischemic heart disease[16]) defined as heart disease caused by atherosclerosis of the arteries providing the blood supply to the heart. In addition, coronary artery disease associated with diabetes can be more severe in part because of the frequent involvement of distal portions of the coronary arteries making therapies such as coronary artery bypass grafting more difficult. In fact, a diagnosis of diabetes is considered to be equivalent to having coronary artery disease when estimating cholesterol goals for hypercholesterolemia as many cardiovascular disease risk factors such as elevated blood pressure, low high-density lipoprotein (HDL) cholesterol levels, elevated triglyceride levels, and impaired glucose tolerance predict the diagnosis of diabetes as well (need evidence if using this, have Scotland Study-Diabetes Care 2005;28(7):1588-93, NCEP guidelines, Finnish

study-Diabetes Care 2005;28(12):2901-7.).

22. There is evidence that the risk of death from coronary heart disease in a diabetic patient with no previous history of myocardial infarction is similar to that of a patient with a history of prior myocardial infarction; in addition, the risk of death from coronary heart disease is much higher in patients with both diabetes and a history of prior myocardial infarction[17]. This association between death from ischemic heart disease and diabetes is established both in men and women. Data from men in the Physicians Health Study showed that risk of death from coronary heart disease was increased with a previous diagnosis of diabetes (without a previous diagnosis of coronary heart disease) and that there was in particular, an excess of risk associated with a previous diagnosis of both coronary heart disease and diabetes[18]. Analogous results were found in the Nurses' Health Study, a study of female nurses; a history of diabetes was found to be associated with a higher risk of death from coronary heart disease, and the group with both diabetes and known coronary heart disease had the highest risk of death from coronary heart disease[19]. A computation of adjusted summary odds ratios for death from coronary heart disease due to diabetes revealed no difference by sex; the odds ratio for men was 2.3 and for women was 2.9[20].

23. In addition, while all-cause mortality and mortality from heart and ischemic heart disease is decreasing for the Unites States population as a whole, it appears that all-cause mortality among diabetics has not changed significantly[21].

Heart Failure

24. Diabetes is associated with development of heart failure and worse outcomes associated with heart failure. This was well established with the Framingham Study[17]. For

example, analysis of a sample of Medicare claims among diabetics from 1994-1999 revealed a prevalence of heart failure of 22.3% in 1994, an incidence rate of 12.6/100 person-years, and a mortality rate of 32.7/100 person-years (versus 3.7/100 person-years in those with diabetes without heart failure)[22]. A study of heart failure patients in Olmsted County revealed an increasing prevalence of diabetes as well and diminished survival rates among diabetics (37%) versus nondiabetics (46%)[23]. Moreover, diabetes is associated with an increased risk of nonischemic idiopathic cardiomyopathy[24].

Stroke

25. At least since 1979 with publication of the Framingham study results[17], it has been accepted that diabetes increases the risk of stroke. A recent meta-analysis confirms the association of between chronic hyperglycemia and cardiovascular disease (including stroke); subgroup analysis of stroke revealed an increased risk of stroke with chronic hyperglycemia as well[25]. In the Honolulu Heart Program, it was found that even glucose intolerance in addition to diabetes increases the risk of thromboembolic stroke.[26] It has even been postulated that diabetes should be considered a risk equivalent for stroke. In the Women's Pooling Project looking at 27,269 women, over 8.3 years 238 stroke deaths were seen; a history of stroke and a history of diabetes without stroke were associated with similar risks with respect to fatal stroke[27]. Additionally, in the Atherosclerosis Risk in Communities Study, on comparison of nondiabetic participants with a history of myocardial infarction with diabetics without a history of myocardial infarction, nondiabetics had a higher risk of cardiovascular events but that stroke risk was the same in both groups.[28]

