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					

VOLUME 14

TRANSCRIPT OF PROCEEDINGS

March 20, 2008 - Pages 1 through 239

BEFORE THE HONORABLE MARK RINDNER Superior Court Judge

		Page 2		Page 4
1	A-P-P-E-A-R-A-N-C-E-S		1	PROCEEDINGS
2	For the Plaintiff:		2	THE COURT: Please be seated.
3	STATE OF ALASKA		3	We are back on the record in Eli
4	Department of Law, Civil Division		4	Lilly versus State of Alaska versus Eli Lilly
5	Commercial/Fair Business Section 1031 West 4th Avenue, Suite 200		5	3AN-06-5630 Civil. All members of the jury are
6	Anchorage, Alaska 99501-1994 BY: CLYDE "ED" SNIFFEN, JR.		6	present, as are counsel.
	Assistant Attorney General		7	We're continuing with the testimony
7 8	(907) 269-5200 FIBICH, HAMPTON & LEEBRON LLP		8	of Dr. Kahn. Dr. Kahn, you realize you're under
9	Five Houston Center 1401 McKinney, Suite 1800		9	the same oath and the same obligations of that
	Houston, Texas 77010		10	oath that you took yesterday?
10	BY: TOMMY FIBICH (713) 751-0025		11 12	THE COURT: Thenk you. Mr. Allen
11	CRUSE, SCOTT, HENDERSON & ALLEN, LLP		13	THE COURT: Thank you. Mr. Allen. MR. ALLEN: Thank you, Your Honor.
12	2777 Allen Parkway, 7th Floor			I'd like to invoke Rule 615, please.
13	Houston, Texas 77019-2133 BY: SCOTT ALLEN		15	THE COURT: Okay. Do you have
14	(713) 650-6600			witnesses here that are in the courtroom?
	RICHARDSON, PATRICK,		17	MS. GUSSACK: Yes, Your Honor.
15	WESTBROOK & BRICKMAN 1037 Chuck Dawley Boulevard, Building A		18	THE COURT: Could you ask them
16	Mount Pleasant, South Carolina 29464 BY: DAVID L. SUGGS, Of Counsel		19	ladies and gentlemen, if you're going to be a
17	(843) 727-6522		20	witness in this case, Mr. Allen has invoked the
18 19			21	rule that requires me to exclude you from the
20 21			22	courtroom until after you've testified in this
22			23	case. So if you're going to be a fact witness in
23 24				the case, could you please wait outside until
25			25	it's your turn to testify. And could you notify
		Page 3		Page 5
1	A-P-P-E-A-R-A-N-C-E-S, continued		1	any of your other witnesses that the rule has
2	For Defendant:		2	been invoked?
4	PEPPER HAMILTON LLP		3	MS. GUSSACK: Yes, Your Honor.
_	301 Carnegie Center, Suite 400		4	MR. ALLEN: May I begin,
5	Princeton, New Jersey 08543			
	BY: IOHN F BRENNER		5	Your Honor?
6	BY: JOHN F. BRENNER GEORGE LEHNER		6	THE COURT: Please.
	GEORGE LEHNER NINA GUSSACK		6 7	THE COURT: Please. CROSS-EXAMINATION, continued
7	GEORGE LEHNER NINA GUSSACK (609) 452-0808		6 7 8	THE COURT: Please. CROSS-EXAMINATION, continued Q. (BY MR. ALLEN) Good morning, Doctor.
	GEORGE LEHNER NINA GUSSACK		6 7 8 9	THE COURT: Please. CROSS-EXAMINATION, continued Q. (BY MR. ALLEN) Good morning, Doctor. A. Good morning, Mr. Allen.
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Page 6 Page 8

1 off -- we're not really going to talk about this,

but we left off on the issue of mood stabilizer. 3

Do you remember that?

4 A. You can refresh my memory as to what you're referring to.

6 Q. I was over here looking at the deposition.

8 Zyprexa is not a mood stabilizer, 9 is it, sir?

A. Mood stabilizer is a term that doesn't 10

11 have a formal agreed-upon scientific definition.

12 It is a term that many psychiatrists use to

13 describe drugs that are used to stabilize mood in

14 patients who have bipolar disorder.

15 Q. So we're clear, as you testified in your

16 deposition, mood stabilizer is not a

17 scientifically-validated term?

18 A. In that it's a term that describes a

19 range of actions of drugs that are used in

20 bipolar disorder. I'm not aware of any

21 scientific body that has given a definition of

22 mood stabilizer.

23 Q. I apologize. It seems like I'm arguing

24 with you. You testified -- this is your

25 testimony under oath. Do you agree with this

1 Do you recall that?

2 A. Yes.

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Q. As you said, it would be improper to try

to minimize, eliminate or neutralize the risk; do

you recall that?

6 A. Yes. I'm sorry, could you just repeat

7 the last sentence again?

8 You said it would be improper, I think,

9 to minimize, eliminate or neutralize risk.

That's correct. Α.

11 I want to talk about -- when I look back

12 at my notes, I don't think I talked about the

13 benefits side of the equation. I briefly did. 14

But it would also be improper to

15 overstate the benefits, right?

16 Α. Yes.

17 O. In fact, the FDA has said that to

18 overstate the benefits would be false and

19 misleading.

20 Are you aware of that?

I'm not aware of that.

22 O. Sir. In Exhibit 1169, which is the

23 November, 1996 letter that the jury has seen --

24 if you want to read any of this other than what I

show you, let me know, okay?

Page 7

They said that Eli Lilly has

engaged in false and misleading practices,

including giving appropriate balance to their

safety and benefits.

Do you see that, sir?

6 I see that.

7 And do you agree with the FDA that it

would be false and misleading to overstate the

9 benefits of a product?

10 A. In general, if someone were doing that,

11 yes.

15

20

12 And in fact, they got more specific --

by the way, I forgot to ask this, sir. Did you

14 read any additional documents last night?

No. Α.

16 On page 3 of the FDA's letter --

17 MR. BRENNER: Your Honor, may we

18 approach on an objection.

19 THE COURT: You may.

(Bench discussion.)

21 MR. BRENNER: Your Honor, I fear

22 that what we're about to do is present a lot of

documents that the witness has never seen. It's

not germane to his testimony. Did the FDA say

25 this --

statement and you may --

MR. BRENNER: Objection,

Your Honor. Is this impeachment?

THE COURT: Yes. What is this? If it's impeachment I don't think you have anything

to impeach.

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7 Q. (BY MR. ALLEN) Okay. Is mood 8

stabilizer a scientifically validated term? MR. BRENNER: Objection; asked and

10 answered, Your Honor. THE COURT: I'll let him ask that 11

12 question.

13 A. Researchers and clinicians use the term

14 to refer to drugs that are used to stabilize mood

in bipolar disorder. I'm unaware of any 15

scientific body that has given a formal fixed 17 definition of the term.

18 THE COURT: Was that a no, it's not 19 a term used scientifically?

20 THE WITNESS: Well, you know, it's

21 not a term that has an official scientific 22 definition.

23 Q. (BY MR. ALLEN) Thank you, sir.

24 We talked about the risk/benefit

25 equation yesterday.

Page 12

THE COURT: To the extent that he

was asked and said he wanted all the documents

- 3 that might be meaningful and might be relevant, I
- 4 that think this is proper cross-examination.

MR. BRENNER: Thank you,

6 Your Honor.

5

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(End of bench discussion.)

- 8 Q. (BY MR. ALLEN) We're back on the 9 risk/benefit equation.
- 10 A. Okay.
- 11 Q. And by the way, this is Exhibit 1169.

When you asked for all potential,

- even remotely relevant documents, did you get this document?
- 15 A. I simply don't remember all the
- 16 documents that may have been sent to me.
- 17 Q. Back to the benefits equation. We were
- 18 talking about in general you agreed, but the FDA
- 19 got specific. They said: The other labeling
- 20 pieces identified above contain one or more of
- 21 the violations enumerated above. They are all
- 22 lacking in balance relating to adverse events and
- 23 precautionary information and present a
- 24 misleading impression of Zyprexa as superior,
- 25 highly effective, virtually free of side effects,

- 1 virtually free of side effects and easy to use.
 - Do you see that?
- 3 A. I see that.
- 4 Q. Okay. Now, the FDA didn't just say
- 5 that; they told Eli Lilly to immediately
- 6 discontinue this -- these labeling pieces and any
- 7 other ones that would make those statements.
 - Do you see that?
- 9 A. Yes, I see that.
- 10 Q. It says immediately discontinue the use
- 11 of all promotional labeling pieces, and it goes
- 12 on, right?

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- 13 A. Yes. It goes on, I don't know. I see
- 14 what you're writing.
- 15 Q. And I don't -- if you want to --
- 16 anything you'd like to look at it.
- 17 A. Yeah.
 - Q. Let me know when you're through.
- 19 A. I just didn't know what you meant by "it
- 20 goes on." But I see exactly what you've
- 21 highlighted.
- 22 Q. Well, I just didn't want to read
- 23 everything, but I didn't want you to think I
- 24 didn't.
 - So they told Eli Lilly in 1996 to

Page 13

Page 11

1 easy to use product. This impression is contrary2 to the approved labeling.

- 3 Do you see that?
- 4 A. Yes, I see that.
- 5 Q. And you, of course, have reviewed the
- 6 labeling, have you not?
- 7 A. Yes.
- 8 Q. And it would be contrary to the approved
- 9 labeling to represent Zyprexa, as you said
- 10 yesterday, as superior to any of the
- 11 second-generation antipsychotics, right?
- 12 A. I don't believe I made that statement
- 13 yesterday.
- 14 Q. I thought I asked you was there anything
- 15 in the label -- the testimony, we can get it --
- 16 A. Yeah.
- 17 Q. I believe I asked you yesterday: Was
- 18 there anything within the label that indicated
- 19 Zyprexa was superior to any of the other
- 20 products --
- 21 A. Anything in the label. You're correct,
- 22 there's nothing in the label that indicates it's
- 23 superior.
- Q. Right. And they said it would be false
- 25 and misleading to say it is highly effective,

- 1 don't do that anymore and it's false and
- 2 misleading; do you agree?
- 3 A. I agree that the document says that.
- 4 Q. And, sir, the document's from the FDA,
- 5 is it not?
- 6 A. Well -- but I don't know what it's
- 7 referring to so all I can agree with is that the
- 8 document states that.
- 9 Q. Well, let me ask you then your: Would
- 0 you agree that if the FDA tells a drug company to
- 11 stop engaging in conduct which the FDA says is
- 12 false and misleading, that the drug company
- 13 should stop engaging in that conduct?
 - MR. BRENNER: Objection,
- 15 Your Honor. It's argumentative and beyond the
- 16 scope of anything this witness has testified to.
 - THE COURT: Overruled.
- 18 A. As a hypothetical, I would agree. In
- 19 this example, I have no opinion because I don't
- 20 know the background or what the facts were.
- 21 Q. (BY MR. ALLEN) And, sir, I didn't ask
- 22 your opinion about this example. Do you agree,
- 23 as a physician who prescribes medications, that
- 24 if the FDA tells a drug company to stop this type
- 25 of misleading conduct, the drug company should

Page 14 Page 16

- 1 stop?
- 2 A. In general, as a hypothetical, yes.
- And you've reviewed documents that
- 4 indicate to you that Eli Lilly did not stop doing
- that, did they?
- A. I don't know what documents you're referring to.
- 8 Well, did you review the Viva Zyprexa 9 Campaign?
- 10 A. Sir, I don't have an opinion on this
- area. 11
- 12 Q. That wasn't -- sir, I'm not trying to be 13
- difficult.
- 14 Did you review the Viva Zyprexa
- 15 Campaign documents?
- 16 A. Not to my recollection.
- 17 So that was more material that you did
- 18 not receive: is that correct?
- 19 I don't recall.
- 20 Well, I'll try -- I may refresh your
- 21 recollection in a minute.
- 22 Now, sir, I also wanted just to
- 23 clear up what I hope is a noncontroversial topic.
- 24 You prepared a PowerPoint
- 25 presentation; is that correct?

1 slide, but I'm not crystal clear.

- Q. Okay. Well, now you have it before you,
- American Diabetes Association Risk Factors for
- 4 Diabetes.
- 5 Can you tell this jury where you
- find schizophrenia as a risk factor for diabetes,
- 7 sir?

2

- 8 A. It's not on that list as a risk factor
- 9 for diabetes.
- 10 Q. All right. So at least as far as the
- 11 American Diabetes Association is concerned, it is
- 12 not a risk factor?
- 13 My slide didn't state it was. Α.
- 14 Q. Okay. You would agree it's not a risk
- 15 factor?
- 16 Α. I don't know.
- 17 Okay. You don't know. But more than
- 18 that, when you were provided with the documents
- from Eli Lilly, did they tell you about the
- meeting they had with diabetes experts down in
- Atlanta in October of 2000?
- 22 Α. No.
- 23 Q. You never heard about that?
- 24 No. A.
- 25 Well, they met with experts down in

Page 15

- A. Yes.
- 2 Q. Sir, did you prepare this PowerPoint, or
- did somebody do it for you?
- A. I did it in conjunction with the lawyers
- at Pepper Hamilton.
- Q. Okay. And one of the things -- and you
- were actually here as we recall, when
- Dr. Inzucchi was here, were you not?
- 9 A. For a portion of his testimony.
- 10 Okay. Just as a reminder, because we're
- 11 going to get to it in a minute, the article you
- 12 discussed the survey was just about
- 13 schizophrenia, right?
- 14 A. Yes.
- 15 Okay. But you had in your PowerPoint
- comorbid conditions and you wrote type 2
- 17 diabetes.
- 18 Α. Yes.
- 19 Q. Okay. Again, when Dr. Inzucchi was
- here, he provided us a PowerPoint, and then
- Mr. Suggs asked him about the American Diabetes
- Association risk factors for diabetes. 22
- 23 Were you here during that
- 24 testimony?
- 25 A. I'm not positive. I may have seen this

Atlanta, and I think this is a Dr. Holcombe, when

- he was -- let me get that.
- 3 He was at the meeting, and he's
- from the endocrinology section of Eli Lilly. You
- know Eli Lilly makes diabetes drugs?
- 6 A. Yes.
- 7 O. So if individuals develop diabetes, Eli
- 8 Lilly has medications to treat them; you
- 9 understand that?
- 10 A. Yes, Eli Lilly makes medications for
- 11 diabetes.
- 12 Q. Okay. Now, there was a series of
- 13 e-mails -- and we're not going to go over every
- one. The jury has seen them on the 9th and 10th
- 15 summarizing what happened at those meetings.
- 16 Did you see any of those e-mails?
- 17 No. I did not. Α.
- Q. Dr. Holcombe from the diabetes side of 18
- the company, when they went to meet with him
 - says, Our advisory group is a Who's Who in
- 21 diabetes.
- 22 Do you see that?
- 23 Yes. A.
- 24 I'm not trying to be mean or anything,
- 25 you but you're not a Who's Who in diabetes, are

Page 20 Page 18

- 1 you, sir?
- 2 A. No.
- 3 You're not an expert in that area?
- 4 That's correct.
- 5 But the Who's Who in diabetes were 0.
- presented data from Eli Lilly. I guess you
- didn't know that?
- 8 A. I don't know that.
- 9 Q. Okay. And here's what the Who's Who
- 10 said: From the data shown, the group did not
- agree with the premise that diabetes mellitus has
- a higher than normal prevalence in schizophrenia.
- 13 Do you see that?
- 14 A. I see that sentence.
- 15 Q. So at least as this document reflects,
- 16 Eli Lilly was told by the Who's Who in diabetes
- they did not believe schizophrenia increased the
- 18 risk of diabetes; do you agree?
- 19 A. That's not what it says.
- 20 Q. I'm sorry. It says: From the data
- 21 shown -- then we'll just move on -- from the data
- shown, the group did not agree with the premise
- that diabetes mellitus has a higher that normal
- prevalence in schizophrenia, right? 24
- 25 A. That's what it says.

- 1 Q. Okay. Now, we were talking about the
- 2 issue yesterday about sources of information. 3
 - Do you recall that?
- 4 Yes.
- 5 O. And that is opinion No. 1, summary of
- 6 your opinion No. 1A, is it not?
- 7 Yes.
- 8 O. You say: Treatment decisions for mental
- 9 health patients are based on many sources --
- 10 THE COURT: Could you lower it down
- 11 a little bit? I just want to make sure we
- 12 don't --
- 13 MR. ALLEN: That's why I wanted you
- 14 to have a copy.
- 15 All right. Let me see where I was.
- 16 (BY MR. ALLEN) Opinion No. 1A:
- 17 Treatment decisions for mental health patients
- 18 are based on many sources of information and the
- 19 unique circumstances of each patient, correct?
- 20 A. Yes.
- 21 And then on page 5 you expound upon Q.
- 22 that, right?
- 23 A. My numbered page 5 is the one that we
- 24 were just on.

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25 I'm sorry, sir. That's right, you say

Page 19

- Q. Okay. You don't disagree with the Who's
- Who in diabetes, do you?
- A. I have no opinion.
- Q. Now, sir, I want to talk about your 4
- report. I guess -- do we need -- you don't have
- a copy? 7 A. No.
- 8 Do we have a copy? Thank you --
- 9 MR. ALLEN: Do you need a copy,
- 10 Your Honor?
- 11 THE COURT: Actually I thought I
- 12 had one, but --
- 13 MR. ALLEN: I have another one.
- 14 THE COURT: Thank you.
- 15 MR. ALLEN: Yes, sir.
- 16 Q. (BY MR. ALLEN) And to briefly recap,
- 17 you prepared this report yourself; it's all your
- words and it's factually accurate?
- 19 A. To the best of my ability.
- 20 Obviously, sir.
- 21 You wish -- well, since you said
- 22 that, do you wish to retract, change, modify,
- 23 alter or in any way modify your report at this
- 24 time?
- 25 A. No.

it again on page 5.

THE COURT: We were just on page 2,

Page 21

your summary of opinions.

THE WITNESS: Okay. Am I on a

different -- I'm on page 5 with you.

6 MR. ALLEN: I apologize.

THE WITNESS: Yeah, no problem.

- 8 (BY MR. ALLEN) On page 5 now --
- 9 A. I got you. Yeah, here we are, the
- 10 underlined section.
- 11 Okay. And then you expound on this
- opinion concerning physician sources of
- 13 information?
- 14 Α. Yes.
- 15 All right. Now, yesterday I asked you,
- 16 are these things doctors rely upon?
 - Do you recall that?
- 18 Α. Yes.
- 19 Q. And you told me, Mr. Allen, I didn't say
- 20 relv.

- 21 A. That's right.
- 22 So I just want to use your words. I'm Q.
- 23 going to put "info" for information; is that all
- 24 right?
- 25 A. All right.

- 1 Q. You were correct. You did not use the
- 2 word "rely". You used the term physicians'
- 3 knowledge about treatment; is that correct?
- 4 A. Yes.
- 5 Q. What's that mean?
- 6 A. Knowledge about treatment alternatives.
- 7 Their understanding of what are the available
- 8 treatments and what are the implications of those
- 9 treatments.
- 10 Q. Okay. Understanding the treatments and
- 11 the implications of the treatments?
- 12 A. Yes.
- Q. So, is there any difference, really,
- 14 between knowledge about treatments and the
- 15 implications than rely upon that information?
- 16 A. Yes, there is.
- Q. Okay. I just -- when somebody has
- 18 knowledge about something, what does that mean?
- 19 A. It means they have a broad understanding
- 20 about a variety of points of view.
- 21 Q. Okay. That's good. Knowledge means a
- 22 broad understanding about a variety of points of
- 23 view, right?
- 24 A. Yes.
- 25 Q. Now, why would you want a variety of

- 1 page, all right?
- 2 A. Yes.

8

18

23

- 3 Q. Why don't you just -- in one word on the
- 4 second page. Why don't you read to yourself the
- 5 last sentence on page 2 and the last word on page
- 6 3 and see if you meant what you said.
- 7 A. I agree with it.
 - Q. Okay. You said: The treatment of
- 9 patients with these diseases -- and what diseases
- 10 were you talking about?
- 11 A. Schizophrenia and bipolar disorder.
- 12 Q. Sir, I thought you were talking about
- 13 more than that. Right up in the prior paragraph,
- 14 you're saying all of the mental health diseases
- 15 and you were talking about agitation secondary to
- 16 dementia, depression, anxiety. You were talking
- 17 about bipolar maintenance --
 - A. Oh, actually, yes, the sentence says:
- 19 All of the mental health diseases that olanzapine
- 20 is used for.
- 21 Q. Right. You weren't talking just about
- 22 schizophrenia, were you, sir?
 - MR. BRENNER: Objection,
- 24 Your Honor. We're drifting into an area you
- 25 excluded.

Page 23

Page 25

- 1 points of view?
- A. Doctors have to sift the validity and
- 3 the reliability of information that they receive
- 4 in order to know how to apply it in the treatment
- 5 decisions that they make about individual
- 6 patients.
- 7 Q. So they need all the information in
- 8 order to do that sifting, do they not?
- 9 A. They need valid and accurate and usable
- 10 information.
- 11 Q. Well, is that what you said in your
- 12 report, sir?
- 13 A. It's what I'm saying to you in answer to
- 14 your question.
- 15 Q. Well, sir, in your report and I'll get
- 16 it for you.
- 17 At page 2, I believe. Let me see.
- 18 I didn't write it down, but I think it's page 2.
- 19 Yes. On your background on mental health --
- 20 mental health illnesses and treatment.
- 21 Do you see that?
- 22 A. Yes, I do.
- 23 Q. Sir, again, you can read any part of
- 24 this that you'd like. But I want to go down
- 25 to -- I think it's the last sentence on this

- 1 THE COURT: We are drifting, but we
- 2 haven't drifted too far yet.
- 3 MR. ALLEN: May I proceed,
- 4 Your Honor?
- 5 THE COURT: Yes.
- 6 Q. (BY MR. ALLEN) You said all of the
- 7 mental health diseases that olanzapine is used
- 8 for, right?