Chronic Kidney Disease

26. Chronic kidney disease is sustained kidney disease and is categorized by different levels mainly according to the glomerular filtration rate. Diabetes is known to cause a predictable, progressive disease of the kidney which leads to end-stage renal disease (chronic kidney disease that necessitates dialysis)[29]. In the United States, diabetes is the number one cause of end-stage renal disease and is responsible for the highest number of cases requiring new dialysis as well[30]. A prospective study looked at the actual excess of end-stage renal disease attributable to diabetes and found that the relative risk of end-stage renal disease among diabetics versus nondiabetics was 12.7[31]. Chronic kidney disease from diabetes causes albuminuria (excretion of albumin in the urine), and this is associated with increased mortality[32]. Moreover, the risk associated with development of chronic kidney in the setting of diabetes is highlighted by a prospective study of 1,120,295 diabetics and nondiabetics followed over an average of 2.84 years: Compared to having normal kidney function, any degree of chronic kidney disease was associated with an increased risk of death, cardiovascular events, and hospitalization[33]. A study of mortality with kidney disease in diabetics specifically revealed that cardiovascular death rates are higher in diabetics with kidney disease and that risk of cardiovascular death increases with progression of kidney disease[34].

Peripheral Vascular Disease/Diabetic Neuropathy/Gangrene

27. Diabetes predisposes to peripheral arterial disease (disease of medium to large arteries excluding that of the arteries supplying the brain and heart) and a peripheral neuropathy. This combination of poor blood flow with arterial disease and loss of sensation associated with neuropathy contributes to the lower extremity complications associated

with diabetes. Diabetes is the number cause of non-traumatic lower extremity amputation[35]. A large retrospective cohort study found an incidence of 2% per year of foot ulcers among diabetics; approximately15% of those who developed foot ulcers underwent amputation. Patients diagnosed with foot ulcers incurred considerable costs when compared to their diabetic counterparts without foot ulcers[36]. Again, as mentioned above, data from a meta-analysis revealed an increased risk of peripheral arterial disease with chronic hyperglycemia[37].

Vision Loss

28. Diabetes is associated with retinopathy, glaucoma, and cataracts which can all lead to blindess. Diabetic retinopathy involves disease of the small blood vessels of the retina. The majority of patients with diabetes for greater than 15 years will have evidence of diabetic retinopathy, and diabetic retinopathy is the main cause of new cases of blindness in patients between the ages of 20 and 74[38]. It is thought that diabetic retinopathy causes between 12,000 and 24,000 cases of blindness each year[39]. Data from 2002-2004 from the Multi-Ethnic Study of Atherosclerosis revealed a prevalence of diabetic retinopathy of 33.2% with an elevated prevalence in blacks and Hispanics and a lower prevalence in whites and Chinese[40].

Cancer

29. Diabetes is associated with increased mortality from cancer. A large prospective study of men and women from 1982-1998 to evaluate cancer mortality associated with diabetes that there was an increased mortality rate from cancer of the liver, pancreas, bladder, and colon in diabetic men and pancreas, colon, and breast in diabetic women[41]. Diabetes is specifically associated with a diagnosis of pancreatic cancer,[42, 43]hepatocellular

obesity, likely through inflammation[55], contributes to the picture of insulin resistance as well.

32. **Physical Inactivity** - A longitudinal study of health professionals revealed that even without obesity or other confounders, physical inactivity in itself measured by TV watching was associated with an increased risk of diagnosis of diabetes during follow-up[57]. In a study of physicians, increased intensity of physical activity was shown to be associated with a decreased incidence of diabetes as well[58]. The Nurses' Health Study, a study of women, confirmed that sedentary behavior is associated with a new diagnosis of diabetes and that increased activity can decrease the associated risk of diabetes[59].

Primary Prevention of Type 2 Diabetes

33. Studies of the primary prevention of type 2 diabetes in subjects with elevated glucose (but not in the diabetic range) further reveal that the aforementioned risk factors are relevant to the development of diabetes. In 1997, results from the Da Qing IGT and Diabetes Study were published and showed that both diet and exercise were associated with a cumulative incidence of diabetes that was approximately 20% lower when compared to those receiving conventional care [60]. In 1999, the Finnish Diabetes Prevention Study Group also showed that diet and weight loss could decrease the incidence of diabetes[61]. In 2001, results from the Nurses Health Study showed that body mass index was actually probably the most important predictor in the development of diabetes in women[62]. In 2002, the Diabetes Prevention Program, a definitive, large multi-center randomized controlled trial, revealed that participants with impaired glucose tolerance experienced a lower incidence of diabetes with intensive exercise and weight loss regimens as compared to those who received standard counseling or even in those

who received metformin, an oral medication used to treat diabetes[63]. These results were corroborated again in 2005 by a trial studying Japanese men with impaired glucose tolerance which showed a decrease in the incidence of diabetes with an intensive intervention aimed at dietary modifications, an increase in physical activity, and weight loss when compared to a conventional regimen[64].