- A. Yes, that's what I said.
- 10 Q. You can read any part you want, but I
- 11 want to look at the last sentence. You said:
- 12 The treatment of patients with these diseases --
- 13 and you're talking about all of the diseases that
- 14 Zyprexa is used for, correct?
- 15 A. Yes.
- 16 Q. -- with prescription drugs involves
- 17 balancing how well the drug addresses the
- 18 particular symptoms -- that's Zyprexa for
- 19 symptoms?
- 20 A. Yes.
- 21 Q. -- being experienced by the patient --
- 22 A. I'm sorry, go back to Zyprexa for
- 23 symptoms. The drug's particular symptoms being
- 24 experienced by the patient. Yeah.
- 25 Q. Okay. The -- I'm sorry, sir, I got lost

- 1 now. Involves balancing how well the drug
- addresses the particular symptoms being
- experienced by the patients against all possible side --
- 5 MR. BRENNER: If we could just read it accurately, Your Honor, and not insert words.
 - THE COURT: Yeah. You stuck "all"

8 in there. It's not in the report.

- MR. ALLEN: Did I? I'm sorry and I 9 10 didn't mean to. I apologize and I'll do it
- again. I'll try to read it correctly this time. 11
- Q. (BY MR. ALLEN) Balancing how well the
- 13 drug addresses the particular symptoms being
- experienced by the patient against possible side
- effects. 15

7

- 16 Α. Yes.
- 17 You stand by that statement? O.
- 18 Yes, I do.
- 19 Okay. Why does a doctor need to know Q.
- 20 about possible side effects?
- 21 A. What possible side effects refers to
- 22 here is the fact that of the known side effects
- 23 of a medication, not every patient will
- experience every side effect. It's possible a
- patient will experience them; it's possible a

- agree, diabetes is serious?
- 2 Α. Yes.
- 3 You agree that weight gain can be
- 4 serious?
- 5 Α. Yes.
- 6 Q. You agree that hyperlipidemia can be
- 7 serious?
- 8 A. Yes.
- 9 You agree that hyperglycemia can lead to

Page 28

Page 29

- 10 serious conditions?
- 11 Α. Yes.
- 12 Okay. And have you ever seen this
- 13 before when you were reviewing the evidence in
- 14 this case?
- 15 A. No.
- 16 Do you see -- and I've got -- the
- 17 labeling shall be revised to include a warning as
- soon as there is reasonable evidence of an
- 19 association.
- 20 Do you see that?
- 21 Yes. A.
- 22 And then it says -- I think it says: A
- 23 causal relationship need not have been proved.
- 24 Do you see that?
- 25 I see that.

Page 27

Q. You're not quibbling with this

1

regulation, are you, sir?

3 MR. BRENNER: Objection,

4 Your Honor, commentary on federal regulations?

5 THE COURT: Yeah --

6 MR. ALLEN: I'll let it -- let me

7 ask this.

- 8 Q. (BY MR. ALLEN) Sir, proving causation
- 9 can sometimes take decades, can it not?
- 10 A. I'm not an expert on causation, sir.
- 11 Of anything? I mean, I'm not -- what
- 12 you said you learned about -- remember you said
- 13 you learned about weight gain in medical school?
- 14 A. Yes.
- 15 Okay. We're going to talk about that in
- a minute, but have you learned through your
- 17 medical experience -- Harvard?
- 18 Α. Columbia.
- 19 Columbia, or your training or working
- there at Columbia Hospital Medical School, sir?
- 21 A. Yes.
- 22 Q. Have you learned that sometimes proving
- 23 causation can take decades?
- 24 That's correct.
- 25 O. Okay. And so if a patient's going to

1 patient won't.

- 2 Q. But as you said, in making that
- 3 determination, the doctor needs to know of the
- possible side effects?
- A. Well, there are known side effects of
- drugs, and we need to know about the known side
- effects. It's possible with respect to the
- individual. Side effects are statistical is the
- 9 meaning of the sentence.

10 THE COURT: I think he's asking

- 11 you, that you're using the word possible. He's
- 12 asking you, you didn't use the word probable, you 13 didn't use the word likely or frequently observed
- 14 or something.
- 15 THE WITNESS: That's right.
- 16 THE COURT: You used the word 17 possible. So, do you mean by that any possible
- side effects? 18
- 19 THE WITNESS: What I mean is that 20
- of the known side effects it is possible that a 21 given patient will experience them.
- 22 THE COURT: Any of them?
- 23 THE WITNESS: Of the known side
- 24 effects.

25

(BY MR. ALLEN) Okay. Doctor, you'd

Page 32

Page 33

- 1 take a medication and they need to be warned2 about possible side effects, it wouldn't be right
- 3 to make the patient and the family wait 20 years,
- 4 would it?
- 5 A. Well, that wasn't the meaning of my
- 6 sentence in the -- as I explained, possible side
- 7 effects refers to known, established side effects
- 8 that a patient -- some patients will experience
- 9 known established side effects and some won't.
- 10 I'm not an expert on FDA regulations.
- 11 Q. Yes, sir. Regardless, just cast the FDA
- 12 regulations aside. A patient, regardless of FDA
- 13 regulations, take out Zyprexa, think about any
- 14 medication. Just as a doctor, it would be wrong
- 15 for a patient taking a medication, not Zyprexa,
- 16 don't worry about the regulations, just worry
- 17 about patient safety.
- 18 It would be wrong to require a
- 19 patient and his or her family to wait 20 years to
- 20 be told about a side effect until some doctor
- 21 somewhere finally proves it as an absolute fact.
- That would be wrong, wouldn't it?
- A. I'm afraid I'm confused by your
- 24 question. To be told about a side effect,
- 25 patients should be told about side effects. I'm
 - Page 31
 - be 1 A.
 - 1 not sure what you mean by waiting 20 years to be 2 told about a side effect.
 - 3 Q. Maybe you and I aren't communicating.
 - 4 So what you're saying is patients
 - 5 should not have to wait 20 years to see if
 - 6 there's absolute causation; they need to be told
- 7 of possible side effects for their own health and
- 8 safety?
- 9 A. I'm not sure --
- THE COURT: He's asking, when do
- 11 you have enough information to have to be told
- 12 about side effects? That's his question. Do you
- 13 have to wait until you know it for sure, or do
- 14 you have to wait until some other point in time?
- 15 And if so, what's the point in time?
- THE WITNESS: Oh, yeah. If you
- 17 know that a side effect exists, patients should
- 18 be informed about side effects. That's separate
- 19 from the question of causation which you added
- 20 into it.
- 21 Q. (BY MR. ALLEN) Yes, sir, and I think
- 22 you're making my point. Side effects is separate
- 23 from the question of absolute causation; is it
- 24 not?

25

A. The existence of a side effect. You're

- 1 right.
- Q. Really, that's about patient care, is it
- 3 not?

- 4 A. The existence of a side effect,
- 5 absolutely.
- 6 Q. You know, Doctor, I have your report,
- 7 and I looked at it last night.
 - And we -- I didn't want to quibble
- 9 yesterday, but, really, it's ultimately the
- 10 patient's choice. In 99.99 percent of the cases,
- 11 it's the patient. Eli Lilly doesn't get to make
- 12 the choice; even you don't get to make the
- 13 choice; the patient has the right to make the
- 14 choice, true?
- 15 A. Outside of those rare circumstances in
- 16 psychiatry where there's involuntarily treatment,
- 17 absolutely.
- 18 Q. Like I said, 99.9 percent of the time.
- 19 A. Whatever the percentage is.
- 20 Q. Would you agree approximately?
- 21 A. Yes.
- 22 Q. And so when we're talking about who
- 23 should get a medication, Eli Lilly is entitled to
- 24 their point of view. Are they not? They are,
- 25 aren't they?
 - A. Yes.
 - 2 Q. You're entitled to your point of view,
- 3 right?
- 4 A. Yes.
- 5 Q. But who is going to be taking the drug
- 6 into their body is the patient, right?
- 7 A. That's correct.
- 8 Q. And they're the people that have to deal
- 9 with the side effects or possible side effects as
- 10 they occur, correct?
- 11 A. That's right.
- 12 Q. So, really, the Hippocratic Oath.
- 13 First, thou do no harm; isn't that right?
- 14 A. Absolutely.
- 15 Q. And so what we want is to give our
- 16 patients the choice, looking at all the risks,
- 17 and then they can decide if they want to take
- 18 Risperdal or Zyprexa or Geodon or Abilify or the
- 19 first-generation, or they can decide I don't want
- 20 to take any of them, right?
- 21 A. That's correct.
- 22 Q. There's nothing wrong with that, is it?
- 23 A. No.
- Q. Now, if the patient gets diabetes -- I
- 25 mean, really, I can go home tonight and if a

Page 34 Page 36

- 1 patient gets diabetes, it's really -- it's not my
- problem, right? There's nothing I can do about 3 it, correct?
- When you say it's not my problem, as a physician, it is my problem.
- Q. Okay. Okay. Well, it's also the State of Alaska's problem too, isn't it, sir?
- 8 MR. BRENNER: Objection,
- 9 Your Honor.
- 10 MR. ALLEN: I could tie this in.
- 11 THE COURT: I'll let you have one
- introductory question and then tie it in. 12
- 13 Q. (BY MR. ALLEN) Yes. You understand I
- represent the State of Alaska.
- 15 Do you understand that?
- 16 Α. Yes.
- 17 And I represent the Medicaid department.
 - Do you understand that?
- 19 I'm not aware of exactly who you
- represent. 20

18

- 21 Well, just assume that I represent the Q.
- 22 State of Alaska, the Medicaid Division. Okay?
- 23 Do you understand that?
- 24 If a patient gets diabetes -- and
- 25 it's in your PowerPoint and it was in your

1 phrase.

5

10

- 2 O. Yes, sir. And it goes on to describe
- 3 that in more detail, does it not?
- 4 Uh-huh.
 - Say yes, sir. O.
- 6 A. Yes.
- 7 Q. I'm not trying to be rude. We have to
- 8 get a record, so it says "uh-huh" --
- 9 I apologize.
 - Q. Now, did you review any testimony from
- 11 the director of global marketing for Zyprexa,
- 12 Denice Torres?
- 13 A. Not that I recall.
- 14 She was asked -- I think her deposition
- 15 was played two days ago. I don't know, two or
- three days ago.
- 17 She was asked this question by me:
- 18 Why does a company and why did Eli Lilly have
- 19 sales representatives?
- 20 Do you see that question?
- 21 A. Yes, I do.
- 22 Q. I'll read it out loud unless -- would
- 23 you prefer, or do you want me to read it out
- 24 loud?
- 25 A. You can read it.

Page 35

She said: One of the -- you know, one

Page 37

- 2 big reason is that in many therapeutic areas, you
- 3 know, whether Prozac or even Zyprexa,
- 4 prescribers/physicians may not know about -- you
 - 5 know, they may not have learned as much in
 - 6 medical school about certain conditions,
- et cetera, because they can't be experts in
- 8 everything. So what a sales representative can
- 9 do is to help bring information about a
- 10 therapeutic area, about treating customers --
- 11 treating patients or an actual drug, bringing
- 12 that information to those customers.
- 13 Do you see that?
- 14 A. Yes. I see that.
- 15 O. That makes sense, doesn't it?
- 16 A. I have no opinion about this.
- 17 Q. That's the PDR, is it not?
- 18 Α. Yes, it is.
- 19 You agree that -- there's a lot of O.
- 20 medications in there, isn't there?
- 21 A. Yes.
- 22 Q. I mean, if I picked one out at random
- 23 and asked you to describe for us what's in the
- adverse reaction section, what's in the warning
- 25 section, what that drug's risks are, what the

- testimony --
- 2 MR. BRENNER: Objection,
- Your Honor.
- THE COURT: I am going to sustain

Q. (BY MR. ALLEN) Sir, on the sources of

- the objection at this point. 6 MR. ALLEN: Okay. Let me look.
- 8 information --9 A. Which page are we on, sir?
- 10 Q. Page 5.

- 11 A. Gotcha.
- 12 Q. 5. I won't write them all down, unless
- 13 you want me to. But you list medical literature,
- 14 continuing education, guidelines, algorithms,
- 15 things of that nature, didn't you?
- 16 A. Yes.
- 17 And you list the Eli Lilly sources. See Q.
- 18 that?
- 19 Well, I don't use the word Eli Lilly.
- 20 It says "other sources." It first describes --
- 21 Q. Sir -- I'm not trying to be difficult,
- 22 but other sources -- this is an Eli Lilly report
- 23 about Zyprexa, is it not?
- 24 A. Right. Other sources include
- 25 information from drug manufacturers is the

Page 40

Page 41

- 1 precautions are, how was it developed, you
- 2 couldn't do it, could you? You couldn't have me
- 3 pick a drug out at random and do that, could you?
- 4 A. From memory?
- 5 O. Yes, sir.
- 6 A. No. Not from -- at random?
- 7 Q. That's not a criticism; it's just a
- 8 fact.
- 9 A. It would be a very difficult task at
- 10 random.
- 11 Q. Right. So as Ms. Torres says, the drug
- 12 company has representatives in many therapeutic
- 13 areas concerning medications because doctors
- 14 can't know all this from medical school and they
- 15 bring the doctors the information. Is that
- 16 right?
- 17 A. That's what it says.
- 18 Q. Right. Well, do you agree with that?
- 19 A. I have no opinion on this.
- 20 Q. Getting back to your sources of
- 21 information, it did include the drug company,
- 22 right?
- 23 A. Yes.
- 24 Q. Ms. Gussack on opening statement told
- 25 the jury: Lilly was sharing its information with

- 1 Q. -- and sources of information, and it
- 2 wasn't me that wrote this, and you started
- 3 listing them, did you not?
- 4 A. That's correct.
 - Q. Okay. Are you an expert in this?
- 6 A. I'm an expert in how doctors assimilate
- 7 information. I'm not an expert in how it's
- 8 organized and provided by companies.
- 9 Q. I didn't ask you about how companies
- 10 organized and provided it. I asked you about
- 11 doctors' assimilation, their knowledge about the
- 12 treatment that comes from the drug company, does
- 13 it not?

5

- 14 A. One component of information that
- 15 doctors may consider is information that comes
- 16 from the drug company. It's far from the only
- 17 source.
- 18 Q. No, sir. In fact, you list in your
- 19 report at page 5 --
- 20 A. Yes.
- 21 Q. -- and if I get one wrong, because I
- 22 wrote a piece of paper out last night, tell me if
- 23 I missed one.
- You said that sources of the
- 25 knowledge about treatment --

- 1 A. Yes.
 - 2 Q. -- are companies' responses to
 - 3 questions, right?
 - 4 A. It is one source of information.
 - 5 Q. Yes, sir. I'm going to go one at a
 - 6 time.
 - 7 That's one source, correct?
 - 8 A. It is a source that doctors may
 - 9 consider.
 - 10 Q. Okay, sir. That's one source?
 - 11 A. That they may consider.
 - 12 Q. Yes, sir, that's all I'm asking.
 - Another one is the package insert?
 - 14 A. Yes, they may consider the package
 - 15 insert.
 - 16 Q. Another one is sales rep detailing?
 - 17 A. Yes
 - 18 Q. Another one is journal advertisements?
 - 19 A. Yes.
 - 20 Q. Another one is detail pieces?
 - A. Bear with me for a second. It doesn't
 - 22 say detail pieces.
 - 23 Q. Okay. Well, that's --
 - A. Sales representative detailing is the
 - 25 phrase that I used, yeah.

- 1 doctors about weight gain and sharing its
- 2 information with the FDA and it wasn't just
- 3 relying on the label.
- 4 Do you see that?
- 5 A. I see that statement.
- 6 Q. Okay. So she goes on to say in her
- 7 opening statement that Lilly trained its sales
- 8 representatives who call on physicians to answer 9 questions about weight gain and diabetes that
- 10 doctors might raise.
- Do you see that?
- 12 A. I see that.
- Q. Isn't that the exact role of the sales
- 14 representatives as described by both Ms. Torres
- 15 and Ms. Gussack?
- 16 A. I have no opinion on the role of sales
- 17 representatives. I have no expertise in that
- 18 area, sir.
- 19 Q. Okay. Well -- you have no expertise in
- 20 what area?
- 21 A. The role of sales representatives.
- 22 Q. Well, sir, with all due respect, you
- 23 prepared a report concerning physicians'
- 24 knowledge about treatment --
- 25 A. Yes.

- Q. Okay. Well, fair? Detail pieces. You think I'm being reasonable? I don't want you to think I'm being unreasonable.
- 4 A. I guess that's what happens.

MR. BRENNER: Objection,

Your Honor, I have an objection on cumulative.

We covered this yesterday.

- 8 MR. ALLEN: No, we didn't.
- 9 THE COURT: I overrule the

10 objection.

5

- 11 Q. (BY MR. ALLEN) Then you said in your
- 12 report exchanges between colleagues, medical
- literature, guidelines and algorithms and CME,
- 14 right?
- 15 A. Those actually came first.
- 16 Q. Yes, sir, I'm sorry. But they're all in
- 17 there?
- 18 A. They're all in there in an order, yeah.
- 19 O. Yes, sir, I apologize. Okay.
- 20 Would you like to change your
- 21 answer in any regard? I want to give you --
- 22 A. No.
- 23 O. I prepared a demonstrative diagram
- 24 myself last night. Now, Lilly, Answers That
- 25 Matter. You've seen documents in this case. I'm

Q. All right. Now, on this doctors'

sources of knowledge -- by the way, the doctor

Page 44

Page 45

- then imparts that information down to the
- patients and the family that he received, right?
 - Sir, you're getting to the end of the
- story before you've outlined the beginning, and
- 7 this -- the drawing that you have bears no
- relationship to anything that I've said.
- 9 Q. Okay. Well, it's kind of my job as a
- 10 lawyer to make this, and you tell me when I'm 11 wrong.
- 12 My question is: After your
- 13 doctors -- as your words, I think today,
- assimilates and sifts through the information,
- 15 they then talk to the family and the patient,
- 16 right?

23

5

- 17 Sir, the drawing that you made bears no
- 18 relationship to my testimony or any opinion that
- 19 I've given.
- 20 MR. ALLEN: Your Honor, I -- can he
- 21 answer the question, please?
- 22 THE WITNESS: What's the question?
 - THE COURT: Go on.
- 24 (BY MR. ALLEN) You testified that the
- 25 doctors -- and I don't have your exact words

- 1 sure when you reviewed documents that Lilly has
- the Answers That Matter.
- 3 Did you not?
- 4 A. Sir, I don't recall seeing this.
- Q. No, not this -- I just drew this last
- night. There's no way you could see it.
- 7 A. I'm not familiar with a document called
- 8 Answers That Matter.
- 9 MR. ALLEN: Well, where are the
- 10 exhibits?
- 11 Q. (BY MR. ALLEN) Sir, they're too thick.
- 12 Would you assume with me that I'm not
- misrepresenting a thing that Lilly has on many of
- its documents the phrase Answers That Matters?
- 15 MR. BRENNER: Your Honor, that's an
- improper question. Assume with me something --16
- 17 THE COURT: Why don't you just
- 18 assume for the purposes of answering this
- 19 question --
- 20 MR. ALLEN: You know, what,
- Your Honor, I don't want to quibble. We'll
- 22 strike out Answers That Matter, okay.
- 23 Q. (BY MR. ALLEN) We have Lilly. You see
- 24 that?
- 25 A. I see that.

- 1 here, sir, but I was sitting here -- standing in
- this courtroom, and I said sources of information
- 3 and knowledge about treatment, right? Your
- 4 report has that in there, does it not?
- 5 A. I'm sorry. I was looking at your
- drawing -- the question you just asked me. My
- report has what in it? I was looking at the
- 8 drawing, so I didn't hear the sentence you just
- 9 stated.
- 10 Q. I think it's page 5 --
- 11 A.
- 12 -- it was about your opinions; it had
- 13 sources of information, right?
- 14 Α. Yes.
- 15 O. And then you had -- and I keep on
- forgetting the phrase, doctors' knowledge about
- 17 treatment: is that correct?
- 18 Α. That's correct.
- 19 Q. Okay. And then you told me -- I said,
- 20 what does that mean? And I think you said
- 21 something along these lines and we'll see in the
- transcript if we have to, what doctors do is they
- 23 assimilate this information, they sift through
- 24 it, and then they advise the patient; is that
- 25 correct?

Page 46 Page 48

- 1 That's one description of the process.
- 2 Okay. Well, that's -- it was your 0.
- description of the process, wasn't it?
- A. Yeah, something like that.
- 5 Okay. Right. And then we -- I went
- through and we listed the sources of doctors'
- information, did we not? These are them --8 guidelines --
- 9 You've given it a graphic representation 10 that has nothing to do with the way that I've 11 described it.
- Q. (BY MR. ALLEN) Well, Your Honor -- I
- 13 mean, Doctor, my job as a lawyer, I'm just going
- 14 to -- CME was the source of that information,
- 15 right?
- 16 A. It is one source of many.
- 17 Yes, sir, it's one? Q.
- 18 A. Okav.
- 19 O. Yes, sir. CME is one; guidelines and
- 20 algorithms are one; medical literature is one;
- exchanges between colleagues is one; detail
- pieces is one; journal advertisements is one;
- 23 sales rep detailing is one; package insert is
- 24 one; right?
- 25 A. Well, sir, look, I'm not an artist but

- 1 A.
- 2 How about in Ketchikan? O.
- 3 No.
- 4 O. Fairbanks?
- 5 No. A.

8

- 6 MR. BRENNER: Are we going to go
- 7 through every municipality in Alaska, Your Honor?
 - MR. ALLEN: No, we're not.
- 9 THE COURT: I don't think so.
- 10 Q. (BY MR. ALLEN) And you're right, sir.
- 11 Doctors may have different weights, they may look
- at things differently. We're just talking about
- the universe of doctors. These are some of the
- 14 sources; these are ones that you put in your
- 15 report, is it not?
- 16 Sir, I'll stand by my testimony in the
- 17 report that physicians' knowledge about treatment
- alternatives comes from numerous sources.
- 19 Q. Can you read out for us, please, the
- 20 numerous sources you list in your report?
- 21 A. Yes.
- 2.2 THE COURT: We're getting to asked
- 23 and answered. Ask the --
- 24 MR. ALLEN: He's arguing with me,
- 25 Your Honor --

Page 47

1 THE COURT: No, I think you've gone

through the numerous sources many times.

3 MR. ALLEN: Okay. I agree.

- 4 (BY MR. ALLEN) You agree that the
- company's responses to questions, sales rep
- detailing, journal advertisements and detail
- 7 pieces are Lilly information, right?
- 8 Yes, but many doctors may not pay
- 9 attention to them, or if they pay attention,
- 10 they'll sift it in relationship to other
- 11 information that they see as well.

12 Particularly peer-review journal

- 13 articles, the advice of their colleagues,
- guidelines and algorithms that they may read,
- 15 conversations that they have, grand rounds that
- they attend. Many, many sources of information,
- 17 sir. Different doctors will weight these
- 18 differently, respond differently, have different
- 19 access to different sources of information.
- 20 Yes, sir. Anything else you want to
- 21 say? Feel free. Anything else?
- 22 No.
- 23 And by the way, is there anything that Q.
- 24 you want to add, subtract to or change from the
- 25 testimony today that you've given?

- 1 your drawing -- I will stand by my testimony and
- not by your drawing. These are not equally weighted. They may not be equally important.
- This graphic --
- 5 THE COURT: That's what you're
- disagreeing -- some doctors might not have -- the
- guidelines and algorithms might not be as
- important or known to some doctors, and that the
- detail pieces might be viewed with skepticism by
- 10 some doctors, and some doctors might heavily rely on some pieces of information and not on other 11
- 12 pieces of information. Is that why you're
- 13 quibbling with the drawing?
- 14 THE WITNESS: That begins to
- 15 describe, Your Honor, exactly why I'm quibbling with the drawing. There are many doctors who may
- 17 never see a detail person.
- Q. (BY MR. ALLEN) Sir, I'm talking about 18
- 19 the universe of sources of information. Do you 20 understand that?
- 21 Have you ever talked to any doctor
- 22 in Bethel?
- 23 A. Where is Bethel, sir?
- 24 Q. How about Wasilla? You ever talk to any
- 25 doctor in Wasilla?

Page 50 Page 52

- 1 A. No, sir.
- 2 Okay. You said they also get their 0.
- 3 information from peer-reviewed literature; is
- that right?
- 5 A. They may, yep.
- 6 This is Eli Lilly's exhibit, 3801 in
- this case. Hard for me to get in, 3801.
- 8 You see that?
- 9 A. Yes.
- 10 Q. Dr. Cavazzoni, Dr. Breier, and then
- 11 Dr. Buse. Do you know who these people are?
- 12 A. No.
- 13 Q. Study was sponsored by Eli Lilly; do you
- 14 see that?
- 15 A. Uh-huh, yes, I do.
- 16 So back to my drawing, the medical
- 17 literature, Eli Lilly has input in that, does it
- 18 not?
- 19 A. Into some of it, they do.
- 20 Q. Yes, sir. Where's my pen?
- 21 So Lilly is involved --
- 22 You're making it appear that it's
- 23 exclusively a source from Eli Lilly.
- 24 Q. No, sir, I'm not. There's a lot of
- 25 literature not written by Eli Lilly, isn't there?

- 1 Q. And it just appears right on the face of
- 2 the call note, Lilly is involved in CME?
- 3 A. As are many, many other sponsors;
- commercial, noncommercial, academic.
- 5 Yes, sir, I'm not arguing with that.
- 6 I'm saying was Lilly involved in CME?
- 7 Sir, I -- Lilly was involved in CME,
- 8 yes.
- 9 Q. Yes. Okay. Guidelines and
- 10 algorithms -- this is your article, correct,
- which you said contains, well, here it is,
- 12 guidelines; correct?
- 13 A. Yes.
- 14 Q. Eli Lilly is involved in funding that?
- 15 A.
- 16 O. The only thing we're left with is
- 17 exchanges between colleagues.
 - Do you see that?
- 19 A. Yes.

18

- 20 O. You know Eli Lilly is involved in that
- 21 also, do you not?
- 22 I'm not sure what you're referring to.
- 23 Q. Well, don't you know Eli Lilly hires
- doctors, pays them money and has them go out and
- speak? Don't you know that?

Page 51

- A. Enormous amounts.
- 2 Q. Yes, sir.
- 3 A. The vast majority.
- 4 Q. I didn't suggest that there wasn't. Eli
- Lilly, though, we've seen right here, is involved
- in the medical literature; isn't that true?
- 7 One participant in funding research.
- 8 Right, and the sources of information.
- 9 Now, AK10186 -- a call note the
- jury's seen -- back in November of 2001 to
- 11 Dr. Duane Hopson.
- 12 Do you see that?
- 13 Yes. A.
- 14 Q. And the sales rep -- I think it was
- Ms. Eski. It was. She's setting up another --15
- possibly setting up another afternoon meeting,
- 17 and possibly setting up another afternoon meeting
- and preparing data, or showing the PsychLink. He
- 19 likes the PsychLinks for CME.
- 20 You see that?
- 21 A. Yes.
- 22 That's a source of information. Q.
- 23 CME. You listed in your report.
- 24 Did you not?
- 25 A. Yes.

- 1 Yes, from a speakers' bureau? A.
- 2 Q. Yes, sir.
- 3 A. I'm generally aware that pharmaceutical
- 4 companies are able to do that.
- 5 Q. Yes, sir. So Lilly's involved in that,
- 6 right?
- 7 A. Yes.
- 8 Now -- and by the way, all those sources
- 9 of information are the ones you listed in your
- 10 report, not me, right?
- 11 Yes.
- 12 Is there any source of information that
- you list in your report that Lilly is not
- 14 involved in?
- 15 A. Well, my objection to your drawing, sir,
- is that it makes it appear that Eli Lilly is the
- sole source of information, and I profoundly 17
- 18 object to the way that this has been graphically
- 19 depicted. I think it's a complete distortion of
- 20 what I said.

23

- 21 MR. ALLEN: Your Honor, that was
- 22 not my question.
 - THE COURT: Well, I know it wasn't
- 24 your question. But maybe I can help deal with
- 25 the objection the doctor has to your -- can you

Page 57

agree that when you're writing Lilly, you're notcontending Lilly is the only source for that

3 information?

MR. ALLEN: I can agree they're not the only source of information in the guideline -- let me rephrase it. I'll get it.

7 THE COURT: You've written Lilly in 8 red, can you agree?

9 MR. ALLEN: Yeah, I just did that 10 on accident.

THE COURT: If he agrees to that, will that deal with what your concern is,

13 Doctor, about the graphic representation?

THE WITNESS: No, I think this is just a gross distortion. You could just as well

6 add the National Institutes of Mental Health to

17 many of the arrows, the FDA to many of the

18 arrows, Columbia University, Harvard University,

19 Stanford, you know, you could add these all.

20 These are all places that help generate

21 scientific information, hypotheses, theories that

22 doctors take into account.

Q. (BY MR. ALLEN) Okay. Let's add the

24 FDA. You wanted to add the FDA, let's add the

25 FDA.

1 add dozens of other contributors.

2 Q. Yes, you could. And every one you

3 mentioned, including medical schools and the FDA,

4 Lilly helps fund them too, don't they?

A. Many, many sources of funding contribute

6 to medical information. Lilly helps in some

7 aspects. I couldn't tell you how much, and to

8 what degree and what sources.

9 Q. Right. Now, talk about speakers. This

10 is an exhibit, 1145. When you looked at anything

11 that might possibly be relevant to this case,

12 however remote, do you remember this exhibit?

13 A. No.

19

21

Q. Okay. I think it was mentioned in the

15 deposition of Ms. Torres. This is an e-mail from

16 Anthony Fiola concerning Dear Affiliates, the

17 hyperglycemia diabetes documents contains new

18 information on diabetes speaker slides.

Do you see that?

20 A. Yes, I see that.

Q. And that's what you talked about

22 earlier, that Lilly hires and pays money to

23 doctors, prepares slides, and they go out and

24 give talks, right?

25 A. It is one source of preparation of

Page 55

A. No, I'm talking about to many of these

arrows. I mean, this is an absurd diagram that I

3 think profoundly misrepresents the ways in which

4 doctors receive information. Lilly -- you know.

5 Q. Sir, you said we could add the FDA. I 6 just added the FDA.

7 A. No, I said to many of these arrows that

8 you already have shown, you make it appear that

9 Lilly is in control of the information that10 doctors receive. It's a distorted picture.

11 Q. You added Harvard and Columbia, we'll 12 get to that in a second. You added FDA.

Lilly provides information to the

14 FDA, do they not?

15 A. Sir, you're distorting the process.

16 Q. Okay. You added Harvard and some other

17 schools, didn't you?

18 A. Sir, my point is that --

19 Q. Lilly gives them money, too, don't they?

20 A. Sir, in many of these arrows, including

21 exchanges between colleagues, medical literature,

22 guidelines and algorithm and you know, from my

23 nonexpert understanding, the role that the FDA

24 plays in approving materials that Eli Lilly

distributes, to those existing arrows, you could

1 educational materials among many.

2 Q. Yes, sir. I'm not asking -- this is the

3 source I'm talking about now.

4 A. Yes.

5 Q. Paying doctors, preparing them slides.

6 You can read any part of this you want, sir.

I want to read this: To maximize

8 Zyprexa's success in the market -- do you see

9 that?

7

12

18

24

25

10 A. By the way, if we could just back up.

11 I'm sorry.

Q. Yes, sir, you can read -- ask the --

MR. ALLEN: Do we have an extra

14 copy of this?

15 A. The previous question that you asked me

16 doesn't say who prepared the slides.

17 Q. (BY MR. ALLEN) Okay.

A. So, I would -- if you asked me the

19 question implying that Lilly prepared the slides,

I have no knowledge of how the slides were

21 prepared. I don't know what this refers to.

22 Q. All right. We'll let other people have

23 to look at that and weigh the evidence --

MR. BRENNER: Your Honor, I object.

THE COURT: I prefer you don't make

Page 60

Page 61

1 comments about his testimony.

MR. ALLEN: All right. All right.

3 Q. (BY MR. ALLEN) March 30th, Eli Lilly

- 4 knew information on hyperglycemia/diabetes. Dear
- 5 Affiliates, the hyperglycemia/diabetes document
- 6 conveys new information on diabetes speaker
- 7 slides, global hyperglycemia market research,
- 8 global response document, a copy of the U.S. sale
- 9 sheet, hyperglycemia/diabetes standby statement.
- Does that help you formulate an
- 11 opinion that we're talking about documents that
- 12 Eli Lilly has prepared in this Eli Lilly
- 13 document?

2

- 14 A. I'm sorry. I don't know anything about
- 15 the things that are referred to here. I don't
- 16 know who prepared them or what they are.
- 17 Q. Well, yes, sir. You -- but you -- in
- 18 your report you talk about weighing of benefit
- 19 and risk, and you told us yesterday quite clearly
- 20 it would be wrong and false and misleading for a
- 21 drug company to minimize, neutralize or attempt
- 22 to eliminate a risk. Remember you told us that?
- 23 A. A known risk.
- 24 Q. Does Zyprexa -- we're talking about
- 25 maximizing Zyprexa success in the market. The

- Do you see the overall goals of the
- 2 team?
- 3 A. You said and the materials they
- 4 prepared. I don't know who prepared the
- 5 materials. I don't know what they are.
- 6 Q. Okay. They -- did they list overall
- 7 goals?
- 8 A. Yes.
- 9 Q. What's goal No. 1? Can you read it out
- 10 loud for the jury, please?
- 11 A. Stop hyperglycemia slash diabetes from
- 12 becoming a top ten attribute influencing
- 13 prescribing.
- 14 Q. So Eli Lilly wanted to stop
- 15 hyperglycemia/diabetes from becoming a top ten
- 16 attribute that would influence doctors regarding
- 17 prescribing.
 - That's what that indicates,
- 19 correct?

18

23

- 20 A. The letter says that. I don't know what
- 21 Eli Lilly intended because I don't know what the
- 22 document is, and I really can't comment on this.
 - Q. Yes, sir. Would you agree with me --
- 24 you knew about the consensus statement. You told
- us -- well, here is what you said, actually.

Page 59

- 1 Zyprexa safety subteam has actively been working
- on this issue so that we can provide you
- 3 information to refute this issue effectively.
 - MR. BRENNER: Your Honor, I just --
- 5 Q. (BY MR. ALLEN) Did I read that 6 correctly?
- 7 A. Yes, you did.
- 8 THE COURT: Wait, we've got -- we
- 9 have an --
- MR. BRENNER: I just have an
- 11 objection, Your Honor. There has to be a
- 12 question here.
- THE COURT: Well, there was a
- 14 question. I mean, there needs to be a question
- 15 beyond did I read it, effectively --
- MR. ALLEN: Oh, there's going to
- 17 be.

20

- THE COURT: -- and I understand
- 19 there will be.
 - MR. ALLEN: Yes. sir.
- 21 Q. (BY MR. ALLEN) Well, first of all, did
- 22 I read this correctly?
- 23 A. Yes.
- Q. Okay. And then they list the goals of
- 25 this subteam and the material they prepared.

- 1 You said you look in the adverse
- 2 reaction section. You remember testifying about
- 3 that yesterday?
- 4 A. Yes, I do.
- 5 Q. Now, we're going to talk about that in a
- 6 little while.
- 7 But as -- Lilly -- see, and this is
- 8 '98. Metabolic and nutritional disorders,
- 9 frequent weight loss.
- Do you see that?
- 11 A. Yes.
- 12 Q. Was that a frequent adverse reaction of
- 13 Zyprexa? Weight loss?
- 14 A. Sir, it's stated in the package insert.
- 15 Q. Well, you said you rely upon it and
- 16 that's where you go.
 - So my question is: Was a frequent
- 18 adverse reaction to Zyprexa weight loss?
- 19 A. It states it in the package insert.
- 20 Q. Yes, sir, I know that.
- 21 A. Yeah.

- Q. But I'm asking you as a doctor: Was
- 23 weight loss a frequent adverse reaction to
- 24 Zyprexa?
- MR. BRENNER: Your Honor, yesterday

Page 62 Page 64

- 1 there was an objection that that was beyond his
- 2 expertise, that he couldn't talk about other
- 3 knowledge and other sources.
- 4 MR. ALLEN: Is that a speaking
- 5 objection, Your Honor?
- 6 MR. BRENNER: I apologize, Your
- 7 Honor.
- 8 THE COURT: That's okay.
- 9 MR. ALLEN: Well, He testified
- 10 about the adverse reaction section. He trains
- 11 his people --
- THE COURT: Excuse me. Can we approach?
- 14
- MR. ALLEN: Yeah.
- 16 (Bench discussion.)
- THE COURT: And if you're going to
- 18 comment on his making speaking objections, don't
- 19 make them back.
- What's your objection?
- 21 MR. BRENNER: My objection, Your
- 22 Honor, is he was -- yesterday when I tried to
- 23 elicit testimony about what was in the field,
- 24 what was known, that was objected to and
- 25 sustained.

- Page 63
- THE COURT: But I allowed him to
- 2 talk about his own personal experience. So if
- 3 you phrase the question as your own personal
- 4 experience, which I thought is what he was doing.
- 5 But make it clearer so then we can -- if the
- 6 question's rephrased, I'll allow it.
- 7 MR. BRENNER: Very good, Your
- 8 Honor.
- 9 (End bench discussion.)
- 10 Q. (BY MR. ALLEN) Was weight loss, in your
- 11 experience, a frequent adverse reaction of
- 12 Zyprexa?
- 13 A. In my own personal experience, no.
- Q. Why is it in the package insert then?
- 15 A. I don't know.
- 16 Q. Well, we know, though, hyperglycemia is
- 17 in the adverse reaction section?
- 18 A. Yes, it is.
- 19 Q. And we have hypoglycemia. Aren't those
- 20 the opposite?
- 21 A. Yes, they are.
- 22 Q. In your personal experience, was
- 23 hypoglycemia a frequent adverse reaction of
- 24 Zyprexa?
- 25 A. No.

- 1 Q. We also have the flu syndrome.
 - Do you see that?
- 3 A. Yes.

2

- 4 Q. Was that, in your personal experience, a
- 5 frequent adverse reaction of Zyprexa? The flu?
- 6 A. No.
- 7 Q. We also have seborrhea, dermatitis, dry
- 8 skin, libido decrease, eye inflammation, dry
- 9 ears, ear pain, urinary incontinence.
 - Were those adverse reactions, in
- 11 your experience, of Zyprexa?
- 12 A. One of them that you listed was. Did
- 13 you list an occular side effect?
- THE COURT: It was eye pain.
- 15 A. No -- I'm sorry. Of the ones that you
- 16 rattled off, one of them is a side effect I've
- 17 seen often and the others no.
- 18 Q. (BY MR. ALLEN) Okay. Well, then -- so
- 19 if a doctor is about to prescribe the drug, we
- 20 have hypoglycemia and we have hyperglycemia,
- 21 don't we?
- 22 A. Yes.
- Q. How are they supposed to determine from
- 24 this section whether the flu is right or --
- 25 gingivitis is down there. Was that a adverse
 - Page 65
 - 1 reaction of Zyprexa?
 - 2 A. Yes, it's listed, sir.
 - 3 Q. Yes, sir. But was it in your experience
 - 4 an adverse reaction of Zyprexa?
 - 5 A. Not that I've seen.
- 6 Q. Okay. You said weight loss wasn't.
- 7 I'll just ask one more. Let's see if I can find
- 8 one that --
- 9 Libido, did I say libido?
- 10 A. Oh, that's the one yes. Decreased
- 11 libido is frequently a side effect, yeah.
- 12 Q. Okay. All right. So, how about
- 13 vertigo?
- 14 A. Vertigo is a term referring to
- 15 dizziness, and, yes, I've seen dizziness with
- 16 Zyprexa.
- 17 Q. Okay. How about leg cramps?
- 18 A. Leg cramps, sometimes.
- 19 Q. Okay.
- THE COURT: I thought you were only
- 21 going to ask one.
- MR. ALLEN: All right.
- 23 Q. (BY MR. ALLEN) When a doctor looks at
- all this list, how's he supposed to know which
- 25 one is and which one isn't?

Page 69

- 1 A. Well, that's actually not the way
- 2 doctors use, you know, lists all the time. This
- 3 is a description of events that occurred during
- 4 clinical trials, is my understanding.
- 5 Q. Right.
- 6 A. And I'm not in a position to dispute
- 7 whether they occurred or didn't occur in the
- 8 clinical trials.
- 9 Q. Okay. Well, in fact, Ms. Eski, who is a
- 10 sales rep, testified that when a warning is given
- 11 in a package insert, it acts as an alert and they
- 12 go out and talk to the doctors.
- Do you have any dispute with that?
- 14 A. Sir, again, I'm not an expert in
- 15 labeling, so I can't offer any opinion on Ms.
- 16 Eski's testimony.
- 17 Q. Okay. You did offer opinions about
- 18 sources of information.
- 19 A. Yes.
- 20 Q. Position: To meet our goals, we must
- 21 continue to drive our position around this issue
- 22 in the minds of our customers. All of the
- 23 strategy elements and all of the tactics need to
- 24 be consistent with this position.
- 25 What's the position listed, sir?

- THE WITNESS: I will read the line
- 2 that says, Position: Diabetes/hyperglycemia may
- 3 occur in patients taking antipsychotics and/or
- 4 mood stabilizers, including Zyprexa, at
- 5 comparable rates with the possible exception of
- 6 clozapine.
- 7 Q. (BY MR. ALLEN) Comparable rate.
- 8 A. Yes.
- 9 Q. What's that mean?
- 10 A. It means that there is this side effect
- 11 of diabetes or hyperglycemia, and that it may
- 12 occur in patients that are taking antipsychotics
- 13 or mood stabilizers, and that it can be seen in
- 14 patients taking Zyprexa, and that it may be seen
- 15 as well in other antipsychotics or mood
- 16 stabilizers at comparable rates.
- 17 Q. Right. We know -- we know that Eli
- 18 Lilly gave the comparable rates message here in
- 19 Alaska, don't we?
- 20 A. I don't know the answer to that
- 21 question.
- 22 Q. Well, Alaska 10 -- 10186. Dr. Hopson
- 23 back in -- he was in Fairbanks in November, 2001,
- 24 they gave him the comparable rates message, did
- 25 they not?

Page 67

1 A. I don't know that, sir.

2 Q. Okay, sir. Let's talk about weight

3 gain.

4 You gave opinions in your report

5 and in your article on weight gain, did you not?

- 6 A. In my re -- in my article. You're
- 7 referring to the practice guidelines or --
- 8 Q. Talks about weight gain, does it not?
- 9 A. Before I answer the question, I'd just
- 10 like to be sure I know what you're referring to.
- 11 Q. Your -- I think -- the 1999 Treatment of
- 12 Schizophrenia Expert Consensus Guideline Series.
- 22 Schizophichia Expert Conschsus Guidenne Sei
- 13 A. Yes, yes.
- 14 Q. Okay. Does Zyprexa cause weight gain?
- 15 A. Zyprexa is associated with weight gain.
- 16 O. Yes, sir.

23

- 17 A. It's a side effect.
- 18 Q. No, sir, that wasn't my question.
- 19 A. Oh, does Zyprexa cause weight gain?
- 20 Q. Yeah, does it cause it?
- 21 A. Yes, Zyprexa causes weight gain.
- 22 Q. All right. Zyprexa causes weight gain.
 - What is it about the pill Zyprexa
- 24 that causes weight gain?
- 25 A. I don't know.

rage

Sir, and my question is: Can you please

- A. Sir, listen, I don't know the context of this document, so by saying what the position is
- 3 I'm not sure that what you asked me to read would
- 4 be their position. I simply don't know what this
- 5 is. I don't know the context. I don't know how
- 6 it's constructed, who it was by or what it was 7 for.
- 8 0
- 9 read out loud for the jury the position of Eli 10 Lilly?
- 10 Lilly?
- 11 A. You can point to the line. I don't know 12 what Eli's -- Eli Lilly's position was, and I
- 13 don't know who this document represents.
- Q. Yes, sir. You've made that clear.Can you just read out loud for the
- 16 jury, please, the position of Eli Lilly?
- 17 A. I don't know that this is the position 18 of Eli Lilly, so I won't read it under that
- 19 perception.
- THE COURT: Can you read the line
- where it says, "Position"?THE WITNESS: The position -- but,
- again, I don't know whose position it is or what
- 24 it means.
- THE COURT: That's clear.