Family History

34. Family history is an independent risk factor for diabetes. In 2003, a review was published to evaluate the usefulness of family history as a public health tool. In exploring this issue, it was found on review of cross-sectional studies, a case-control study, and cohort studies that a report of a family history, independent of other known risk factors, conferred a two to six times greater risk of diabetes when compared to those without a family history of diabetes[65]. If one identical twin has type 2 diabetes, it is highly likely that the other identical twin will have diabetes as well[66]. This association with family history may have to do with genetics and well as a shared environment.

Genetics

35. It is accepted that there is a strong genetic component to type 2 diabetes mellitus. For example, the prevalence of type 2 diabetes varies widely between different populations[67]. However, there is not simply one gene that causes diabetes; rather, multiple genes, in addition to the environment, likely contribute to susceptibility.[68] Evidence for which specific genes involved is accumulating at this time. Categories of genes associated with type 2 diabetes include those which affect the beta cells of the pancreas and those which affect the activity of insulin. Candidate susceptibility genes affecting beta cell function include the following:[69] glucose transporter 2, glucokinase,

insulin, ATP-sensitive K+ channels, insulin receptor, insulin receptor substrate I, phosphoinositide 3-kinase, hepatocyte nuclear factor 1- and 4-alpha, NEUROD1, and calpain 10. Specifically, calpain 10 has been found to be associated with diabetes[20] in Mexican Americans;[21] this association was also shown in African Americans in the Atherosclerosis Risk in Communities Study and in fact, the population attributable risk for homozygosity of the variant associated with diabetes was found to be approximately 25%.[22] Also, a meta-analysis of case control studies in Caucasians to evaluate for predisposition to type 2 diabetes with variations in two genes encoding ATP-sensitive K+ channels found that when compared to the "normal" variant of the KCNJ11 gene, the KCNJ11 EK and KK variants were associated with a population attributable risk of 10.1%[23]; thus there would be 10.1% fewer cases of type 2 diabetes with the presence of only the normal EE gene. There are multiple candidate susceptibility genes which seem to affect insulin sensitivity both directly and indirectly. It appears that PPARgamma variation may be associated with the strongest evidence at this time.[24,25], Recently, data from the Diabetes Prevention Program, an aforementioned prevention trial, revealed that variation in the transcription factor 7-like gene may increase the risk of diabetes; this risk was diminished in the groups receiving pharmacotherapy with metformin and the intensive lifestyle intervention[26]. Overall, specific data for the genetics of type 2 diabetes are accumulating; at this time, it appears that while the genetic aspect of diabetes is important, genetic predisposition cannot account for the majority of diabetes as population attributable risks for specific genes have not been overwhelming.

Established Pharmacologic Risk Factors for Diabetes

36. Corticosteroids - Corticosteroids have a myriad of effects on different bodily tissues.

They are known to induce hyperglycemia through decreasing peripheral tissue sensitivity to insulin, increasing glucose production in the liver, and through inhibition of beta cell production of insulin in the pancreas[77]. The risk of initiation of a medication to treat diabetes has been shown to be increased in patients taking steroids when compared to patients not taking steroids, and this effect appears to be increased with higher doses of steroids[78]. While hyperglycemia from steroids is known to increase risk of diabetes, the risk of a diagnosis of diabetes has not been often studied independently. In a study of elderly patients in Canada, The risk of diabetes among users of oral corticosteroids was significantly higher than that in the control group[79].