- 1 Q. Okay. You know the pill causes it?
- 2 A. Yes.
- 3 Q. And, in fact, I don't know if you
- 4 reviewed this. It's Exhibit 1453, and I'm not
- 5 going to pull it back out, but Eli Lilly knew
- 6 that normal patients who were not schizophrenics
- 7 who were put on Zyprexa, they gained weight.
- 8 Did you know that?
- 9 A. I didn't know that.
- 10 Q. You did not know that?
- 11 A. No.
- 12 Q. 1453 also says that animals on fixed
- 13 diets, they can't eat any more calories. You
- 14 know what that means.
- 15 A. Yes.
- 16 Q. They also gained weight. Did you know
- 17 that?

1

- 18 A. Didn't know that.
- 19 Q. How is it that Zyprexa can cause weight
- 20 gain in animals on fixed diets?
- 21 A. I don't know biochemically why it causes
- 22 it, but so be it.
- Q. It's a metabolic response, right?
- A. Sir, I don't know the mechanism.
- 25 Q. Okay. You just know it causes it?

- 1 A. Because --
- Q. -- to tell doctors that the pill doesn't
- 3 cause weight gain?
- 4 A. Because in some patients it does appear

Page 72

Page 73

- 5 to be associated with weight gain.
- 6 Q. Well, sir, you changed the word again.
- 7 You've already told us it causes it, right?
- A. Well, it's certainly a side effect. You
- 9 know, again, if we're getting to a level of
- 10 technicality here, it's a known side effect of
- 11 Zyprexa.
- 12 Q. Well, sir, the testimony -- let's look
- 13 at what the testimony is.
- 14 A. Yeah.
- 15 Q. There it is. One more thing before I
- 16 get to these documents.
- False, deceptive, misleading. Now
- 18 we're going to go to, I learned it in medical
- 19 school. Do you remember saying that? I learned
- 20 it in medical school?
- 21 A. Yes.
- 22 Q. M-E-D is going to mean medical; is that
- 23 all right?
- 24 A. Sure.
- 25 Q. Those were your words, right?

Page 71

- A. It causes it in some individuals, yes.
- 2 Q. Okay. The pill causes it. The pill
- 3 causes weight gain.
- 4 A. In some individuals.
- 5 Q. Yes, sir. That's --
- 6 A. Yeah.
- 7 Q. So Eli Lilly shouldn't be out telling
- 8 doctors the pill doesn't cause weight gain,
- 9 should they?
- 10 A. I'm not aware that they did.
- 11 Q. Okay. But my question is: Eli Lilly
- 12 should not be out telling doctors the pill does
- 13 not cause weight gain, should they?
- 14 A. Sir, it -- I'm not aware that they said
- 15 that to anybody.
- 16 Q. Sir, you're going to see some of it in a
- 17 minute, but my only question is: Eli Lilly
- 18 should not be out telling doctors the pill does
- 19 not cause weight gain, should they?
- 20 A. Correct.
- 21 Q. And to do so would be false, deceptive
- 22 and misleading, true?
- 23 A. Yes.
- Q. Why would it be false, deceptive and
- 25 misleading --

- 1 A. With respect to?
- 2 Q. Weight gain.
- 3 THE COURT: Ask him the question.
- 4 Q. (BY MR. ALLEN) Do you recall telling
- 5 Mr. Brenner -- you all were actually talking
- 6 about the package insert and you were talking
- 7 about the adverse reactions section and he said:
- 8 Did you know about weight gain?
 - Do you recall that?
- 10 A. Did I know about weight gain as a side
- 11 effect? Yes.

9

- 12 Q. And you said, did you know about -- I
- 13 think, and I'm paraphrasing, sir. I can't get it
- 14 exactly, but see if you recall this.
 - He said: Did you know about the
- 16 side effects of weight gain?
- 17 A. Yes.
- 18 Q. And then you said --
- 19 A. Well, the side effects of weight, the
 - 0 consequences or the associated, you know,
- 21 problems that occur with weight gain.
- Q. Okay. Consequences, that's a good word.
- A. Sir, don't take my words out of context.
- 24 We can go back, you know -- the associated
- 25 problem with weight gain.

- Q. Did you learn about the consequences of
- weight gain in medical school?
- A. I learned about the problems associated
- with weight gain in medical school.
- Q. The problems. Did you learn about the sequelae of weight gain?
- 7 A. I learned about the problems associated 8 with weight gain.
- 9 Q. And a different question. Did you learn 10 about the sequelae of weight gain?
- A. Sir, I don't recall precisely what words 11
- 12 would be connected, but I learned about the
- problems associated with weight gain.
- 14 Q. What does sequelae mean in medicine?
- 15 A. I don't have a precise definition
- 16 available to me, but sequelae generally means
- things that happen in association with each 17
- 18
- 19 Q. Okay. Now, I never got it clear what it
- 20 is you learned about weight gain in medical
- 21 school. Tell us what you learned about weight
- 22 gain in medical school.
- 23 A. Weight gain is a health problem that has
- 24 a number of associated other health issues that
- occur, and these include arthritis.

- 1 gain.
- 2 O. What about diabetes?
- 3 A. As -- within the set of problems
- 4 associated with high blood sugar.
- 5 So you knew that in college? Or not
- 6 college, medical school? 7
 - Yes.
- 8 All right. How much weight gain was
- 9 associated with Zyprexa?
- 10 In the package insert it describes over
- 11 approximately an eight-month period -- I think
- 12 it's 238, 234 days, I forgot precisely how
- much -- patients gained, I think the figure is
- 14 5.4 kilograms.
- 15 Q. Eleven pounds?
- 16 About 11, 12 pounds.
- 17 Okay. Now, I'm looking in this adverse
- 18 reactions section. And we actually had -- Dr.
- Inzucchi testified -- you saw him testify, didn't
- 20 you?
- 21 A. Yes, a portion of his testimony.
- 22 Q. He testified under oath for this company
- 23 that Zyprexa does not cause diabetes. Were you
- 24 here for that?
- 25 A. Yes.

- Q. Yes, sir. 1
- 2 A. Back pain.
- 3 Q. Yes, sir.
- A. Hypertension, heart disease. 4
- 5 Q. Okay. Almost through. Did you say
- hypertension?
- 7 A. Hypertension.
- 8 That's high blood pressure?
- 9 That's right.
- 10 Q. Okay. I can draw an arrow up like that
- 11 and put --
- 12 Sure. BP, yep.
- 13 Q. -- BP?
- 14 I think you said --
- 15 Heart disease. Α.
- 16 Q. Heart disease. I'm going to put D-X for
- 17 disease --
- 18 Α. Sure.
- 19 Q. -- is that all right?
- 20 A. Elevated blood sugar.
- 21 Q. I'm going to put elevated sugar.
- 22 A. Elevated lipids and cholesterol.
- Q. What else? 23
- 24 A. I could keep going. A list of things.
- 25 Sleep apnea is seen in people who have weight

- Q. But we know, according to you, it causes 1 2 weight gain, right?
- 3 A.
- 4 Q. Therefore, it causes diabetes, doesn't
- 5 it?
- 6 A. No.
- 7 Well ---O.
- 8 A. We don't know the cause of diabetes.
- 9 Oh, you don't. Matter of fact, you say
- 10 that in your article when you're discussing
- another topic. Do you recall saying that in this
- article? You're not even discussing -- you
- 13 remember that?
- 14 A. No.
- 15 Q. I'll show it to you later.
- 16 Well, would it be proper and
- 17 appropriate -- let me ask this: Would it be
- misleading for Eli Lilly to go around and try to
- 19 unlink the connection between weight gain and
- 20 diabetes?
- 21 A. Unlink is an awfully broad term.
- 22 Q. What's it mean to you?
- 23 A. I'm not sure what you mean by it, sir.
- 24 Yes, sir. And I -- what we're going to
- 25 do here today is I'm going to use words and if

1

2

3

Page 81

- 1 you don't understand it, you ask me, and I'm
- going to give you the right to use whatever
- definition you would like.
 - What's unlink mean to you, sir?
- 5 A. Sir, you're asking me the question. I'd like to answer your question.
- 7 Q. Yes, sir, I know, but that's not the way 8 things work.
- 9 THE COURT: Doctor, what he's 10 willing to do is if you don't understand what he
- means by something, he'll use whatever definition 11
- you use to answer the question. So he's asking
- you what unlink means, and then he's going to
- 14 say, using your definition and he's going to ask
- 15 another question.
- 16 THE WITNESS: Right. What concerns
- 17 me is that if he's asking me if Eli Lilly did
- 18 something and I don't know what he means by what
- 19 they did, I can't answer the question.
- 20 Q. (BY MR. ALLEN) Sir, with all respect,
- 21 and I mean all respect, we're going to go a
- 22 question at a time. And isn't it your response
- 23 when you said I'm going to tell the truth, the
- 24 whole truth and nothing but the truth so help me
- 25 God --

Yeah.

causal chain?

- 4 A. Is that what you're asking me?
- 5 Yes, sir. I said you can use anything

A. Unlink can -- if you're talking about a

- you want, and I just said yes. Let's call it a
- 7 causal chain.

O.

- 8 Okay. A.
- 9 Let's call it a causal chain. I'm going
- 10 to use whatever words you want.
- 11 A. Okay.
- 12 And if you unlink that chain, you would
- 13 -- what it clearly means is you take the chain
- that was that long and you unlink it, it's no
- 15 longer together, right?
- 16 Correct. A.
- 17 Q. All right. That's what I thought unlink
- 18 meant.
- 19 A. Okay.
- 20 And you've told us from med school you O.
- 21 knew there was a link between diabetes and weight
- 22 gain, right?
- 23 A. That there is an association.
- 24 Q. Okay. An associative link; is that
- 25 right?

4

- Association. 1 Α.
 - 2 Q. Okay. Well --
 - 3 We've defined link differently.
 - All right. Well, we'll see.
 - 5 Have you read -- when you asked for
 - 6 anything that possibly might be relevant, did you
 - -- I got it out of focus, hold on.
 - 8 Did you read Exhibit 1901, AK1901,
 - 9 that's in evidence in this case?
 - 10 Α. Not that I can recall.
 - 11 Q. Do we have an extra copy of this? I'll
 - give it to you. Mr. Noesges was in here earlier.
 - Do you know -- he was here, he's left. He's the
 - 14 -- and I'm paraphrasing the title. He at one
 - 15 time was in charge of the western region for
 - 16
 - Zyprexa.
 - 17 Did you meet Mr. Noesges?
 - 18 A. I've met him briefly.
 - 19 Where? Q.
 - Here this morning in the courtroom. 20
 - 21 Okay. He testified that they trained
 - 22 the sales representatives to have the same
 - 23 training in Alaska and across the country.
 - 24 Does that make sense to you?
 - 25 I have no comment.

- MR. BRENNER: Objection, Your
- 2 Honor.
- 3 THE COURT: Yeah. That's -- that's
- -- Doctor, we will go a question at a time, and
- if you don't understand a question or you can't
- answer a question, it's your right to say I can't
- answer the question, explain why, and then if Mr.
- Allen can clarify or do other things, he will.
- 9 But --
- 10 THE WITNESS: Precisely what I
- 11 meant, sir.
- 12 Q. (BY MR. ALLEN) Okay. What does unlink
- 13 mean to you? 14 A. Look, in this context, I have no idea
- 15 what you mean. 16 Q. Okay. Well, then let me try and see if
- 17 this helps and we'll come up with a definition
- 18 together. I'm not a very good artist.
- 19 I think about a link as a chain
- 20 with links in it, do you not? Links of a chain?
- 21 A. That's one way to think of the term.
- 22 That's a concrete definition.
- 23 Q. Is there any other way? Any other way
- 24 to think of the term unlink? That's what I'm
- asking. You can give any definition you want.

- 1 Q. No comment. All right. And Ms. Eski 2 said that they had resource guides -- she
- 3 testified under oath they have resource guides
- 4 and things called implementation guides that
- 5 train the sales reps what to say.
- 6 Do you know anything about that?
- 7 A. No.
- 8 Q. Of course, these would be the sales reps
- 9 that you listed as one of the sources of
- 10 information, right?
- 11 A. Yes.
- 12 Q. And Ms. Torres has testified distinctly
- 13 that they're the people that are going to bring
- 14 information to the customers, right?
- 15 A. Yes.
- 16 Q. All right. Turn to page 2 of this
- 17 document, sir.
- 18 A. Yes.
- 19 Q. We're going to look at Eli Lilly's
- 20 strategy. You see strategy?
- 21 A. Yes.
- 22 Q. Eli Lilly, second paragraph: Our goal
- 23 is to continue to drive new patient starts on
- 24 Zyprexa, keep patients on therapy longer and to
- 25 ensure the appropriate dose is utilized. In

- 1 Q. All right. Now, would it be -- and you
- 2 testified it would be false, deceptive and
- 3 misleading to try to neutralize a possible side
- 4 effect, correct?
- 5 A. Well, sir, it says to neutralize the
- 6 hyperglycemia/diabetes issue, health physicians
- 7 manage weight gain. Doesn't look like they're
- 8 denying it to me.
 - MR. ALLEN: Objection;
- 10 nonresponsive, Your Honor.
- THE COURT: Yeah. Listen to the
- 12 question --

9

- 13 A. I can't give you an opinion on this
- 14 document, because, clearly there's a context of
- 15 this that I'm not an expert in.
- 16 Q. (BY MR. ALLEN) Sir, I'm not asking you
- 17 for an opinion about this document.
 - Can you lay the document to the
- 19 side?

18

- 20 A. Yes.
- 21 Q. It would be false, deceptive, and
- 22 misleading to try to neutralize a doctor's view
- 23 of hyperglycemia and diabetes as it relates to
- 24 the drug Zyprexa, true?
- 25 A. It's a very broad statement. What I

Page 83

- 1 order to maximize this effort, we must neutralize
- 2 the hyperglycemia/diabetes issue.
- 3 Do you see that?
- 4 A. Yes.
- 5 Q. And that's the very thing you told us
- 6 yesterday and this morning would be false,
- 7 deceptive and misleading, right?
- 8 A. I used the word neutralize with
- 9 reference to neutralizing or denying element of a
- 10 risk or a side effect.
- 11 Q. I thought you told me what's an adverse
- 12 reaction is a risk or side effect.
- 13 A. That's right.
- 14 Q. Okay. Whatever your testimony, at
- 15 least, hyperglycemia and diabetes is in here,
- 16 right?
- 17 A. Yes.
- 18 Q. And you actually told me that doctors
- 19 need to know about possible side effects.
- 20 Remember?
- 21 A. Yes.
- 22 Q. Okay. Well, using all of your own
- 23 definitions, diabetes and hyperglycemia would be
- 24 possible side effects of Zyprexa, true?
- 25 A. That's right.

- 1 testified is it would be false and misleading to
- 2 neutralize -- it's to deny a fact. Neutralize in
- 3 the sense of denying that something is a side 4 effect.
- 5 Q. Possible side effects, you said that in
- б your report?
- 7 A. To deny that something is a side effect.
- 8 Q. And you said possible side effects?
- 9 A. A known side effect that an individual
- 10 may possibly experience was what I explained my
- 11 phrase meant.
- 12 Q. Okay. So -- let me ask this, and then
- 13 we'll move on to the next point.
- Are you changing any of the
- 15 testimony that you gave me earlier this morning?
- 16 A. No. What I explained earlier this
- 17 morning, possible side effect means a known side
- 8 effect that an individual patient might
- 19 experience.
- 20 Q. No, sir. I was standing right over
- 21 here --

- 22 A. Yes.
 - MR. BRENNER: Your Honor, I think
- 24 we're just arguing.
- 25 THE COURT: Ask a question.

- Q. (BY MR. ALLEN) I was standing right 2 over here and I said it would be wrong to make a patient wait 20 years, didn't I?
- A. Sir, what I said was that if there is a known side effect that a patient may possibly experience.
- 7 O. Okay. Let me ask you a new way. 8 Is diabetes and hyperglycemia a
- 9 known side effect that patients might possibly experience? 10
- 11 A. Yes.
- 12 Q. Okay. So, therefore, it would be wrong
- to neutralize the hyperglycemia/diabetes possible
- 14 side effect, wouldn't it?
- 15 A. Look, again, I hate to quibble with you,
- but neutralize a side effect is a phrase that I
- described to you what would be wrong. It would 17
- be wrong to deny that the side effect exists.
- 19 Q. Oh, okay. Let's look at message point 20 2.
- 21 This says it would help patients manage
- their -- help doctors manage their patients' 22
- 23 weight gain.
- 24 Q. Sir, do you want to say anything else?
- 25 No.

Page 87

- Q. I mean I want you to have full
- opportunity. You can look at this jury and tell
- them anything you would like to tell them.
- MR. BRENNER: Your Honor.
- 5 THE COURT: No.
- 6 Q. (BY MR. ALLEN) Now, sir, why don't we
- turn to page 3. Message point. We've heard
- testimony in this trial from Mr. Michael Bandick,
- 9 among others, and I think Mr. Jordan, a message
- 10 is something we communicate to an audience.
- 11 Do you know what a message is?
- 12 A. I'm sorry, sir. I was just looking at
- 13 the document when you asked me the question.
- 14 Q. Yes, sir. Do you know what a message is? 15
- 16
- A. Sure.
- What's a message? 17 Q.
- It's a point of view. 18 A.
- 19 Q. Point of view. This is Lilly's point of
- view, because this is a Lilly document, right? 20
- 21 A. Yes. I presume this is a Lilly
- 22 document.
- 23 Q. Yes, sir. As long as I'm telling you
- the truth, that this is a Lilly document, will
- 25 you just accept that?

- A. Where within Lilly? Again, I don't know
- the context of this document, what was done with
- it, who it was produced for. I just want to make
- that clear.
- 5 Q. I actually do, sir. This is a Resource
- Guide and Ms. Eski testified and sworn under oath
- 7 she testified that Resource Guides --
- THE COURT: I mean, he doesn't know 8
- 9 and you're telling him doesn't make it true. The
- 10 jury has heard the testimony, and the jury will
- 11 be able to decide where the document came from.
- 12 (BY MR. ALLEN) I'll move forward.
 - Message point, many physicians
- 14 think there is a logical link between weight gain
- 15 and diabetes.

13

16

- You see that?
- 17 A. Yes.
- 18 O. You're in that group, are you not?
- 19 A. That there's an association, yes.
- 20 That's right. I want to go with a
- 21 logical link. Are you in that group of a logical
- 22 link?

7

- 23 A. You know, I prefer to use the precise
 - term. I'm in the group that knows that there's
- an association between weight gain and diabetes.

- Q. Okay. Many physicians think there's a
- 2 logical link between weight gain and diabetes.
- 3 In market research, we see that many of them even
- use those two words interchangeably. We believe
- it is essential to weaken this link in order to
- 6 neutralize the diabetes and hyperglycemia issue.
 - Do you see that?
- 8 Yes, I do. A.
- 9 Q. It appears just from the plain English
- 10 Eli Lilly was trying to break the chain of
- 11 association or causation between Zyprexa and
- 12 weight gain and diabetes, true?
- 13 THE COURT: Do you have an
- 14 objection?
- 15 MR. BRENNER: Maybe we can
- approach, Your Honor. 16
- 17 THE COURT: Please.
- 18 (Bench discussion.)
- 19 MR. BRENNER: All we're doing is
- having the witness read the statement and then 20
- 21 comment on Lilly's intent --
- 22 THE COURT: He's asking him whether
- 23 he agrees with whether it would be wrong and
- inappropriate and false and misleading, and he's
- got to read the statement before he can answer.
 - 23 (Pages 86 to 89)

Page 92

MR. BRENNER: I think the question

2 that was asked -- what did Lilly believe. I

- 3 don't think this witness can comment on corporate 4 intent.
- THE COURT: Right. That's a fair question. Why don't you go to what he believes rather than what Lilly believes.

8 (End of bench discussion.)

- 9 Q. (BY MR. ALLEN) Do you think it's fair 10 to try to break the logical link between weight
- 11 gain and diabetes?
- 12 A. Sir, again, let me say again, you know,
- 13 without knowing the full context of this, it
- 14 seems to me that they're talking about
- 15 specifically here with respect to Zyprexa and not
- 16 as a general medical principle.
- 17 Q. Well, let's go back to the pill causes 18 weight gain.
- You remember telling us that?
- 20 A. Yes.
- 21 O. There's no doubt -- let me see here.
- MR. ALLEN: Do you want to take a
- 23 break, Your Honor? I don't know what time it is.
- THE COURT: It's 10:00. We can
- 25 take a break or take a break in a few minutes.

- 1 Q. Yes. Well, this is a call note in 2002
- 2 on -- again, I'll try to focus.
- And the sales representative is
- 4 Kristen, I'm going to say Clouthier -- or
- 5 Clouthier? Do you see that?
- 6 A. Yes, I do.
- 7 Q. She's calling on a doctor here in
- 8 Anchorage. She's doing that on June the 27th,
- 9 2002, right?
- 10 A. Yes.
- 11 Q. We've learned from Dr. Hopson and
- 12 others, the name of the doctor is right here,
- 13 Madeline Grant.
- You see that?
- 15 A. Yes, I do.
- 16 Q. Okay. Now, in this call it says: Pam
- 17 Engle was concerned about weight gain.
 - We've heard that doctors have, what
- 19 do you call it? The nurses and nurse
- 20 practitioners. You understand that?
- 21 A. Yes.

18

- Q. Matter of fact, are you called upon by
- 23 detail personnel for drug companies?
- 24 A. No.
- 25 Q. Oh, you're not?

Page 91

- 1 Between 10:00 and 10:30 is when I like to take
- 2 the first break. When you get to a convenient
- 3 point, let me know.
- 4 MR. ALLEN: Okay. I have to get
- 5 this from Ms. Rivers. While we're doing that,
- 6 I'll get an exhibit number in a minute. We 7 didn't --
- / ulull t --
- 8 You have it?
- 9 Thank you.
- 10 Q. (BY MR. ALLEN) Sir, we admitted
- 11 yesterday into evidence, yesterday morning,
- 12 Alaska AK10205, which are call notes of actual
- 13 discussions between the sales representatives
- 14 here in Alaska with the doctors here in Alaska.
- Have you reviewed any of those?
- 16 A. No.
- Q. Okay. But, again, as you've said, we
- 18 started the day with, these are sources of
- 19 information that act as a knowledge of treatment
- 20 options and treatment, right?
- 21 A. They're one source of information that
- 22 physicians may take into account.
- Q. Yes. Now, you told us that the pill
- 24 causes weight gain, right?
- A. Yes, in some patients.