37. HIV-Related Medications

A. Highly-Active Antiretroviral Therapy (HAART) - HAART and in particular, the protease inihibitors, is associated with diabetes mellitus[80]. The cause of diabetes from these medications is thought to be multifactorial with body habitus and induction of insulin resistance by protease inhibitors playing a role[81]. Early studies found a high prevalence of abnormal glucose homeostasis among patients on protease inhibitors[82,83,84,85]. A role for nucleoside reverse transcriptase inhibitors has been suggested as well[86]. A study of an outpatient clinic cohort on HAART showed a high prevalence of diabetes; in addition, participants exposed to longer duration of HAART were more likely to have diabetes[82]. In the Women's Interagency HIV Study, a cohort of women with HIV and women without HIV but at high-risk, participants on protease inhibitor therapy were found to be a higher risk for self-report of new diagnosis of diabetes during the study follow-up period[82]. In the Multicenter AIDS Cohort Study, a study of

homosexual and bisexual men with and without HIV, it was found that the prevalence (14% versus 5%) and incidence (4.7 versus 1.4 per 100 person-years) of diabetes were much higher in subjects with HIV on HAART as compared to HIV negative subjects[89]. A few studies have shown no apparent effect of HAART on diabetes risk[90,91].

B. **Pentamidine** - The use of pentamidine to treat Pneumocystis jiroveci pneumonia (associated with AIDS) is associated with hyperglycemia and the development of diabetes which may be self-limited[92,93,94]. Initially, there may be low glucose because a lytic effect of pentamidine on the beta cells of the endocrine pancreas[95].

38. **Other Drugs** - There has been concern about thiazide diuretics and beta-blocking medications increasing the risk of diabetes. A prospective analysis of data from the Atherosclerosis Risk in Communities study showed no increase in the risk of diabetes with thiazide diuretics and a small risk associated with beta-blockers[96].

39. **Secondary Prevention Trials** There are multiple trials that address the question of whether the complications of diabetes can be reduced or eliminated with medical care. The Diabetes Control and Complications Trial[97] studied the effects of tight glycemic control (with frequent insulin administration) on the effects of the long-term complications of type 1 diabetes. Results included that glycemic control could be improved upon with frequent insulin administration and that this leads to a decreased incidence of microvascular complications including diabetic retinopathy, nephropathy, and neuropathy. Macrovascular complications, including cardiovascular disease were not affected in the initial study. However, a follow-up study, the Epidemiology of

Diabetes Interventions and Complications Study, suggested that the intensive glycemic control group from the DCCT had a decreased risk of macrovascular complications[98]. The United Kingdom Prospective Diabetes Study also found that in type 2 diabeteics, tight glycemic control was associated with a decreased risk of microvascular complications but not a significant decrease in macrovascular complications.[99] In the Steno-2 trial, patients with type 2 diabetes and microalbuminuria were randomized to receive conventional therapy or multifactoral intensive therapy (through diet, exercise, and medications) targeted at blood pressure control, control of dyslipidemia, and glycemic control. Those in the intensive group experienced a lower rate of cardiovascular complications as well as microvascular complictions[100]. All of these trials show that the complications of diabetes can be reduced by intensive treatment; however, intensive therapy is difficult to accomplish on a large scale, and even with the benefits of intensive therapy, the risk of the complications associated with diabetes are only decreased by ~50% at best.

ATYPICAL ANTIPSYCHOTICS AND DIABETES

40. The majority of available peer-reviewed scientific evidence demonstrates that Zyprexa and a number of other antipsychotic medications are associated with an increased risk of type 2 diabetes. This conclusion is supported by evidence from case studies, case-control and cross-sectional studies, cohort studies and experimental studies.