- 1 A. No.
- 2 Q. Why not?
- 3 A. I work at a medical center that
- 4 discourages unsolicited visits by detail people.
- 5 Q. Why is that?
- 6 A. I don't know. Safety, security. Just a
- 7 policy of the medical center.
- 8 Q. So, really, you personally don't have
- 9 any experience with detail people?
- 10 A. I have some experience.
- 11 Q. How?
- 12 A. I sometimes call them to get information
- 13 or literature.
- 14 Q. Why do you call them?
- 15 A. When a new product comes out and I want
- 16 to see the package insert, for example.
- 17 Q. Anything else?
- 18 A. That's the main reason.
- 19 Q. Okay. Can't you get the package insert
- 20 out of the PDR?
- A. Well, when something is brand-new, the
- 22 PDR is often quite out of date.
- Q. That's a good point. I thought you
- 24 could get it on the web on WebMD.
- 25 A. Yes, but sometimes when a new product

1

Page 97

- 1 comes out I'll want to get information from the company about it.
- 3 Right. That's what I thought. Why are 4 you calling them? What information are you 5 looking for?
- A. They can provide literature reviews, they can provide medical letters. From time to time, I'll call a company representative to get
- 9 information about the product.
- 10 Q. They're not only a source of
- 11 information, they're a very valuable source of
- 12 information, right?
- A. I didn't say that. 13
- 14 Q. Pam Engle was concerned about weight
- 15 gain for Zyprexa patients, but we discussed
- proper diet and the fact that if patients are
- feeling better, perhaps they will be able to
- actually exercise. Did I read that correctly?
- 19 A. Yes.
- 20 Q. Also discuss the mechanism of Zyprexa,
- 21 and that the drug does not cause weight gain. Do
- 22 you see that?
- 23 A. Yes.
- 24 Q. That's false, deceptive and misleading,
- 25 is it not?

- Q. Okay. Now, we'll talk about that in a 2 minute. 3
- You said the pill causes weight
- 4 gain. Remember, the pill causes weight gain?
 - Yes, in some patients.
- 6 Q. That's what you said. So, isn't it true
- that when they told a doctor that the drug does
- not cause weight gain, that was false?
- 9 A. Sir, this isn't a transcript of a
- 10 meeting, and it's clear from the context of the
- sentence that the salesperson acknowledged that
- 12 the patient had an increase in weight because
- they were taking Zyprexa. So, I don't know what
- 14 she meant.
- 15 Q. Oh, you don't?
- 16 I really don't know what she meant.
- 17 Well, I thought we saw and I thought
- 18 that you agreed that the pill caused weight gain
- and we see it occur in normal patients, we've
- 20 seen it can occur in --
- 21 MR. BRENNER: Objection; asked and
- 22 answered.
- 23 THE COURT: Yeah, move on.
- 24 (BY MR. ALLEN) Let's go to the next
- call note with Pam Engle. Right here. It's in

Page 95

- A. I would disagree with the statement.
- Q. Yes, sir. Not only disagree, you said
- the pill does cause weight gain. So therefore,
- to tell somebody that the drug does not cause
- weight gain would be false, deceptive and
- 6 misleading; true?
- 7 A. Well, it's funny because she says in
- here that there's weight gain in Zyprexa patients
- and they need to do things to help lose weight so
- 10 I'm not quite sure what this meant or what she
- 11 meant.
- 12 Yes, sir. I'm just reading and writing
- 13 the English language. Also discussed the
- 14 mechanism of Zyprexa, and that the drug does not
- cause weight gain. What's that mean to you? 15
- 16 MR. BRENNER: Your Honor, could we
- 17 read the entire sentence?
- 18 MR. ALLEN: Sure. We're going to
- 19 read it.
- 20 THE COURT: That's fair.
- 21 Q. (BY MR. ALLEN) The drug does not cause
- 22 weight gain, but it increases the patient's
- 23 appetite.
- 24 Do you see that?
- 25 Yes.

- there again.
- 2 Do you see that?
- 3 Yes.
- 4 Q. If I asked you: Does the pill cause
- 5 weight gain, your answer is yes, isn't it?
- 6 A. Yes.
- 7 Thank you, sir. Now.
- 8 MR. BRENNER: Objection,
- 9 Your Honor.

12

- 10 Q. (BY MR. ALLEN) The position on weight
- 11 gain is in document 1110.
 - Did you review this when you asked
- 13 for anything possibly relevant to this case?
- 14 Not that I can recall.
 - Well, you said you had three volumes of Q.
- 16 marketing material. I'm trying to figure out
- 17 what you had.
- 18 A. Sir, that was in preparation for the
- 19 report that was written a year ago, and it's
- impossible to remember everything that I have
- 21 read in preparation.
- 22 Q. Have I showed you one document that
- 23 you've read so far?
- 24 A. Sir, it's impossible to recall
- 25 everything that I saw over a year ago.

Page 98 Page 100 1 1 Q. All right. Issues, management planning. THE COURT: You may. 2 2 Our position, weight gain can occur with Zyprexa (Bench discussion.) 3 as with other antipsychotics and mood MR. BRENNER: That may be a typo, 4 stabilizers. and Mr. Allen can't testify to that in front of 5 5 A. Yes. the jury. 6 Q. For most patients this can be managed, 6 THE COURT: The jury has been allowing them to receive the overwhelming 7 advised and I'll advise them again at the end of benefits Zyprexa offers, right? the trial that his questions aren't evidence. 9 A. Yes. 9 This --10 Q. So, I guess that Risperdal, Seroquel, 10 MR. BRENNER: The problem with the and I'm going to abbreviate that SQ. documents -- read them as they're written. 11 11 A. Yes. 12 12 THE COURT: The document is what 13 Q. Geodon, Abilify causes the same amount 13 the document says. 14 14 of weight gain as Zyprexa; is that right? MR. ALLEN: No problem. 15 MR. BRENNER: Your Honor, can we 15 (End bench discussion.) restrict that to the doctor's experience? 16 THE COURT: Yeah, let's take a 16 17 THE COURT: No, given a article 17 15-minute break. Ladies and gentlemen, we're 18 going to take our first break of the day, and 18 that he wrote. 19 19 we'll be in recess until about 10:30. Q. (BY MR. ALLEN) So I guess all these, 20 20 Risperdal, Seroquel, Geodon, Abilify cause the We'll be off record. same amount of weight as Zyprexa? 21 THE COURT: Off record. 22 22 A. Not necessarily. (Break.) Q. They don't, do they? They just flat 23 23 (Jury out.) don't, do they? 24 24 (Break.)

Page 99

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Page 101

Q. Then, why are they going out with a position that says weight gain can occur with 3 Zyprexa as with other antipsychotics, for most patients it can be managed, allowing them to receive the overwhelming benefits. Do you know why? 6 7 THE COURT: Again, to ask him why Lilly does something is -- he's made clear that he doesn't know what Lilly did or didn't do. And 9 10 so --11 MR. ALLEN: Your Honor, he's also 12 made clear that he reviewed marketing documents. 13 I have to test that. 14 THE COURT: But you've already

25

A. No.

Q. (BY MR. ALLEN) Sir. What's a
rationale, please, sir? A rationale?
A. A reason.
MR. BRENNER: Objection,
Your Honor. That's not the word.
Q. (BY MR. ALLEN) Rational. I'm going to
call it rational but I'm thinking it's a
misspelling. But we'll just say rational.

15 established that he didn't review this one.

MR. BRENNER: Your Honor, can we approach?

We received a communication from
one of the jurors, and just so the record is
clear, my understanding is that a remark was made
to Mr. Borneman by the juror. I asked the
juror if she would -- I asked that the jurors be
brought back. I told Mr. Borneman to tell the
juror to put it in a note. The note reads the
call note with Pam Engle and Dr. Grant are
physicians at the health center I work at,
Anchorage Neighborhood Health Center. Does this
create a problem? And it's signed by Ms. Sand,
who is juror No. 11.

THE COURT: Please be seated.

rest of jurors and make sure it doesn't create a
problem.
MR. FIBICH: Well, Your Honor, I
respectfully would disagree with the Court. I
don't think it creates a problem. I think you
can cure this with an instruction to her that she
is to decide the evidence in this case based on
the evidence in the courtroom and not consider

bring in Ms. Sand outside the presence of the

So what I would propose is that we

anything else. But to bring her in and put her
under the microscope I think is inappropriate. I
mean, obviously she's a conscientious juror

Page 102 Page 104

1 because she brought it up to us. That was not something that she was required to do under any rule. But I think focusing on it is going to exacerbate the problem.

THE COURT: Well, I may end up giving an instruction, and it may be that I can cure it or it may be I don't have anything that I need to cure, but until I make a record I don't think I can know.

MR. ALLEN: I think it ought to be 11 done back in your chambers as the other issue. 12 We don't need to do this here.

13 THE COURT: I don't have any 14 problems with that.

5

9

5

10

15 MR. ALLEN: And I think you should be the one to talk to her and not anybody else. It's not voir dire. 17

18 MS. GUSSACK: Your Honor, for 19 Lilly, I think that the fact that the juror 20 raised it plainly makes it a concern that needs 21 to be explored. And I would appreciate receiving a copy of the call note that is being referenced 23 by the juror so that we can follow along about what her concern is or that what she's focusing 25 on. But certainly to the extent that she

1 Engle and Dr. Grant are physicians at the health

center I work at, parenthesis, Anchorage

3 Neighborhood Health Center, closed parenthesis.

4 Does this create a problem, question mark.

Signed by Ms. Sand.

6 So what I'm going to do is we'll 7 take her back in chambers and ask her if it creates a problem for her. We'll find out about 9 it and find out what the nature -- maybe she'll

10 say no.

18

19

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24

11 MR. ALLEN: With due respect, I 12 know the Court is wise and has done a good job. This is not the test. The test is in voir dire she was a qualified juror and when you hear 15 evidence you have to weigh and evaluate the evidence. You're going to hear some you like and 17 some you don't like.

THE COURT: Again, I'm not even sure this is an issue in any particular way. Maybe she says, doesn't affect me at all. I just 21 wanted to let everyone know about this. Then we're going to be done with this.

MR. FIBICH: Your Honor, I think we all understand what's going on here. They're going to want a mistrial if there's any way to

Page 103

believes that she has a connection with any of the participants in that call note, I think it is

something that needs to have some inquiry about and a record created.

MR. ALLEN: Well, let me say, Your Honor. At the start of the trial, you asked the people who they know and who they don't know.

8 THE COURT: That was based on 9 witnesses and I recognize these people are not 10 witnesses. That may be significant or it may not 11 be significant.

12 At this point all I have is a note, 13 and this all may be a tempest in a teapot, and it may be something extremely significant. And I 14 have no idea until I talk to -- until we talk to 15 16 the juror.

17 MR. ALLEN: Yes, sir. I just point out in the middle of a trial as opposed to a voir 19 dire selection, the test is different --

20 THE COURT: You're telling me what 21 the legal standards are before I even know 22 there's a problem.

23 MS. GUSSACK: Your Honor, can you 24 just -- can you just read us the inquiry --25 THE COURT: The call note with Pam

Page 105

get one. We do not. But how you phrase the

inquiry, I think, is important. And I don't mean

to impose on the Court to tell me in advance, but what we ask her is extremely important. I think

that's what Mr. Allen is alluding to.

6 MS. GUSSACK: I suggest to the implication that the Defendant wants anything 8 other than a fair trial by fair and impartial

juror, untainted and unpolluted by relationships 10 and I understand the Court will make appropriate

11 inquiry to determine if there's an issue there.

12 THE COURT: If you want me to make 13 the inquiry -- I'll make the inquiry the way I

14 want to make the inquiry. If you want to make 15 the inquiry, that's fine, too. I'll let you

follow up. I don't know what she's going to say.

17 I can't say what kind of follow-up questions we

18 have or what cautions.

19 The juror, I think, was being 20 conscientious and said these people's names come 21 up and I know them. And does this matter? And 22 she's asking us if it matters, but I think the 23 first thing we need to do is find out --

24 MR. ALLEN: Right, Your Honor, I 25 would on behalf of the State, we object to

1 attorneys asking her questions. It's not voir

dire. The instruction is attorneys are not

supposed to talk to jurors. I think that would

4 be improper and we object.

5 THE COURT: Your objection is 6 noted. I'll see if I think -- I mean, I want

- 7 there to be a record of this given that we're
- 8 down to 12 jurors, and I think it's important to 9 make a record.

9 make a record.
 10 MR. ALLEN: Mr. Fibich is prepared

to go back to chambers with Your Honor.THE COURT: Okay. Why don't we

13 have one person from Lilly.
Why don't you go get her and bring

Why don't you go get her and bring her in, Mark, and we can stay on the record and then I've got a microphone.

17 (Break.)

THE COURT: I've given the jury a

19 two-minute heads up.

Based on the witness' testifying, and there's no application being made at this

22 point. We're just going to continue with the

23 trial. Please be seated.

So we'll bring the jury in a couple

25 of minutes and resume cross-examination.

1 he thinks he can understand what the thing means,

Page 108

Page 109

2 he can understand it. If not, you can argue what

3 you argue.

4 Q. (BY MR. ALLEN) Let me ask you this,

5 Doctor, without regard to the document, to

6 minimize weight gain, would that be to minimize a 7 side effect?

8 A. That's not what the document said.

9 Q. I'm not asking about the document. To

10 minimize weight gain, would that be to minimize a

11 side effect?

12 A. The phrase minimize weight gain could

13 mean to lessen the amount of weight gain, it

14 could be to minimize the impact of weight gain,

15 it could mean a lot of different things.

16 Q. It says: While at the same time

17 increasing the focus on Zyprexa's superior

18 efficacy.

Would that be to overstate the

20 benefits?

21 MR. BRENNER: Same objection,

22 Your Honor.

2

THE COURT: Yeah, the document is

24 what the document is, and you can argue to the

5 jury and the jury is going to decide what they

Page 107

Page 1

1 (Jury in.)

2

9

THE COURT: Please be seated.

Back on the record and all members 4 of the jury are present.

5 Mr. Allen.

Q. (BY MR. ALLEN) Doctor, I'm going to get
through. My partners reminded me shorter is
sweeter. Let me see if I can get on.

The rational for position -- in

10 this document -- the rational -- to minimize the

11 liability of weight gain while at the same time

12 increasing focus on Zyprexa's superior efficacy.

Did I read that correctly?

14 A. Yes.

15 Q. And, again, it looks like they're

16 minimizing -- minimizing an adverse event or side

17 effect, correct?

18 A. Sir, I don't know how they mean the

19 phrase.

20 Q. Well, in ordinary English as used by you

on a daily basis, they were minimizing a side

22 effect, true?

MR. BRENNER: Same objection as

previously, Your Honor.THE COURT:

THE COURT: Yeah. He's not -- if

think the document means, and --

MR. ALLEN: Okay. Yes, Your Honor.

3 Q. (BY MR. ALLEN) You remember 1196,

4 however, where the FDA told Eli Lilly that it

5 would be a misleading impression of Zyprexa if it

6 was noted as superior, highly effective,

7 virtually free of side effects and an easy-to-use 8 product.

9 You remember that, don't you?

10 A. Yes.

11 Q. Thank you, sir. Now, on the issue of

12 whether or not --

MR. ALLEN: I need 3860 and I think

14 it's been marked.

15 Q. (BY MR. ALLEN) On the issue of false,

16 deceptive, misleading, you've told us that the

17 pill causes weight gain?

A. Yes.

18

25

19 Q. And if, in fact, Eli Lilly said the pill

did not cause weight gain, that would be contrary

21 to what you have stated in this courtroom, right?

22 A. Yes.

23 Q. I want to hand you what's been marked

24 for identification purposes at this time --

MR. ALLEN: Mary Beth, do we have

Page 110 Page 112

- 1 one for the other side?
- 2 MR. BRENNER: Yes, could we see a 3 copy?
- 4 (BY MR. ALLEN) I'm going to hand you what's been marked as Exhibit 3860 --
- 6 MR. BRENNER: Is this in evidence?
 - MR. ALLEN: No, it's marked for
- 8 identification purposes.
- 9 THE COURT: I understand that. Is
- 10 that AK or EL --

7

- 11 MR. ALLEN: I'm sorry, AK3860.
- 12 THE COURT: Thank you.
- 13 Q. (BY MR. ALLEN) Is that one of the
- documents you reviewed in the marketing records
- 15 of this case?
- 16 A. Not that I recall.
- 17 Q. It may have been one you reviewed?
- 18 I don't know. No recollection.
- 19 So in order to refresh your
- recollection, we need to review it, true? 20
- 21 A. Sure.
- 22 Q. Okay. 3860 --
- 23 MR. BRENNER: If, Your Honor,
- please, for that review it should be done not in
- 25 the presence of the jury.

1 evidence. I'll offer 3860.

2 THE COURT: Sure. And until you

establish it through a witness, I'm not going to

- admit it at this point. I don't even know this
 - is a Eli Lilly document.
 - MR. ALLEN: It's Lilly document.
- 7 MR. BRENNER: As you are aware,
- 8 Your Honor this witness can't authenticate this
- 9 for us or establish a foundation.
 - MR. ALLEN: It's an admission by
- 11 party --

6

10

18

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18

- 12 THE COURT: I'm not going to admit
- 13 it at this time. If you want to ask him
- questions subject to eventually being
- 15 admitted you can and you can -- but, again, I
- 16 don't want it shown to the jury up on the screen
- 17 until that happens.
 - MR. ALLEN: I'll -- to say it's not
- 19 a Lilly document is false.
- 20 THE COURT: That may be, and
- 21 there's a lot of Lilly people that I'm sure we'll
- have a long cross-examination on. And -- but at
- 23 this point, that's the order I want the evidence
- 24 to go in.
 - MR. ALLEN: I will do what you tell

Page 113

Page 111

THE COURT: It's not going to be 1

- done on the screen to refresh his recollection.
- 3 Q. (BY MR. ALLEN) Yes, sir. Do you see page 4 -- excuse me -- 1, 2, 3 of this document
- concerning --
- 6 MR. BRENNER: Your Honor, could we 7
- approach on this?
- 8 THE COURT: You may.
- 9 (Bench discussion.)
- 10 MR. BRENNER: Your Honor, I think
- 11 it's clear that he can't establish a foundation
- 12 for the document through this witness. If we go
- 13 through it under the guise of refreshing his
- 14 recollection, we will have introduced, in effect,
- evidence that may ultimately not be introduced. 15
- 16 MR. ALLEN: It's Eli Lilly's
- 17 document. It's an admission by party opponent.
- I can offer an admission at any time and I tender
- 3860 as an admission by party opponent --19
- 20 THE COURT: You have to establish
- 21 all the things through a different witness that
- 22 it's an admission by party opponent. It doesn't
- 23 just come in on its face to me.
- 24 MR. ALLEN: Your Honor, admissions
- 25 by party opponent are not hearsay and admissible

- 1 me. sir.
- 2 MR. BRENNER: I understand,
- Your Honor, that the proffer is going to be
- linked up appropriately.
- 5 MR. ALLEN: You told me that I can
- try to link it up.
- 7 MR. BRENNER: I'm just noting my
- 8 objection for the record.
 - (End bench discussion.)
- 10 Q. (BY MR. ALLEN) I'm sorry, sir.
- 11 AK3860 has Lilly's logo on the
- 12 front, does it not?
- 13 There is a logo that says Lilly. I
- 14 don't know exactly what their logo is, but this
- does say Lilly. I don't know if it's Lilly's 15
- logo but it says Lilly.
- 17 Q. What does it say under Lilly?
 - A. It says, Lilly, Answers That Matter.
- 19 Okay. Did you read marketing documents
- 20 that said, Lilly, Answers That Matter when you
- 21 reviewed?
- 22 A. I don't recall the trademark.
- 23 Okay. Let me just ask this: That's not
- 24 an equal sign, isn't it?
- 25 In mathematical terms, that's what the

Page 114 Page 116

- 1 sign means.
- 2 Q. Right. WG for weight gain?
- 3 A. Yes.
- 4 Q. Of course, if somebody told you that the 5 pill does not equal weight gain, you'd tell them
- 6 they were wrong; true?
- 7 A. No.
- 8 Q. Okay, so the pill -- I thought you told
- 9 me earlier that the pill did equal weight gain?
- 10 A. I never said that.
- 11 Q. What did you say?
- 12 A. I said in some patients the pill can
- 13 cause weight gain.
- 14 Q. Can cause?
- 15 A. Yes. Can cause in some patients.
- 16 Q. Right. The pill?
- 17 A. In some patients.
- 18 Q. Okay. If I was to say to you that the
- 19 pill cannot cause weight gain in patients, would
- 20 that be right or wrong?
- 21 A. If you said that, but that's not what
- 22 this says.

1

- Q. Well, the pill does not cause weight
- 24 gain, that would be wrong? Is that right?
- 25 A. That's not what this says, sir.

1 when he tried to turn the side effect of weight

2 gain into a benefit.3 Have you see

- Have you seen that?
- 4 A. Do I have that in front of me?
 - Q. No, sir. You want me to get you one --
- 6 A. I'll look at it on the screen with you.
- 7 Yeah, why don't I see the document. I don't have
- 8 the whole thing on my screen.
- 9 Q. It's all right. Any time.
- 10 A. Thanks. Where should I turn to?
- 11 Q. I think it's the next to last page
- 12 before the signature line, I think. Yes, sir,
- 13 it's page 4 -- no, it's page 5, actually, sir.
- 14 Four and 5.

5

- 15 A. Got it.
- 16 Q. I want you to go to page 5, please.
- 17 A. Okay.
- 18 Q. All right. We'll read it together:
- 19 When asked a question about weight gain,
- 20 Dr. Toleffson's response misleadingly turned an
- 21 adverse event into a therapeutic benefit.
- Do you see that?
- 23 A. Yes, I do.
- Q. It goes on to say -- I apologize for the
- 25 reading -- he states: So we went back and

Page 115

THE COURT: That's not the question. The question is: If that question

- 3 that he asked you is said to you, would that be
- 4 wrong? We'll let the jury, if they look at the
- 5 document, decide what the document means.

6 THE WITNESS: Sure. He just

- 7 pointed to this, Your Honor, when he asked me the
- 8 question so I wanted to make it clear that what
- 9 he was pointing to wasn't the same as what he was
- 10 saying. So if you'd like me to respond to the
- 11 picture, the answer is no. I don't remember if
- 12 it was yes or no. So ask me your question in
- 13 words. Let's disregard the picture.
- 14 Q. (BY MR. ALLEN) We'll move on, sir, I
- apologize, do you have anything else you'd like
- 16 to say on this point?
 - MR. ALLEN: I want to make sure --
- THE COURT: I'm sure that defense
- 19 counsel, if they have other questions to ask him,
- 20 are going to ask him.
- 21 MR. ALLEN: Yes, sir, I'm moving
- 22 on.

17

- 23 Q. (BY MR. ALLEN) On Exhibit 1169, you've
- 24 seen where the FDA said that Dr. Gary Toleffson
- 25 had misrepresented and contained false statements

1 analyzed our data and saw that the vast majority

Page 117

- 2 of weight gain reported initially as an adverse
- 3 event, in fact, was weight gain occurring in
- 4 patients who had baseline before starting
- 5 treatment, had been below their ideal body
- 6 weight.

7 And then the document, it may not

- 8 show up here.
- 9 The next sentence is bolded: So we
- 10 really look at this with the majority of patients
- 11 as being part of a therapeutic recovery rather
- 12 than an adverse event, and that data, I think, is
- 13 fairly compelling because it was included in our
- 14 labeling.

- Then the FDA says -- closed quotes.
- 16 Emphasis added.
- The information on weight gain was
- 18 indeed included in the approved labeling, but as
- 19 an adverse event, not a therapeutic benefit.
- 20 Since the product was approved at the time of the
- 21 teleconference, Dr. Toleffson knew or should have
- 22 known what information the approved labeling
- 23 contained and in what section it appeared. His
- 24 statements were, therefore, false and misleading.
- Did I read that correctly, sir?

- 1 Yes, you did. A.
- 2 And would you agree it would be false
- and misleading for Eli Lilly to turn an adverse
- event or adverse reaction into a therapeutic
- benefit?
- 6 MR. BRENNER: Same objection as 7 previously.
- 8 THE COURT: I'll sustain the 9 objection.
- 10 Q. (BY MR. ALLEN) Do you agree, in your
- 11 experience, that it would be wrong for a drug
- 12 company to turn an adverse reaction into a
- 13 therapeutic benefit?
- 14 A. In general?
- 15 Q. Yes, sir.
- A. There might be -- I can imagine 16
- 17 situations where some adverse events under other
- circumstances for some patients would be
- benefits. If you're asking in general, I can't
- 20 answer.
- 21 Q. Okay, sir.
- 22 In reviewing the documents and
- 23 asking for anything remotely relevant in this
- 24 case, did you get provided AK04007?
- 25 A. Can't recall.

- Page 119
- Q. And by the way, again in 1196, which was
- the FDA letter, quoting Dr. Toleffson, the FDA
- told Eli Lilly to stop this immediately; is that
- 5 MR. BRENNER: Objection; asked and
- answered. Your Honor. We've been over this
- document a lot.
- 8 MR. ALLEN: I'm entitled to frame a
- 9 question and lay a predicate and move forward,
- Your Honor. 10
- 11 THE COURT: As long as you're just
- 12 laying a predicate, but at times your predicate
- tends to be reading the document and moving on
- 14 And I want to make sure there's a question
- 15 regarding this.
- Q. (BY MR. ALLEN) There's one coming. It
- 17 says: The FDA said, Immediately discontinue this
- conduct, right? 18
- 19 A. It says immediately discontinue the use
- 20 of all promotional labeling pieces et cetera, so
- 21 I don't know what conduct was occurring.
- 22 Q. And cancel all advertising containing
- 23 any of the false and/or misleading statements
- 24 discussed above, provide. It goes on to say --
- do you want to read the whole thing?

- 1 A. No.
- 2 O. Doesn't it indicate they need to stop
- this conduct immediately?
- 4 Again, I don't know -- I don't know the
- 5 context of this.
- 6 Q. Thank you, sir. 4077, AK4077 (sic).
- Did you receive this document in all the material
- that you wanted that would be remotely relevant
- 9 in the case?
- 10 A. I don't know.
- 11 THE COURT: Did you say 4077? Was
- 12 that what you referred to? Because it's not.
 - MR. ALLEN: I meant AK4007.
- 14 Q. (BY MR. ALLEN) Did you receive this
- 15 document, sir?
- 16 A. I don't know, sir.
- 17 Okay. Did you know about the Viva
- 18 Zyprexa -- you knew about the primary care
- 19 physician launch, did you not?
- 20 Can't recall it, sir.
- 21 Isn't it referenced in your report Q.
- 22 about --

1

13

- 23 A. The primary care physician launch?
- The use of Zyprexa by primary care 24 Q.
- 25 doctors. Wasn't that referenced in your report?

Page 121

- There was no reference to a launch.
- 2 All right, sir. Viva Zyprexa, audio Q.
- program No. 3, post-meeting communications
- campaign, cassette version, December of 2000, Eli
- Lilly, Viva Zyprexa.
- Do you know who Dr. Alan Breier is? 6
- 7 A. No.
- 8 Q. Dr. Alan Breier's comments are recorded.
- 9 He said: I came to Eli Lilly and Company almost
- 10 four years ago from the National Institutes of
- 11 Health because I thought this was an opportunity
- 12 to make an impact. He goes on to say -- let's go
- to the first one: Growing sales in the elderly.
- 14 How many people in their own lives and their own
- 15 families --
- 16 MR. BRENNER: Your Honor.
 - THE COURT: I'll sustain the
- 18 objection.

- 19 O. (BY MR. ALLEN) Is weight gain a plus in
- 20 the elderly, sir?
- 21 A. Sometimes it is; sometimes it isn't.
- 22 Depends on the person.
- 23 Q. Is the weight gain -- is the weight gain
- 24 with Zyprexa a plus in the elderly?
- 25 In an emaciated elderly person, it might

Page 122 Page 124 1 be. 1 document? 2 THE COURT: Let me ask you, Doctor. 2 No. I don't recall it. Α. 3 3 When you give people Zyprexa --Zyprexa launch meeting. 4 THE WITNESS: Yes. 4 We saw the Geodon document 5 5 THE COURT: -- and you give them yesterday. Do you recall talking about Geodon? your warnings and discuss the drug with them and 6 A. Yes. 7 you give them informed consent. 7 Q. It is AK00019, and we go down, talking 8 THE WITNESS: Yes. about Geodon, and implementation guide. It says: 9 THE COURT: Do you say, you're 9 Eli Lilly said it's simply not a primary-care going to gain weight and that's a really good 10 10 drug. 11 thing, or do you say you're going to gain weight 11 Do you see that? 12 and that could be a problem. We're going to 12 Yes, I do. A. 13 13 watch it? Q. Do you agree with that? 14 Sir, I don't know the context of the 14 THE WITNESS: Generally I tell them 15 it's a problem. I have treated depressed 15 document or what was meant here, so I can't 16 patients where I have chosen Zyprexa in the 16 answer. 17 course of bipolar illness, psychosis, 17 Eli Lilly, Zyprexa launch meeting, 18 schizophrenia, where Zyprexa has been part of 18 Zyprexa primary care, ours is a gross strategy, 19 their regimen, because it stimulates their not a niche strategy, and Zyprexa can and will 20 20 appetite. become an everyday agent in primary care. 21 Q. (BY MR. ALLEN) Do you use Zyprexa for 21 Do you believe that Zyprexa should 22 depressed people? 22 be an everyday agent in primary care? 23 MR. BRENNER: Objection, Your 23 MR. BRENNER: Objection, 24 Honor. 24 Your Honor. Beyond the scope of any direct, 25 A. In the context of maintenance treatment beyond the scope of any issue.

Page 123

1 in bipolar illness where it's indicated. THE COURT: That's a fair question

2 whether he does.

Q. (BY MR. ALLEN) You use the Zyprexa in depression.

A. In the maintenance treatment of bipolar 7 disorder.

8 O. Is that on-label?

9 A. The maintenance treatment of bipolar 10 disorder is on-label.

11 Q. Do you use it for generalized 12 depression?

13 A. No.

14 Q. Why not? Why don't you use it for

15 generalized depression?

16 THE COURT: That he doesn't use it 17 is significant.

A. Generalized depression is not a 18

19 diagnosis.

20 MR. BRENNER: Wait a minute,

21 Doctor. There's no question. 22

THE COURT: I'll sustain the

23 objection.

24 (BY MR. ALLEN) Sir, on the issue of

25 balancing risks and benefits, did you review this

THE COURT: I'll sustain the

objection.

1

3 MR. ALLEN: Your Honor, can I 4 approach?

5 THE COURT: You may.

6 (Bench discussion.)

7 MR. ALLEN: The uses in other -- in schizophrenia and bipolar mania are admissible.

This man weighs the risks versus the benefits,

10 and I have to be able to show both the risks and

11 the benefits.

12 THE COURT: And I think he's

13 testified as to what he uses -- he personally

14 uses Zyprexa for. To the extent you're showing a

15 lot of documents about what Lilly may or may not

16 have tried to do, documents that he doesn't know

about and he's consistently said that he doesn't

18 know what the context is or what Lilly does,

19 those -- that topic, I'm sustaining objections to

20 it. But I think you've established what he uses

21 Zyprexa for.

22 MR. ALLEN: Your Honor, he

23 testified he reviewed all these marketing

24 documents on --

25 THE COURT: He testified that he

Page 128

1 reviewed the documents that he got, and you've established a lot of documents that he didn't

3 get and --

4 MR. ALLEN: I'm going to go through some of the documents and see if he got them.

6 THE COURT: I would assume that when his deposition was taken you got to see what

the documents that he reviewed.

9 MR. ALLEN: That isn't the way 10 things worked. This was the MDL deposition.

Wasn't anybody involved in the Alaska case --11

12 THE COURT: I know you didn't take 13 the deposition. I would have thought that the

people who took the deposition would have gotten

the file --15

16 MR. ALLEN: Your Honor, I accept 17 it. I'm going to ask him what documents he

18 reviewed.

19 THE COURT: I think we've been

20 through that, too.

21 (End of bench discussion.)

22 Q. (BY MR. ALLEN) Sir, I'm going to go and

23 ask you about your survey, and we will be done.

24 I apologize. I just don't want to

25 lose any paper.

1

9

1 every article; is that right?

2 Α. No.

3 Okay. We'll move on. Do you recall

reading the issue of a conflict of interest? Do

you recall reading those articles in American

6 Journal of Psychiatry back in 2006?

7 No.

8 O. Do you know any of the editors of the

9 American Journal of Psychiatry?

I have to see a list.

11 Robert Friedman? O.

12 Α. No.

10

13 David Lewis? O.

14 Α. No.

15 **Robert Michaels?** Q.

16 A. Yes.

17 How do you know Dr. Michaels? Q.

18 Dr. Michaels is a psychiatrist

19 affiliated with New York Presbyterian Hospital

20 where I work.

21 Q. Do you find him to be a reputable and

22 fine physician?

23 A. Yes.

24 Q. So, you would think he -- let me ask you

25 if you agree with this statement: Many doctors

Page 127

Do you have your survey?

2 A. Not handy right here with me.

3 Q. Can we get him a copy? Do you need a 4 copy?

5 A. Yeah, that would be great. Thanks.

6 O. Y'all need a copy of mine --

7 A. Thanks, Mr. Allen.

8 Certainly. All right, sir, we see --

Do you read the American Journal of

10 Psychiatry, sir?

11 A. Yes, I subscribe to it, and I can't say

12 I read it cover to cover, but try to get a chance

13 to look at it.

14 Q. Yes, sir, that's a good point. Doctors,

15 even though they subscribe to magazines, they

16 can't read every article published in the medical

17 literature, can they?

18 A. Impossible.

19 Q. It would be totally and completely

20 impossible?

21 A. That's right.

22 Particularly, that's one of the reasons

23 that the sources of information that doctors have

24 to rely upon is a drug company to bring them the

synthesized information because they can't read

do not believe that they are influenced by

pharmaceutical industry funding and therefore do

Page 129

not see a need for self-disclosure of other

funding. However, as -- let me go on -- however,

as our credibility as a field requires complete

disclosure of authors' sources of income from the

7 pharmaceutical and biomedical industry, the

American Journal of Psychiatry requires full

disclosure of all industry-derived personal

10 income and research funding from all authors for

11 all articles. Do you agree with that?

12 That's a standard policy that all

13 academic journals adhere to in every field.

14 Q. When did that happen?

15 I don't know, but it certainly is the Α.

16 case now.

17 Q. It wasn't the case until very recently;

18 isn't that correct?

19 I don't know.

20 Do you agree with this: For

psychopharmaceuticals in particular, the public's

perception that medications are prescribed by

23 physicians free from industry influence is

24 critical. Thus, we need to establish boundaries

25 for our ethical behavior. The pharmaceutical

- 1 industry needs to use its industrial
- 2 organizations to set new boundaries and standards
- 3 for ethical support of physician education. We
- 4 as psychiatrists cannot allow treatment of our
- vulnerable patients to be compromised by the
- 6 unintended effects of overzealous marketing.
 - Do you agree with that?
- 8 A. Sir, I don't know the whole context of
- 9 the statement or why it was generated or what
- 10 else was stated in the article. So I can't agree
- 11 or disagree with that phrase.
- 12 Q. Sir, regardless of an article, do you
- 13 agree that the pharmaceutical companies, in
- 14 general, are engaged in overzealous marketing?
- 15 A. No.

7

- 16 Q. All right, sir. In your Journal of
- 17 Clinical Psychiatry article -- first of all, I
- 18 saw it was written in 1999?
- 19 A. Yes.
- 20 Q. And the information contained within was
- 21 gathered when?
- 22 A. The information would have been -- I
- 23 can't tell you precisely, but roughly within the
- 24 year prior to the publication.
- 25 Q. '98?

- Page 131
- A. Sometime in '98, '99. These evolved
- e over about a 12-month period.
- 3 Q. Has a lot happened since the time you 4 gathered this information?
- 5 A. A lot in the world?
- 6 Q. No, sir. And I guess I meant a lot in
- 7 regard to the facts of this kind of case and
- 8 atypical antipsychotics and typical
- 9 antipsychotics and Zyprexa.
- MR. BRENNER: Your Honor, I have to
- 11 object to the form of that question. There's a
- 12 lot happened -- a range of events?
- 13 THE COURT: If the doctor
- 14 understands the question, he can answer the
- 15 question.
- 16 A. I don't understand the question,
- 17 Mr. Allen.
- 18 Q. (BY MR. ALLEN) Has there been
- 19 significant developments in the last -- you said
- 20 the information was gathered in '98 -- in the
- 21 last ten years or so in the field of
- 22 second-generation antipsychotics and atypicals
- 23 and Zyprexa?
- A. Boy, you know, I'm not sure how you
- 25 would say what's significant, what's not

- 1 significant, what's a lot, what's a little.
- 2 O. Let me ask it again, then: In your
- 3 opinion, has there been a fair amount of
- 4 significant -- your opinion, significant
- 5 developments in the field of second-generation
- 6 antipsychotics, first-generation antipsychotics
- 7 and Zyprexa in the last ten years?
 - A. Look, I don't mean to quibble about it,
- 9 but this is such a qualitative question --
 - THE COURT: He's asking you to
- 11 provide your standards for those qualitative
- 12 things.

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- 13 A. I mean, psychiatry is such a complex
- 14 area. Our understanding of the brain evolves
- 15 slowly. Our understanding of the -- you know,
- 16 effects of drugs, ways that they're used evolves
- 17 over time. Is it significant? I wouldn't say
- 18 that there's been a revolution, you know, since
- 19 1999. Has there been changes in understanding?
- 20 In some areas, yes; in some areas, no. Will they
- 21 be significant? Time will tell us whether
- 22 they're significant.
- 23 Q. (BY MR. ALLEN) In your review of
- 24 documents, did you review the internal e-mail --
- 25 internal report of Eli Lilly in 2000 concerning

Page 133

- 1 the global labeling committee's request to change
- 2 the listing of hyperglycemia from infrequent to
- 3 common or frequent.
 - Did you review that document?
- 5 A. I can't recall that specific document
- 6 by name, sir.

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- 7 Q. Did you review -- and I'm talking about
- 8 events that occurred since 1998 -- did you review
- 9 the October, 2000 e-mails -- internal to Eli
- 10 Lilly in October of 2000 concerning Eli Lilly's
- 11 meetings with the endocrinologists in Atlanta?
- 12 A. Don't recall seeing e-mail, sir.
- Q. Did you see anything concerning the
- 14 message from endocrinologists that Eli Lilly
- 15 needed to come clean?
- 16 A. Don't recall seeing that.
- Q. Did you review the letter in October of
- 18 2000 from the FDA that their attempt to change
- 19 and their changing of the label concerning blood
- 20 glucose was a wrong statement implying
- 21 therapeutic benefit and they needed to remove it?
- Did you review that?
 - MR. BRENNER: Object to the
- 24 characterization of a document that's in
- 25 evidence.

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A.

case.

- 1 THE COURT: I think what he's
- 2 trying to do is save some time. You can show him each document.
- 4 MR. BRENNER: No, Your Honor, but there are adjectives added to there, is my 6 objection.
- 7 MR. ALLEN: I'll rephrase it for 8 him, Your Honor.
- 9 Q. (BY MR. ALLEN) Did you review the 10 letter addressed to Eli Lilly in October of 2000
- asking them to take language out of their label? 11
- 12 A. No.
- 13 Q. Did you review the continuous analysis
- 14 report of Dr. Patrizia Cavazzoni showing that
- 15 there was statistical significant elevations in
- 16 blood glucose in Zyprexa patients compared to
- 17 placebo and Haldol?
- 18 A. I'm not sure that I can tell you which
- 19 document that was, so I don't know.
- 20 Q. You don't know. Did you review any
- 21 information in that regard?
- 22 A. If it was a paper, I might have read it.
- 23 If it was an unpublished document, I don't know
- 24 if I reviewed it or not.
- 25 Q. Let me ask you this in another way and

- 3 Q. So prior to the preparation for this
- case, you were unaware of that, is that correct? 4 5

In connection with preparation for this

- That's correct.
- 6 Q. Were you aware that in the Japanese
- 7 warning in April of 2002 when you got prepared
- for this case, where it said causation with
- 9 Zyprexa cannot be denied.
 - Were you aware of that?
- 11 A. I can't recall the precise wording, so I
- 12 can't say without seeing the document.
 - Q. Thank you, sir. At the time you
- prepared this material you could not have been
- 15 aware of the consensus panel recommendations; is
- 16 that correct?
- 17 Α. Because those came later.
- 18 Yes, sir. O.
- 19 A. The ADA consensus panel.
- 20 We started with has a lot of significant
- 21 developments occurred between the time the
- 22 material was gathered and today?
 - That was a development. That's why I
- 24 didn't want to quantify them by significance.
- 25 Yes, sir. I apologize that we're having

Page 135

- 1 I'm just trying to see if we can agree.
- 2 Were you aware of Dr. Cavazzoni's
- 3 continuous analysis showing a statistically
- significant difference in blood glucose
- 5 elevations between Zyprexa as compared to placebo
- and Haldol?
- 7 A. I can't recall it off the top of my
- 8 head.
- 9 Q. Did you review the HGFU study report
- 10 where Lilly said using the letter A that blood
- glucose elevations were probably causally related
- 12 to Zyprexa? Did you review that?
- 13 A. Not that I can recall.
- 14 Q. Were you aware that special warnings and
- precautions for diabetes and hyperglycemia were 15
- added to the European label on Zyprexa in 1999?
- 17 Were you aware of that?
- 18 A. No.
- 19 Q. Were you aware that the Japanese
- required a new warning in a red box, what we call 20
- 21 over here a black box, in Japan in April of 2002?
- 22 A. I've been aware of that.
- 23 Q. When did you become aware of that?
- 24 A. Recently, sir.
- 25 How recently?

- 1 this disagreement. I was going to see whether or
- not -- you agree, then, you obviously were not
- aware of the consensus panel's recommendations?
- A. No one was, because it hadn't occurred
- 5 at this time.
- 6 O. Yes, sir. Therefore, when we're looking
- at Exhibit No. 99, it did not take that into
- account, right? 8
- 9 A. Could not possibly have.
- 10 Of course, you're aware -- Doctor, did
- 11 you review all of the English language literature
- 12 on the subject of atypical antipsychotics in
- 13 order to prepare yourself to come down here
- 14 testify?
- 15 A. All the literature?
- 16 All of the English language literature
- 17 in the world, did you review it?
- 18 A. I read a lot, but I can't say 100
- 19 percent.
- 20 Q. Did you review the animal studies?
- 21 A. No.
- 22 Did you -- before you wrote your report,
- 23 did you meet with doctors who disagreed with you
- 24 as well as doctors who agreed with you and then
- formed your opinion? 25

- 1 A. That's not how I prepared, sir.
- 2 Q. Thank you, sir. Were you aware, at the
- 3 time you prepared this report that Eli Lilly --
- 4 at the time you prepared your report in this case
- 5 as opposed to the article --
- 6 A. The report a year ago?
- 7 Q. And when did you prepare the report,
- 8 sir?
- 9 A. Approximately a year ago.
- 10 Q. I'm not -- do you recall? April?
- 11 A. It would have been, I think -- when was
- 12 the deposition? April. It was more or less than
- 13 a year ago. The report must have been prepared
- 14 leading up to it. March, April.
- 15 Q. Okay, sir. Were you aware that the
- 16 FDA -- have you ever been aware at the time you
- 17 prepared your report or as we sit here today,
- 18 that the FDA wrote a letter to Eli Lilly asking
- 19 them to provide new information that the FDA had
- 20 seen in the New York Times?
- A. Yes, I'm aware that they sent a letter.
- 22 Q. That who sent the letter?
- 23 A. That the FDA sent the letter to Eli
- 24 Lilly.
- 25 Q. And what happened after that?