EPIDEMIOLOGY

41. Case Reports The majority of papers supporting atypical antipsychotics' role in increasing diabetes risk are case reports. More than fifty case reports and case series have been published regarding patients who develop diabetes or initiate atypical

antipsychotic use; the majority of these cases developed type 2 diabetes or diabetic ketoacidosis.[101-159] Most case reports have been in patients using either clozapine or olanzapine. In many, development and then improvement of hyperglycemia was temporally related to beginning and then ceasing medication use. Studies have also shown that if treatment resumes, hyperglycemia quite often reappears.[101] Such challenge/rechallenge evidence is strongly supports causal relationship. Reports of case series from the FDA MedWatch Drug Surveillance describe hyperglycemia describe hundreds of cases of hyperglycemia, new onset (or newly discovered) type 2 diabetes, and diabetic ketoacidosis (either as the presentation of new diabetes or as worsening hyperglycemia in patients with diabetes) in patients taking atypical antipsychotics, with clozapine the most commonly cited, followed by olanzapine, risperidone and quetiapine in decreasing order.[160-163]

42. Case-Control and Cross-Sectional Studies Five case control studies[164-168] and three cross-sectional studies[169-171] examine the relation between atypical antipsychotics and type 2 diabetes diagnoses. Four out of five case-control studies showed an increased risk of diabetes onset with atypical antipsychotic use. Guo et al.[165] found that in an analysis of 920 incident cases of diabetes in persons taking antipsychotics relative to 5828 general population controls with neither characteristic, use of clozapine (HR=7.0, 95% CI=1.7-28.9), risperidone (HR=3.4, 95% CI=2.8-4.2), olanzapine (HR=3.2, 95% CI=2.7-3.8) and quetiapine (HR=1.8, 95% CI=1.4-2.4) resulted in increased risk. Koro et al.[164] performed a nested case control study in which patients with schizophrenia and incident diabetes were matched with 2696 controls. In this study, olanzapine users had an increased risk over non-users of antipsychotics (OR=5.8, 95% CI=2.0-16.7) and over

those taking typical antipsychotics (OR=4.2, 95%CI=1.5-12.2).

43. Cohort Studies Cohort studies show mixed results. At least seventeen cohort studies have been published in which the relation between atypical antipsychotics and diabetes onset have been examined.[172-188] Five cohort studies[172, 173 176, 184, 186] have found a statistically significant relationship between atypical antipsychotic use (relative to typical antipsychotic use) and the subsequent risk of new onset type 2 diabetes. For example, in a pharmaco-epidemiologic analysis of a Veterans Administration database, Lambert et al.[186] found recent use of atypical antipsychotics (relative to haloperidol) predicted the subsequent occurrence of new diabetes claims (olanzapine HR=1.64, 95% CI-1.22-2.19; risperidone HR=1.60, 95%CI=1.19-2.14; quetiapine HR=1.67, CI=1.01-2.76). Patients with schizophrenia were followed for just over one year following initiation of use. Farwell et al.[184] also found an increased risk of type 2 diabetes among olanzapine users relative to those on phenothiazines (OR=1.9, p=0.03

44. Two cohort studies found an increased risk for diabetes in olanzapine compared to risperidone users.[174, 185] Four cohort studies found no difference between conventional and atypical antipsychotic use, but did find that antipsychotic use resulted in increased risk over the general population.[175, 177, 179, 183] Two cohort studies found no increased risk in diabetes onset between typical and atypical antipsychotics; no testing relative to the general population was performed in these studies.[181, 188] One cohort study indicated that high glucose levels may occur more frequently in persons with schizophrenia than the general population and found no relationship between antipsychotic users and the general population after adjusting for these risk factors.[178] Two other studies that examined the relationship between antipsychotic use and type 2 diabetes found that,

among persons with diabetes who are currently taking antipsychotics, initiation of insulin therapy occurred within the first two years of the disease and that certain atypical antipsychotics (clozapine, olanzapine, and quetiapine) were associated with new-onset glucose intolerance.[180, 187]

45. **Experimental Studies** Mostly small, short-term, experimental studies of atypical antipsychotics measured combinations of glucose levels, insulin levels, insulin resistance and insulin sensitivity with varying results. A pre/post study in which patients with schizophrenia received clozapine showed increases in fasting glucose and 2-hour glucose tolerance tests without change in insulin resistance (by homeostasis model assessment) or insulin levels.[189] A randomized trial of olanzapine and ziprasidone showed a non-significant increase in fasting glucose from pre to post within the olanzapine group.[190] Lindenmeyer et al.[191] performed a 14 week double-blind randomized trial on 157 patients with schizophrenia or schizoaffective disorder. Patients were randomly assigned to clozapine, olanzapine, risperidone or haloperidol. The authors found olanzapine was associated with increases in plasma glucose levels from baseline (91.7 mg/dl to 105.5 mg/dl, $p<0.02$.) Rettenbacher et.al. describe elevated fasting glucose levels and abnormal glucose tolerance tests in patients taking clozapine but not those taking amisulpride.[192] Studies with aripiprazole have shown minimal to no increases in fasting blood glucose compared to placebo.[193-197]