- 1 A. Couldn't tell you.
- 2 Q. Well, do you recognize the name of Dr.
- 3 Hirschfeld from my hometown of Galveston, Texas?
- 4 Do you know Dr. Hirschfeld?
 - A. Actually I do know Dr. Hirschfeld. Yes.
- 6 Q. Isn't he from Galveston, Texas?
- 7 A. Yes, he is.
- 8 Q. At the University of Texas Medical
- 9 Branch.

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- 10 A. That's right.
- 11 Q. Isn't he a hired -- a speaker for drug
- 12 companies?
- 13 A. I don't know.
- 14 Q. Okay. Let me see. What about Henry
- 15 Nasrallah. As I recall, he was in Cincinnati,
- 16 wasn't he?
- 17 A. I know the name. I don't know where Dr.
- 18 Nasrallah was or where he is now.
- 19 Q. You don't know if he's a speaker for
- 20 drug companies?
- 21 A. I don't know.
- Q. Paul Keck. Where's Dr. Keck from? Is
- 23 it North Carolina?
- 24 A. Cincinnati. Cincinnati, unless he's
- 25 moved.

Page 139

Page 141

- 1 A. I don't know, sir, in detail.
- 2 Q. Aren't you aware that after that the FDA
- 3 got information that it never seen before and
- 4 required a label to be changed on Zyprexa?
- 5 A. Sir, I'm not aware that they got
- 6 information that they'd never seen before.
- 7 Q. But you're aware that FDA asked to see
- 8 information that they'd never seen before?
- 9 A. To that level of detail, sir, I can't
- 10 answer the question.
- 11 Q. Okay, sir. Now, in your Journal of
- 12 Psychiatry -- it's the last round of questions --
- 13 there's an editorial board, is there not?
- 14 A. That is the editorial board for the
- 15 Journal of Clinical Psychiatry, not for this
- 16 supplement.
- 17 Q. Yes, sir. And this is where this
- 18 article was published was in the Journal of
- 19 Clinical Psychiatry?
- 20 A. That's right. I wanted to be clear what
- 21 they were the editorial board for.
- 22 Q. Yes, sir. Do you know -- how many of
- 23 the editorial board members do you recognize as
- 24 being spokespeople or people hired by the drug
- 25 companies?

- Q. That may be. You know he's a speaker
- 2 for drug companies?
- 3 A. Yes, I do know he's spoken for drug
- 4 companies.
- 5 Q. Then on the editors for policy
- 6 guidelines, you know some of these people are
- 7 paid by drug companies?
- 8 A. Sir, when in time, I don't know. This
- 9 was ten years ago.
- 10 Q. Tell the jury the ones you know were
- 11 paid by drug companies.
- 12 A. I couldn't tell you.
- 13 Q. Well, how about Mark Olson?
- 14 A. I don't know if he's been paid by drug
- 15 companies.
- 16 Q. He's listed as a witness for Eli Lilly
- 17 in this case.

- Did you know that?
- 19 A. No, I did not know that.
 - Q. Okay, sir. Now, just so the record is
- 21 clear, and I know we said it, but this was only
- 22 on schizophrenia only in 1999, right?
- 23 A. The guidelines?
- 24 Q. Yes, sir.
- 25 A. Yes, the guidelines were about

Page 142 Page 144

- 1 schizophrenia.
- Q. And don't you know that a majority of 2 3 the use of Zyprexa in this country by doctors is

not for schizophrenia?

MR. BRENNER: Objection,

Your Honor.

7

THE COURT: No. I'll let him

8 answer that question.

- 9 A. I don't know what proportion of it is used for what conditions. 10
- Q. (BY MR. ALLEN) Do you have an 11 12 indication in any regard?
- 13 A. No.
- 14 Q. How -- how does -- do you know -- what's
- 15 more prevalent in -- in your opinion as a doctor,
- 16 high blood pressure, high cholesterol or
- 17 schizophrenia?
- 18 A. You know, it's a fair question, but I,
- 19 frankly, don't know the statistics on prevalence.
- 20 They're all common and serious public health
- 21 problems.
- 22 Q. Yes, sir. High cholesterol. You think
- 23 high cholesterol may be as prevalent as --
- schizophrenia -- excuse me, let me rephrase,
- 25 strike that.

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that's what he did or you ask him if he knows

whether other people did that. But that's the

3 extent of it.

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- MR. ALLEN: Okay.
 - (End of bench discussion.)
- 6 MR. BRENNER: Your Honor, just for
- 7 the record, though, I object.
 - THE COURT: Okay.
- 9 Q. (BY MR. ALLEN) Did you know -- did you
- know other people and did you prescribe Zyprexa 10
- 11 for children?
- A. I'm not a child psychiatrist, so I
- 13 haven't. Among my colleagues who were child
- 14 psychiatrists, I'm aware of children who have
- 15 received it. I can't say that I know colleagues
- 16 who have prescribed it for children.
- 17 Q. It's real important to give a true and 18 accurate picture --
- 19 A. I am. I am.
- 20 THE COURT: He's not referring to
- 21 you. Let him finish the question, and you'll
- 22 understand what he's talking about.
- 23 Q. (BY MR. ALLEN) It's real important to
- give a clear and accurate picture of the risks
- and benefits of a drug, though, isn't it?

Page 143

Do you think that schizophrenia is as prevalent as high blood pressure?

- A. No, I'm sure more Americans have high
- blood pressure and have high cholesterol than
- have schizophrenia. I couldn't tell you the
- precise percentages, but as illnesses in the
- population, I wouldn't dispute that.
- 8 Q. Well, Lipitor is a high cholesterol 9 drug, right?
- 10 A. Right.
- 11 Q. Now, Zocor is a high cholesterol drug?
- 12 A. Yes, it is.
- 13 MR. BRENNER: Your Honor.
- 14 THE COURT: Where are we going with
- 15 this?
- 16 MR. ALLEN: What do you want me to

17 do?

20

18 THE COURT: I'm trying to be sure

- 19 we have relevance here.
 - (Bench discussion.)
- 21 MR. ALLEN: Your Honor, I'm
- 22 entitled to show that this drug was widely used
- 23 in weighing benefits and is not used in
- 24 schizophrenia.
- 25 THE COURT: You can ask him if

A. Yes.

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2 Q. Let's go back to your article.

3 Now, just for the record, you're

4 not telling this jury to read your article and

- say these are the rules, are you?
- 6 A. That's correct.
- 7 In fact, you're specific in your report
- guidelines saying that that's just not the case.
- Any set of guidelines can provide only general
- 10 suggestions for clinical practice and
- 11 practitioners must use their own clinical
- 12 judgment in treating and addressing the needs of
- 13 each individual patient -- I've got to focus
- 14 down -- taking into account the patients' unique
- 15 clinical situation. There is no representation
- of the appropriateness or validity of these
- 17 guideline recommendations.

Did I read that correctly?

19 A. For any given patient.

MR. ALLEN: I'm trying -- I'll read

21 the whole thing and then we'll go on.

THE COURT: I think the whole thing 22

23 has been read now. It was just the last part of

- 24 it was --
- 25

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- 1 Q. I wasn't trying to. I'm sorry. There
- 2 is no representation of the appropriateness or
- 3 validity of these guideline recommendations for
- 4 any given patient. Did I read that correctly?
 - A. You read that correctly.
- 6 Q. Matter of fact, you go on to say: The
- 7 developers of these guidelines disclaim all
- 8 liability and cannot be held responsible for any
- 9 problems that may arise from their use. Did I
- 10 read that correctly?
- 11 A. That's correct.
- 12 Q. But you've got even more detailed than
- 13 that. You say the reports of whatever opinions
- 14 are in these guidelines, you said, the
- 15 recommendations in the guidelines are derived
- 16 from the statistically aggregated opinions of the
- 17 group of experts and do not necessarily reflect
- 18 the opinion of each individual expert on each
- 19 question.
- Did I read that correctly?
- 21 A. Absolutely.
- 22 Q. Therefore, even if you have it in the
- 23 book, some of the doctors you consulted with may
- 24 disagree with you?
- 25 A. Oh, sure.

- 1 researcher in schizophrenia.
- 2 Q. Okay. By the way, I want to make sure
- 3 you and I are just -- we're almost done. We're
- 4 totally communicating. You're not here speaking
- 5 for Dr. Casey or people on the board. You're not
- 6 speaking for Dr. Buchanan, Caroff, Casey,
- 7 Chouinard or Cole, are you?
- 8 A. Individually, no.
- 9 Q. You're not even attempting to do that
- 10 are you?
- 11 A. To speak for them individually?
- 12 Q. Yes.
- 13 A. To represent their personal opinions?
- 14 Q. Right.
- 15 A. No.
- 16 Q. Now, what were Dr. Casey's interactions
- 17 with Eli Lilly?
- 18 A. Don't know.
- 19 Q. Did you review any documents on that
- 20 point?

23

- 21 A. Not on that point.
- 22 Q. Let's go on.
 - Then you were asked a question, you
- 24 asked and answered your own question in this
- 25 report about the validity of what's contained in

Page 147

- Page 1
- 1 Q. And, in fact, sir, on that point, what 2 you did is you contacted, I think, 62 people in
- 3 this country to put this input in here?
- 4 A. For the psychopharmacology section,
- 5 that's correct.
- 6 Q. Where is the person from Alaska?
- 7 A. I don't believe there is one in the
- 8 medication section.
- 9 Q. Yes, sir. And the medication sections
- 10 are the doctors that helped with all the things
- 11 you discussed with Mr. Brenner, all those graphs,
- 12 right?
- 13 A. That's right.
- Q. And there's not anybody from Alaska?
- 15 A. That's correct.
- 16 Q. Did you talk to Dr. Hopson?
- 17 A. No.
- 18 Q. Okay. And then you go on to say -- by
- 19 the way: One of the persons, though, you sent
- 20 this material to is Dr. Casey. Dan Casey. Who
- 21 is he?
- 22 A. Let me just explain something. That I
- 23 didn't personally assemble this expert panel.
- 24 Dr. Francis, who is the editor for the section
- 25 assembled the expert panel. Dr. Casey is a

- 1 here, did you not?
- 2 A. Can you direct me to the phrase you're
- 3 looking at?
- 4 Q. Yes, sir. Page 8, introduction.
- 5 A. Okay.
- 6 O. You see the introduction?
- 7 A. Yes, I'm with you on the introduction.
- 8 Q. Did you write this?
- 9 A. Pardon me?
- 10 Q. Did you write this?
- 11 A. Well, Dr. Francis signed this page. I
- 12 did not write this page, but it's very similar to
- 13 wording that I wrote in other guidelines where
- 14 the group of us worked as a team.
- 15 Q. Yes, sir. I'm not trying to quibble
- 16 with you --
- 17 A. I certainly would stand behind --
- 18 Q. You stand behind it?
- 19 A. We can go to individual phrases to
- 20 discuss my opinions about them.
- 21 Q. Is there any particular one you would
- 22 like to discuss?

- THE COURT: Ask him a question.
- 24 MR. ALLEN: Okay.
- Q. (BY MR. ALLEN) They have a question in

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- 1 here. Introduction. Changes in the accept best
- 2 clinical practice often occur at a much faster
- 3 rate than the necessarily slow-paced research
- 4 efforts that would eventually provide scientific
- documentation for change. Did I read thatcorrectly?
- 7 A. That's right.
- 8 Q. Okay. Back to my question asked
- 9 earlier, this was gathered in '98, written in
- 10 '99, have we had some fast-paced developments in
- 11 the field of second-generation antipsychotics and
- 12 particularly with Zyprexa within the last ten
- 13 years.
- 14 A. I don't know how to quantify fast-paced,
- 15 so --
- Q. Okay, sir, I'll move on. Then you have
- 17 in your report, how valid are the expert opinions
- 18 provided in these guidelines and how much can I
- 19 trust the recommendations? Did I read that
- 20 correctly?
- 21 A. That's right.
- Q. You said: We should be able to answer
- 23 this question when our current research projects
- 24 on guideline implementations are completed.
- 25 A. That's right.

Page 151

- Q. For now, the honest answer is that we
- simply don't know. Right?
- 3 A. That's right.
- 4 Q. Are you telling me now you know?
- 5 A. Sir, there's a lot of things in this
- 6 guideline. To generalize an answer to all of
- 7 them is impossible.
- 8 Q. Thank you, sir. And, in fact, you go
- 9 further and say: Expert opinion -- remember, you
- 10 told us yesterday you were here not speaking for
- 11 anybody, you were just giving your opinion, do
- 12 you recall that?
- 13 A. In some of the questions that you asked
- 14 me, that's right.
- 15 Q. Let the record reflect that you say:
- 16 Your expert opinion must always be subject to the
- 17 corrections provided by the advance of science.
- 18 Has there been any advances in science regarding
- 19 Zyprexa in particular since 1999?
- 20 A. I'd say so.
- 21 Q. Moreover, precisely because we asked the
- 22 experts about the most difficult questions facing
- 23 you in clinical practice, many of the
- 24 recommendations must inevitably be based on
- 25 incomplete research information and may have to

- 1 be revised as we learn more.
 - Did I read that correctly?
- 3 A. Yes, you did.
- 4 Q. Have these ever been revised?
- 5 A. The guidelines?
- 6 Q. Yes, sir. For schizophrenia?
 - A. There was a related guideline that was
- 8 published in 2003, treatment of psychotic
- 9 disorders. I was not involved in the project at
- 10 that point -- yeah, I mean that's part of the
- 11 revision process, the series of guidelines that
- 12 this project was a member of.
- 13 Q. The experts -- expert consensus
- 14 guideline series on the treatment of
- 15 schizophrenia 1999. Have those guidelines been
- 16 revised?
- 17 A. These are part of a series of
- 18 guidelines. There are aspects of treatment of
- 19 patients with schizophrenia which were reasked of
- 20 a different expert panel, many of the same
- 21 members of it, by the group that put these
- 22 together several years later. I couldn't give
- 23 you the exact date, we could look up the
- 24 bibliography. And there was a revision.
- 25 Q. You have a bibliography in your report,

- 1 did you not?
- 2 A. Yes.
- 3 Q. I couldn't find any revisions.
- 4 A. Because I didn't participate personally
- 5 in later revisions.
- 6 Q. Okay, so whatever you gave us is
- 7 outdated, outmoded and no longer any good, right?
- 8 A. No.
- 9 O. But there's been revisions; is that
- 10 correct?
- 11 A. To aspects of this, there were
- 12 subsequent guidelines. I don't know if the
- 13 results were different from this or not, so I
- 14 don't know if there have been revisions.
- 15 Q. I asked you a minute had there been
- 16 revisions?
- 17 A. There had been a new version of the
- 18 guideline. Did it revise recommendations, I
- 19 don't know.
- 20 Q. Have you read it?
- 21 A. Sir, I would have to compare it side by
- 22 side.
- Q. That wouldn't make any difference, have
- 24 you read the guidelines?
- A. The guidelines that were a subsequent

- 1 version of this I read some time ago.
- O. Were they different? 2
- 3 A. I'd have to look at each item and see.
- 4 Q. Did you review them in preparation for
- your testimony here today?
- 6 A. No.
- 7 Q. Did you review them in preparation of
- your report?
- 9 A. No.
- Q. You don't have the most recently 10
- 11 available information for this jury; is that
- 12 correct?
- 13 A. Sir, you're asking me about a document
- 14 that I didn't author and whether I reviewed it in
- preparation, and I didn't review it in
- 16 preparation for this testimony because I didn't
- 17 write it.
- 18 Q. Yes, sir. But didn't you review a lot
- 19 of material you didn't write?
- 20 Yes, but in respect to the guidelines
- 21 you're asking me if these guidelines were
- 22 revised. The guidelines as a document underwent
- 23 a revision. What did that revision change is
- 24 what I can't answer for you today.
- 25 Q. Or this jury. You can't tell the jury

- 1 a lot of room for disagreement among experts on
- these opinions. You've got 57 out of 40,000,
- 3 right?
- 4 A. I didn't say there were 40,000 experts,
- there were 40,000 practicing psychiatrists and we
- sent it to a representative group of research
- 7 experts in schizophrenia.
- 8 Q. Oh. Research -- are you a research
- 9 expert?
- 10 A. I'm not a research expert, myself, sir.
- 11 There's fine doctors have offices in
- 12 nice buildings and in doctors' buildings every
- 13 day that don't do research who are good
- practicing doctors?
- 15 A. Absolutely.
- 16 Who use that book right up there by you?
- 17 The PDR? A.
- 18 Yes, sir. Q.
- 19 A. Yes.
- 20 To take care of patients? Q.
- 21 A. Yes.
- 22 O. And you sent it to 57 doctors in this
- 23 country and nobody from Alaska, correct?
- 24 A. We sent it to 62 people who are defined
- in the criteria that we used at the beginning as

- 1 what the revisions are?
- 2 A. Not without comparing them side by side.
- Q. Let's go to page 9 of this, how to use
- the guidelines. Are you there?
- 5 A. Yes.
- 6 Q. How many psychiatrists are there in this
- country, sir?
- 8 A. I believe it's somewhere close to
- 9 40,000.
- 10 Q. Okay. The 1999 guidelines are based on
- 11 a survey of 57 doctors, right?
- A. That's right. 12
- 13 Q. 57 out of 60 -- I can't find it, 62?
- 14 A. I think it's -- yeah.
- 15 Q. Okay. How many primary care doctors are
- 16 there in this country, sir?
- 17 A. I don't know.
- 18 Q. Hundreds of thousands, right?
- 19 A. I don't know.
- 20 Q. Okay. You sent this survey back in 1998
- 21 to 57 psychiatrists, right?
- 22 A. We sent it to 62.
- 23 Q. 62 and you got answers from 57?
- 24 A. That's right.
- 25 Common sense will tell you that there's

- 1 research experts in schizophrenia.
- 2 Q. Okay, sir, so now turn to page 12.
- Strategies from selecting medications.
- 4 Yes. Α.
- 5 Here's where you say expert opinion has
- 6 changed dramatically -- that's an adjective, is
- 7 it not?
- 8 A. Yes.
- 9 Q. Expert opinion has changed dramatically
- 10 since our last survey in 1996. Is that correct?
- 11 That's what it says.
- 12 Okay. So, from '96 to '98 when you sent
- 13 this out, expert opinion had changed
- 14 dramatically; is that correct?
- 15 That was Dr. Francis' conclusion.
- 16 Q. Yes, sir, and you say you stand by these
- 17 words?
- 18 A. No, you asked me about the introduction
- that he wrote, describing how guidelines were
- used. I stood by those words.
- 21 Q. You stand by these words?
- 22 That's Dr. Francis' opinion. A.
- 23 Q. Do you agree or disagree with it?
- 24 Between '96 and '99 I'd say that there
- 25 was -- you know, a significant change.

- 1 Q. Yes, sir, and I'm not trying --
- 2 A. I just wanted to be clear what we said
- 3 before when I stood by his words, you were asking
- 4 me about the introduction.
- 5 Q. You stand by part of his words and not
- 6 all of his words; is that correct?
- 7 A. Sir, I didn't say I don't stand by some
- 3 of his words. You asked me did I stand by the
- 9 introduction; I said yes. Do I agree with his
- 10 statement, expert opinions change dramatically?
- 11 Yes, I think that that's true. Between 1996 and
- 12 '99 there was a change.
- 13 Q. Yes, sir, to be fair, it wasn't '99 --
- 14 A. '98
- 15 Q. That's when it was written. The survey
- 16 was sent out in '98?
- 17 A. The survey was sent out sometime in the
- 18 year prior to publication.
- 19 Q. '98?
- 20 A. Sometime in late '98 perhaps, yeah.
- 21 Q. Do you remember when?
- A. I can't tell you the exact date that it
- 23 was mailed out. Yeah, sorry.
- 24 Q. Expert opinion has changed dramatically
- 25 since our last survey in 1996 when the experts

- 1 Q. Then you have a footnote reference and
- 2 you go to 11, you go to the bottom of the page,
- 3 right?
- 4 A. Right. And that keys you into the
- 5 survey question.
- 6 Q. Yes, sir, and that's what I was going to
- 7 ask you about and I want you to help me, maybe
- 8 we're almost done. We're on our last leg. It
- 9 keys you into the medication survey questions
- 10 about what, side effects?
- 11 A. Yeah, that were used to generate this
- 12 table.
- Q. And I think we're communicating, sir, I
- 14 don't want to miscommunicate. So the side
- 15 effects that were used to create this table,
- 16 which is guideline 5 --
- 17 A. Right.
- 18 Q. Selecting medication to avoid side
- 19 effects. The side effects listed are what, sir?
- 20 A. These were a list of side effects that
- 21 the editors of this particular section of the
- 22 guideline felt were important considerations in
- 23 the treatment of patients with schizophrenia.
- 24 Q. You were an editor, I thought?
- 25 A. Of the medication section. I was not

- 1 still considered conventional antipsychotics to
- be a first-line treatment for schizophrenia in
- 3 many clinical situations.
- 4 Did I read that correctly?
- 5 A. Yes, you did, sir.
- 6 Q. Yesterday I had this note. That's why
- 7 I've had it here, so I wouldn't forget. You
- 8 talked about lobotomies and ice baths. Do you
- 9 recall that?
- 10 A. Yes.
- 11 Q. You said that took place before the
- 12 invention of the first-generation antipsychotics,
- 13 isn't that what you testified to?
- 14 A. Yes.
- 15 Q. If Zyprexa disappeared off the face of
- 16 the earth, would you have to go back to ice baths
- 17 and lobotomies?
- 18 A. Of course not.
- 19 Q. That's just ridiculous, isn't it?
- 20 A. Yes.
- 21 Q. Now, sir, let me see.
- Now, page 15.
- 23 Selecting medications to avoid side
- 24 effects. I'm sorry, you see that?
- 25 A. Yes, I do.