46. The largest clinical trial to-date measuring blood glucose was the Clinical Antipsychotic Effectiveness Trial (CATIE). The olanzapine arm experienced a 13.7 mg/dl mean increase in glucose compared to quetiapine (7.5), risperidone (6.6), perphenazine (5.4) and ziprasidone (2.9); this was not statistically significant. Results combined fasting and

non-fasting blood samples. Olanzapine did result in larger changes in glycosylated hemoglobin (0.40%, p<0.01) compared to the other antipsychotic medications that essentially had not change (quetiapine 0.04%, risperidone 0.07%, perphenazine 0.09%, zipradisone 0.11%.)[198]

47. Several experimental studies report fasting insulin levels are higher in patients treated with olanzapine than other medications.[199-202] Recent reports have used clamp methods to measure insulin sensitivity. One study showed decreased insulin sensitivity with both olanzapine and risperidone compared to placebo[203], another showed no difference in insulin sensitivity with olanzapine and risperidone compared to control.[204]

Biologically Possible Mechanisms

48. Weight gain - The propensity of individual atypical antipsychotic agents to cause weight gain varies substantially with clozapine and olanzapine conferring the most risk and aripiprazaole and ziprasidone the least. [205 195, 206, 207] In their 1999 meta-analysis, Allison et. al. reported that after 10 weeks of treatment, clozapine resulted in a mean weight change of 4.45 kg and olanzapine resulted in a mean weight change of 4.15 kg (Figure 1.)[205] Data from this report also provide evidence that weight gain may continue after 10 weeks through treatment at one year. In the CATIE Study, patients randomized to olanzapine gained a mean of 9.4 +/- 0.9 (SE) lbs.[198] Mean weight change for those randomized to quetiapine was 1.1 +/- 0.9 lbs; risperidone 0.8 +/- 0.9 lbs; perphenazine -2.0 (+/-1.1) lbs and ziprasidone -1.6 +/- 1.1 lbs.

49. Much of the weight gain from antipsychotics appears to be fat.[208] Differences in binding affinities to histamine H-1, serotonin, norepinephrine and dopamine receptors likely contribute to changes in appetite and satiety leading to weight gain with particular

medications.[206, 209]

50. The weight gain risk conferred by atypical antipsychotics (clozapine, olanzapine > risperidone, quetiapine > aripiprazole, ziprasidone) appears to mirror their risk for glucose dysregulation and type 2 diabetes.[206, 207] Weight gain, in turn, leads to changes in adiposity and insulin resistance, beginning the continuum towards diabetes. However, glucose abnormalities have been reported without weight changes in cases of patients taking clozapine and olanzapine [161] and in two cross-sectional studies matching for adiposity.[160, 210, 211] Thus, it is plausible that particular antipsychotic medications may have a direct effect on insulin-sensitive tissues or beta-cell function.

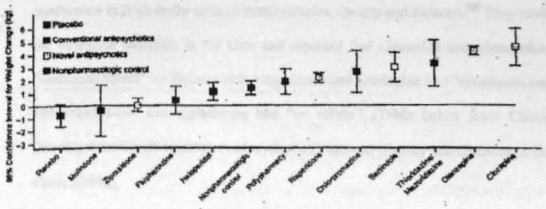


Figure. 95% Confidence Intervals for Weight Change After 10 Weeks on Standard Drug Doses, Estimated from a Random Effects Model
From Allison DB, et.al, *American Journal of Psychiatry*, 1999.

51. **SUMMARY** - A number of case reports implicate olanzapine, and clozapine, in the onset of hyperglycemia, diabetic ketoacidosis and type 2 diabetes. Observational cohort studies showed increased relative risk for claims diagnoses of diabetes among uses of olanzapine and other atypical antipsychotic agents. Most of these studies were performed before the release of ziprasidone or aripiprazole. The weight of evidence

from experimental studies, including some randomized controlled trials, appears to implicate olanzapine in glucose dysregulation to a higher degree than other atypical antipsychotic medications, except for clozapine. It is plausible that much of the glucose abnormalities are related to weight changes with these medications. Longer-term prospective experimental studies are needed both to understand mechanisms and to appropriately estimate true diabetes risk from these medications.

52. **Consensus Statement** - The American Diabetes Association, the American Psychiatric Association, the American Association of Clinical Endocrinologists and the North American Association for the Study of Obesity convened a consensus development conference in 2003 on the topic of antipsychotics, obesity and diabetes.[207] They reviewed the evidence available at the time and reported that clozapine and olanzapine had "increased effect" for diabetes risk, risperidone and quetiapine had "discrepant results" and aripiprazole and ziprasidone had "no effect." (Table below from Consensus Development Conferences on Antipsychotic Drugs and Obesity and Diabetes, *Diabetes Care*, 2004.)

53. The panel also reported on evidence for weight gain with atypical antipsychotics. The panel acknowledged the limitations in the literature that was largely derived from pharmacovigilance studies, cross-sectional studies and retrospective database reviews. The panel called for randomized controlled trials in this area and also set out a monitoring scheme for antipsychotic use that includes ongoing monitoring of weight, waist circumference, blood pressure, and fasting glucose and lipid profile.

Drug	Weight gain	Risk for diabetes	Worsening lipid profile
Clozapine	+++	+	+
Olanzapine	+++	+	+
Risperidone	++	D	D
Quetiapine	++	D	D
Aripiprazole*	+/−	−	−
Ziprasidone*	+/−	−	−

+ = increase effect; − = no effect; D = discrepant results. *Newer drugs with limited long-term data.

Table. SGA's and metabolic abnormalities

54. Diabetes and Related Conditions in Persons with Severe Mental Illness – Mortality

Over three decades of research document that persons with severe mental illness have a substantially higher mortality risk, and have life expectancies at least 10 years lower than the general population.[210-217,218] While suicide and other accidental deaths are known to be increased, these account for a small overall proportion of deaths in persons with severe mental illnesses.[219, 220] Miller et al.[221] examined mortality and medical comorbidity among patients with serious mental illness in Ohio. The aggregated all-cause mortality ratio found in this study was 3.2 and the aggregate ratio for diseases of the heart was 3.4. Brown et al.[210], in a small cohort study, found increased incidence of cerebrovascular disease death (SMR=534, 95% CI=256-982). Osby et al.[211] found increased incidence of death in a larger cohort in Sweden for both cardiovascular disease (male Obs./Exp.=2.3, 95% CI=2.0-2.6; female Obs./Exp. 2.1, 95% CI=1.9-2.4) and cerebrovascular disease (male Obs./Exp.=1.3; 95% CI=0.9-1.9; female Obs./Exp.=1.9, 95%CI=1.5-2.3). Indeed, persons with severe mental illness largely die of the same

causes as the general population, cardiovascular disease and cancer, albeit at much higher rates.[219] Other major causes of death include cerebrovascular disease, chronic lung disease, diabetes and pneumonia.

55. Diabetes Mellitus Even before the advent of antipsychotic medications, an increased prevalence of diabetes mellitus in patients with schizophrenia was reported. Several studies in the past two decades indicate that patients with schizophrenia or bipolar disorder have a high prevalence of type 2 diabetes.[192, 215, 222-226] In a national study examining 14,182 randomly chosen Medicare and Medicaid recipients with schizophrenia before the widespread use of atypical antipsychotics, Dixon et al.[225] found a lifetime rate of diabetes of 14.9%. In a population of 200 psychiatric inpatients, Sokal et al.[226] found that 25% had diabetes. Lindenmeyer et al.[192] found in a randomized trial of schizophrenic patients that 14% of their sample of 157 patients had type 2 diabetes. Carney et.al. reported an odds of 1.6 (95%CI 1.2-2.1) for diabetes for privately insured patients with schizophrenia compared to controls.[227] Subjects enrolled in the CATIE Trial had a baseline prevalence of diabetes of 13%.[228] Although these studies used varied methods for ascertaining a diabetes diagnosis and many were set in populations of only those using health care services or enrolling in clinical trials, in sum they provide good evidence for an increased prevalence of diabetes mellitus in persons with severe mental disorders, documenting this population as being already 'at-risk' for the development of diabetes mellitus. Thus, efforts to reduce the risk factors for diabetes mellitus, including loss of weight and careful monitoring for the development of hyperglycemia, should be undertaken whenever feasible. In addition, avoidance of additional risk factors, such as drugs which both increase weight gain, glucose

dysfunction and which are associated with increasing the risk of diabetes mellitus should especially be avoided.

56. Obesity - Overweight and obesity are highly prevalent among persons with severe mental illness. In a study of 169 community psychiatric outpatient compared to 2404 matched individuals from the National Health and Nutrition Examination Survey (NHANES) III, Dickerson et al.[229] found that 50% of female patients and 41% of male patients were obese as compared to 27% female and 20% male in NHANES. Daumit et.al. compared obesity prevalence in a community-based sample of persons with severe mental illnesses to a national sample (NHANES III) and a Maryland sample (Behavioral Risk Factor Surveillance System) of the general population adjusted to the demographic characteristics of the SMI sample including tobacco smoking, age and ethnicity.[230] Men and especially women with SMI had a higher prevalence of obesity (BMI>= 30 kg/m^2) than the general population. Sixty-one percent of men with SMI were either overweight or obese, (BMI>=25 kg/m^2), compared to 56.3 percent of men in NHANES III, and 63.2% in Maryland BRFSS. Eighty-one percent of women with SMI were overweight or obese, compared to 56.3% of women in NHANES III and 58% of women in Maryland BRFSS. Other studies have found similar increased obesity in persons with serious mental illness relative to the general population.[231-233] These studies are published within the peer-reviewed literature and readily available for review and analysis. It is my opinion, held to a reasonable degree of medical certainty, that this population, to the extent medically possible, should avoid taking those drugs known to be associated with marked weight gain, such as olanzapine.

57. Hypertension, Hyperlipidemia and the Metabolic Syndrome Population-based

evidence is scant on the prevalence of hypertension and hyperlipidemia in persons with severe mental illness. It appears that the prevalence of hypertension, hyperlipidemia and the metabolic syndrome are increased in persons with severe mental illnesses, at least among clinical trial enrollees. Data from the CATIE study show that at baseline, 14% of subjects had hyperlipidemia, 20% had hypertension and 41% met criteria for the metabolic syndrome.[234, 235]

58. Coronary Artery Disease and Stroke While prevalence of most coronary artery disease risk factors are increased in persons with severe mental illness, and cardiovascular mortality is increased, less data are available about prevalent coronary disease. Carney et al. performed a retrospective analysis of Blue Cross/Blue Shield data in Iowa.[227] Subjects with schizophrenia or schizoaffective disorder (n=1074) were compared to non-schizophrenic controls who had filed at least one claim for medical services (n=726,262) The authors did not find an increased odds of ischemic heart disease in schizophrenia, but did find an increase in congestive heart failure (OR 2.38) and stroke (OR 2.11). Among patients with schizophrenia, Enger et.al. found an increased risk of myocardial infarction in patients using typical antipsychotics.[236]

59. The opinions expressed above are based on my training, research and experience and my review of the peer-reviewed medical literature, and are held to a reasonable degree of scientific certainty. My consulting fee for Plaintiffs' counsel is $1,000 per hour. Other charges apply for depositions and travel.

60. I have spent approximately 50 hours in the review of the pertinent medical literature specifically in preparation for writing this report. However, I have spent the past 15 years of my professional life conducting original research, clinical pathology and

contributing to the medical literature, all of which has included reviewing the peer-reviewed medical literature germane medicine, diabetes and epidemiology. In the last four years, I have testified in no depositions or trials.

Signed this 7th day of January, 2007 Frederick Brancati, MD, MHS