- 1 the editor of the medication section, I explained
- 2 that was Dr. Francis and two other authors.
- 3 Q. Do you stand by this guideline?
- 4 A. Yes. Oh, I do, yeah.
- 5 Q. I'm looking on the medication side
- 6 effects. I'm looking for hyperglycemia, I'm
- 7 looking for diabetes, and I'm looking for
- 8 hyperlipidemia. Can you find it for me, please?
- 9 A. No.
- 10 Q. Why not?
- 11 A. They're not listed.
- 12 Q. And they're not even listed by the
- 13 authors of this expert panel that was assembled
- 14 back in 1998 of 57 people, are they, sir?
- 15 A. That's correct.
- 16 Q. Let's go on. But it did list weight
- 17 gain. This is what you learned about in med
- 18 school, right?
- 19 A. Yes, sir. It lists weight gain.
- 20 Q. What you learned about in med school?
- 21 A. We learned about a lot of things in med
- 22 school, what do you mean. I learned about weight
- 23 gain in med school, yes, not in relation to
- 24 guideline.
- 25 Q. All right, sir. Don't you accumulate

- 1 knowledge -- and you start using it. I used what
- I learned in college.
- 3 A. Sure.
- 4 O. Most likely to, what, sir, cause --
- 5 A. Yeah, this is the way that we took the
- survey results. The question that the question
- was asked, as I recall if we go to the actual
- survey questions, is what medications -- I have
- to tell you, the way the table is written, we
- 10 took the results, the editors took the results
- and tabulated these in a format so that a
- 12 clinician would see what medications are most
- 13 likely to cause a side effect, what medications
- are least likely to cause a side effect.
- 15 Q. What was the medications that were most
- likely to cause weight gain?
- 17 A. Let's see, Clozapine and olanzapine.
- 18 Q. Just like the consensus panel reiterated
- 19 again in 2003, isn't that right?
- A. Sir, I'd have to see the language of the 20
- 21 consensus panel to agree or disagree with you.
- 22 Q. You don't recall table 2?
- 23 A. I'd have to see the language.

The next page.

- 24 Q. Let's turn to the next page. We have
- 25 the maintenance phase. Do you recall the

- 1 included here as the recommendations. The
- majority, though, in the survey did respond that
- 3 it was a very highly rated test to monitor for.
- 4 Is that what you're looking for -- I'm sorry,
- sir, ask the question again, I may be conflating
- two questions in my head. Ask the question
- 7 again, sir.
- 8 Q. Blood glucose monitoring is not anywhere
- 9 listed in the maintenance phase, is it, sir?
- 10 That is correct. Scanning it quickly,
- 11 but let me read it carefully and just be sure.
- 12 That's correct.
- 13 Q. No doubt about it anymore is there?
- 14 A. Today?
- 15 Q. Today, as we sit here?
- That's right. 16 Α.
- 17 Now, there was blood monitoring, but it
- 18 was to make sure the patient was taking the drug,
- 19 right?
- 20 Sir, let me just look at that and see.
- 21 Yes, sir. Q.
- 22 Wait a second. Actually, sir, I'm going
- 23 to go back and revise this in terms of
- maintenance phase because before I answer that I
- may want to revise the answer that I gave you. I

Page 163

Page 165

- maintenance phase? 1 have to see what this question referred to, if A. Let's see. What page are you on?

 - 3 fast here, I wanted to make sure I knew what you
- Tell the jury what the maintenance phase Q. 6 means?
- Maintenance phase means that in
- long-term treatment after a patient is stabilized
- from an episode and you're continuing them on
- medication, that's the maintenance phase. 11 Q. Continuing the patient on medication?

There we go. Yeah, got it.

12 A. Yes.

Α.

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- 13 Q. I'm looking for blood glucose monitoring
- 14 on the page. Do you see it?
- 15 Yes. A.
- Q. You see blood glucose monitoring? Do
- 17 vou see it?
- 18 A. No, it's not on here.
- 19 Q. Because back in 1998 that was not part
- of the protocol, was it, sir? 20
- 21 A. Well, I wouldn't use the word protocol.
- 22 What word would you use? Q.
- 23 The way that the table was assembled is
- that those results that met the statistical
- criteria for an absolute first-line priority were

- you pardon me for just a moment. We're going
- 4 were asking and what I was answering.
- 5 Q. Take your time.
- A. During maintenance phase -- sir, this
- didn't have to do with medical monitoring of
- tests in the questions that we were answering
- yesterday. I'm sorry. I apologize. I
- 10 misunderstood your question and what this table
- is for. This table has to do with the general
- clinical psychiatric monitoring. This has not to
- 13 do with monitoring of side effects or medical
- 14 problems.
- Q. Well --15
- 16 A. It does say, monitor for and manage
- 17 emerging side effects at each visit. But this
- really had to do with psychiatric monitoring, not
- 19 monitoring for comorbid medical strategies, and I
- think the -- I was misled as you asked your
- question to think that this had to do with
- 22 overall detailed recommendations for side effect
- 23 monitoring. This had to do with how you monitor
- 24 the psychiatric symptoms of the patients during
- 25 the maintenance phase and I retract the answer I

- 1 give earlier, because it was irrelevant. This
- 2 wasn't about medical monitoring. This is about
- psychiatric monitoring.
- That's strange. Let's look at what it
- says. Ongoing monitoring, on the maintenance phase.
- 7 A. Right. But here --
- 8 Sir, I hadn't asked the question yet.
- 9 Do you want to say anything else?
- 10 A. I'm sorry.
- Routinely evaluate for and promptly 11
- 12 respond to prodromal signs of relapse. What does
- 13 that mean?
- 14 A. That has to do with monitoring for signs
- 15 of relapse of schizophrenia.
- 16 Q. Monitor for and manage emerging side
- 17 effects at each visit?
- 18 A. That's right.
- 19 What side effects? 0.
- 20 A. Well, I'd have to go back to the survey
- 21 question to tell you, and the footnote to that is
- 14. And the question that generated this
- 23 guideline, can we go to question 14 --
- 24 Q. Here it is.
- 25 Footnote is for the psychosocial survey

- Q. I'm going back to monitor and manage for
- emerging side effects and as a footnote, it says 3 14?
- 4 A. Now, I got my glasses on. It's fine
- print but it says 14, psychosocial survey,
- questions 1 through 4. Those were the survey
- 7 questions used to generate that recommendation.
- 8 Q. Okay. I'm trying to find high blood
- 9 glucose, diabetes or hyperlipidemia?
- 10 Those wouldn't have been part of the
- 11 psychosocial survey, sir.
- 12 Q. Sir, let's go back to the -- so, we
- agree, at least, that the maintenance phase of 13
- this medication doesn't say anything about
- 15 hyperglycemia, right?
- 16 Sir, give me just a second to review
- 17 this here.
- 18 O. Yes. sir.
- 19 I want to make sure we're in the right
- 20 section to answer the question that you're
- 21 looking for. You're in the psychosocial portion
- 22 of the survey, the medical monitoring section
- 23 where it talks about blood tests is not what
- 24 you're looking at. This is for monitoring
- 25 psychiatric symptoms, it's not the medical

- Page 169
- 1 monitoring portion. 2
- Sir, I'm under strategies for selecting medications. That starts on page 12, doesn't it?

- Sir, let's see, strategies for selecting
- 5 medications. That's Roman numeral I.
- 6 O. On page 12?
- 7 Right. And then in the -- then we get
- 8 to guideline 6 which has to do --
- 9 O. Sir --
- 10 A. -- with psychiatric monitoring during
- 11 the maintenance phase.
 - THE COURT: Let him ask the
- 13 questions one at a time and I think we'll get
- 14 through this quicker.
- 15 A. Sure.
- 16 Page 12? Q.
- 17 A. Page 12.
- 18 Strategies for selecting medications? Q.
- 19 A. That's right.
- 20 O. This is part of the survey of doctors,
- 21 is it not?
- 22 A. Well, no, different questions in the
- 23 course of the guideline are drawn from various
- 24 sources, depending on the question we were trying
- 25 to answer.

- 1 question. You have to go to the right one, show you how to read this. Psychosocial survey
- questions 1 through 4.
- Q. I thought it said --
- A. No, sir. It says psychosocial survey
- questions 1 through 4.
- Q. Let's talk about that quickly. The
- psychosocial survey, was that to the doctors?
- 9 No, they weren't.
- 10 O. No, it wasn't, was it?
- 11 A. Well, some of them. They were health
- 12 care providers. We'll have to look at them and
- see. It was not to the psychopharmacologists
- 14 because it wasn't about the medical monitoring,
- 15 it was about the overall monitoring of the course 16 of treatment.
- 17 Q. So when you were answering Mr. Brenner's
- 18 questions, and you were using some of the graphs,
- you were using graphs and charts not from the 20 doctors; isn't right correct?
- 21 A. No, that's not correct. The graphs that
- 22 we looked at yesterday were the graphs that we 23 sent to the doctors for the medical component of
- 24 the treatment, not the psychosocial component of
- 25 the treatment.

3

5

- 1 Q. Okay, sir?
- 2 A. And it's footnoted to show who the
- 3 respondents were.
 4 O Let's turn the page.
- 4 Q. Let's turn the page, I want to go one at 5 a time, we turn to page 13, 14, and 15. You're 6 giving listing guidelines?
- 7 A. They follow a logical sequence in terms 8 of the flow of decisions that clinicians need to
- 9 make in the course of treating patients with
- 10 schizophrenia. They're laid out in a logical 11 sequence.
- 12 Q. Yes, sir, I'm not quibbling with you.
- 13 A. Right.
- 14 Q. Guideline one, guideline two, guideline
- 15 three on the next page.
- 16 A. Sure.
- 17 Q. And then you have guideline 3A and 3B,
- 18 you actually break it down, right?
- 19 A. Right.
- 20 Q. Then you have guideline 4, selecting the
- 21 medications for specific complicating problems,
- 22 right?
- 23 A. Right.
- Q. Then you go to guideline 5, which we
- 25 talked about where it says most likely to cause

1 newer atypical antipsychotics, and nine months2 for clozapine.

Did I read that correctly?

- 4 A. That's right.
 - Q. So just back to what we said yesterday,
- 6 tardive dyskinesia is something you need to
- 7 monitor for, and that's why it's in the warnings
- 8 and the adverse reaction section?
- 9 A. I can't tell you why it's in what
- 10 section, it is something you have to monitor for.
- 11 Q. Now, plasma, that's blood, is it not?
- 12 A. That's right, it's a blood component.
- 13 Q. This does talk about blood monitoring,
- 14 doesn't it?
- 15 A. Let me see the line you're looking at
- 16 here. I think as you said that refers to drug
- 17 levels specifically.
- 18 Q. Yes, sir, it does.
- 19 A. That's part of the treatment of the
- 20 schizophrenic syndrome.
- 21 Q. The plasma monitoring under the
- 22 maintenance phase has nothing to do with
- 23 hyperglycemia and diabetes?
- A. This has to do with maintenance phase of
- monitoring the psychiatric status of the patient.

Page 171

- the side effect of weight gain is Zyprexa, right?
- 2 A. That's right.
- 3 Q. And then you go to guideline 6.
- 4 A. Right.
- 5 Q. The maintenance phase?
- 6 A. Right. Maintenance phase in long-term
- 7 treatment of schizophrenia.
- 8 Q. That's all I've asked you.
- 9 A. Yeah.
- 10 Q. They we're going what you need to do in
- 11 ongoing monitoring; isn't that what it says?
- 12 A. Monitoring of their schizophrenic
- 13 symptoms.
- 14 Q. Sir, why don't you look at it?
- 15 A. I'm telling you what it says. This is
- 16 the context of monitoring for symptoms of
- 17 schizophrenia.
- MR. ALLEN: Your Honor, can I have
- 19 a question and answer format.
- THE COURT: Just ask your next question.
- 22 Q. Yes, monitoring for tardive dyskinesia?
- 23 A. Right.
- Q. At least every four months for
- 25 conventional antipsychotics and six months for

- 1 Just trying to clarify that. It doesn't exclude
- 2 anything else, it includes psychiatric situation.
- 3 Q. Okay, sir. Now, you did tell me back on
- 4 No. 5 -- we're almost done -- that on the side
- 5 effects that you all quizzed on, footnote 11 and
- 6 that's the medication survey questions 19 and 21, 7 right?
- 8 A. That's right.
- 9 Q. Okay. Now, your editorial board and all
- your advisers, I'm sure wanted to do a complete,
- 11 thorough, accurate, best job possible, right?
- 12 A. The editorial board --
- Q. Whoever wrote these questions?
- 14 A. Right. That would have been the
- 15 Dr. Francis and his editors for these various
- 1.6 Dr. 1 tancis and his editors for these various
- 16 sections of the guidelines.
- 17 Q. I'm looking in the questions -- 19 --
- 18 you can take your time.
- 19 A. Sure and we're in the medication section
- 20 there, not the psychosocial section.
- Q. Wasn't that where I was supposed to go
- 22 to? Medication section?
- 23 A. Sir, what page are you on?
- 24 Q. Isn't that 47?
- A. Let's see. Let's see, yeah, page 47,

Page 174 Page 176

- 1 there we are.
- Q. All right. When all these good experts
- got together, the 57 of them, tell them where
- 4 they said we need to start monitoring for side
- effects of hyperlipidemia?
- A. Well, the experts were posed questions
- by the editors of the guideline.
- Q. Yes, sir. And tell me where it asked
- 9 about hyperlipidemia?
- Didn't ask about it here. 10 A.
- 11 Tell me where it asked about diabetes O.
- 12 mellitus.
- 13 A. Give me a moment.
- 14 Q. Yes, sir. It's not there, is it, sir?
- 15 A. In this question, it's not asked.
- 16 Q. Yes, sir, and I'm not trying to play
- 17 tricks on you. The question No. -- guideline 5
- tells us where to go. I didn't write it. It
- 19 says selecting medications to avoid side effects,
- 20 right?
- 21 A. Yes, sir.
- 22 Q. And it tells us to go to these
- 23 questions?
- 24 A. That's absolutely correct.
- 25 Q. Okay, sir. Let's go to the questions

- questionnaire was this all on?
- 2 This was question 38.
- 3 O. Yes, sir.
- 4 And it was in -- I'm just giving
- background here. This was in the section of the
- survey that, again, dealt with the medication
- 7 treatment of schizophrenia.
 - But psychosocial or doctors, who was it?
- 9 A. It was in the doctors section.
- 10 Medication section.
- Okay. The doctors session, weight 11
- 12 monitoring, blood pressure check. Medical
- history, physical, that's pretty standard stuff
- 14 for all of us, isn't it?
- 15 A. Yes.

8

- 16 Complete blood count, standard for all
- 17 of us, isn't it?
- 18 A. Yes.
- 19 0. Blood chemistry screening, standard for
- 20 all of us, isn't it?
- 21 A. Yes.
- 22 Q. Electrocardiogram. Standard for all of
- 23 us, isn't it?
- 24 A. These things are standard parts of
- 25 medical evaluation.

Page 175

- 1 O. Dental checkup?
 - 2 A. Yes.
 - 3 Q. Pelvic examination or Pap smear. That's
 - if you're a woman, right?
 - 5 A. Yes.
 - 6 Q. Drug screen, that's just to make sure
 - the patient is not on drugs, right?
 - 8 A. And a patient at high risk for substance
 - 9 abuse, that's right.
 - 10 The point of this, sir -- and then you
 - 11 go on down, it gets to HIV and mammography. This
 - 12 is just general guidelines and recommendations
 - 13 for an annual checkup, isn't it, sir?
 - 14 A. Well, actually, I'll read you the
 - 15 question. It says, Please rate the
 - 16 appropriateness of including each of the
 - following tests as part of an annual routine
 - 18 screening for patients in maintenance treatment
 - 19 for chronic schizophrenia. So the focus here on
 - 20 what are the health needs of patients with
 - 21 schizophrenia. Not about the general population.
 - 22 It happens that many of the health
 - 23 needs of schizophrenics overlap with the patients
 - 24 of general population, but this was asking the

 - 25 needs of patients with schizophrenia.

- 1 and let's look at the questions 19 and 21, and
- tell me when it directs me to go there, where
- does it say a word about diabetes?
- MR. BRENNER: Asked and answered.
- 5 A. It does not.
- 6 Q. Does not. Where does it say a word
- about hyperglycemia?
- 8 MR. BRENNER: Asked and answered.
- 9 A. It does not.
- 10 THE COURT: I'll overrule the
- 11 objection.
- 12 Q. (BY MR. ALLEN) Where does it say that?
- 13 Α. Cardiovascular side effects.
- 14 Q. Does it say related to diabetes,
- hyperglycemia or hyperlipidemia? 15
- 16 A. Doesn't specify.
- 17 Yes, sir. Let me see if I have any
- other thing. I might -- oh, sir, on page 56, one
- 19 of these charts you went over with Mr. Brenner
- 20 vesterday.
- 21 A. Yes, sir.
- 22 Q. And you -- remember that you talked
- 23 about SMAC testing?
- 24 A. Yes.
- 25 What part -- what part of the

- Q. Okay. Remember, you talked about --
- 2 were you trying to imply that this answer on page
- 3 57 -- let me see, 57, were you trying to imply
- that this medication and symptom monitoring was
- somehow supposed to be blood glucose monitoring?
- Were you trying to imply that in your testimony?
- 7 A. Let's see, page 57. If you're on page
- 57, I think you're here in the psychosocial
- 9 survey.
- 10 Q. Tell the jury what the psychosocial
- 11 survey is?
- 12 A. Well, the psychosocial survey -- I'd
- 13 have to look, refresh my memory, this was ten
- 14 years ago. But the psychosocial survey was put
- 15 together to describe those aspects of care that
- 16 have to do with providing psychological support,
- 17 living support, psychotherapeutic support,
- 18 variety of supportive services that are used in
- 19 the care of people with chronic mental illness,
- schizophrenia in particular. 20
- 21 Q. Wasn't talking about blood testing, was
- 22 it?

2

- 23 A. I'd have to look at it, if it mentions
- blood testing. 24
- 25 Q. Well, you answered Mr. Brenner's

- 1 anything to do with blood glucose monitoring for
- 2 high glucose?
- 3 Here, it wouldn't specifically.
- Thank you, sir. Find for me anywhere in
- there where it says we recommend that we do
- routine baseline and followup blood monitoring
- 7 for glucose in schizophrenic patients. Find it
- 8 for me, please, sir?
- 9 A. That phrase doesn't appear in these 10 questions.
- 11 No, sir, I mean in this entire document.
- 12 Sir, I don't think that phrase appears
- 13 in the document.
- Whether it's that phrase or something 14
- 15 similar, routine baseline and ongoing plasma
 - glucose monitoring, where is it in this document?
- 17 Well, sir, every time the patient is
- 18 admitted to the hospital, you know, when you do a
- 19 survey of this nature.
 - MR. ALLEN: Your Honor.
- 21 Let me answer the question.
- 22 THE COURT: Let him answer the
- 23 question.

20

4

- 24 A. When we admit a patient to the hospital,
 - for example, we take their blood pressure, we get

- questions very easily yesterday, didn't you?
- MR. BRENNER: Your Honor.
- 3 THE COURT: No. That's
- 4 argumentative.
- 5 Q. (BY MR. ALLEN) Okay. Are my
- questions -- I'll rephrase. Sir, medication and
- symptom monitoring, does that have anything to do
- with blood glucose testing, top side or bottom
- and you have all the time you need to read this 9
- 10 entire report?
- 11 A. It's a pretty general phrase, sir. I
- 12 couldn't say what it includes of doesn't include.
- 13 Q. Yes, sir. In fact, though, you actually
- 14 can, though, I think, if you look -- go ahead.
- Sav whatever --15
- 16 A. Go ahead, ask your question, I condition
- 17 go back.
- 18 Q. What would you like to tell me?
- 19 Reask me your first question, if you
- wouldn't mind. 20
- 21 No, sir. I have a new question.
- 22 What did you have to say?
- 23 A. I was going to try to respond to your
- 24 request.
- 25 The question is: Does this have

- 1 baseline blood tests, we get an
- electrocardiogram, we do a mental status
- examination, we do a physical examination.
 - There's a whole process that occurs
- when we bring a patient into treatment. When a
- new patient comes into the clinic, every
- psychiatrist gets a -- should get a full medical
- screening when they enter the clinic. When I see
- 9 a patient in my practice I get a full medical
- 10 screening of that patient before I undertake
- 11 treatment or if its an emergency, within a few
- 12 days of the time that I undertake treatment.
 - When a patient comes into the
- 13
- 14 emergency room, every hospital has a protocol for
- 15 the types of tests that it does to evaluate the
- patient. When we do a survey of this nature, we
- don't ask about stuff that's so basic that every
- 18 doctor worth his salt knows to do it. We ask
- 19 about those areas where guidance is needed in terms of clinical decision-making that might call
- 21 for some extra attention.
- 22 THE COURT: Let me ask you a
- 23 question about that. You just said that you
- don't ask for things that every doctor worth his
- 25 salt knows about. I saw blood pressure

Page 182 Page 184 1 monitoring on the survey questions, I would 1 THE COURT: Do you want to take our assume any doctor worth his salt knows to monitor 2 second break before you start? people's blood pressure when they first come in 3 MR. BRENNER: If this would be appropriate, that would be good, Your Honor. for a screening. 4 5 5 THE COURT: Thank you, ladies and THE WITNESS: At a basic initial screening when we evaluate a patient. gentlemen. We'll be in recess for 15 minutes. 7 7 THE COURT: And so you did ask (Jury out.) 8 8 those kinds of questions. (Break.) THE COURT: Mr. Brenner. 9 THE WITNESS: We asked here in 9 10 terms of prioritizing, given that schizophrenics 10 MR. BRENNER: Your Honor, with the are a vulnerable population, where it's difficult Court's permission, I'd like to publish to the 11 11 12 to do everything, and where you have to focus 12 jury the exhibit we had marked yesterday, EL3907. 13 your energy, what are the important things to 13 THE COURT: If it was admitted, you 14 look at when you take care of your patients over 14 may publish it to the jury. 15 the long haul. 15 MR. BRENNER: Also, with the 16 Court's permission, there was a PDR that shown to 16 Q. And my original question was, in this whole document that you were an editor on and you 17 Dr. Kahn in reference. I'd like to mark that for and Mr. Brenner discussed --18 identification. 19 A. Yes. 19 THE COURT: Sure. I'm not sure 20 Q. -- find me anywhere that it says monitor 20 that it isn't already in as an exhibit. 21 routine blood glucose at baseline and following 21 MR. ALLEN: Yes, the 1998 PDR up? Can you find it? 22 22 reference to Zyprexa was admitted yesterday. I'm A. Baseline is assumed. Following up is 23 23 sorry, 2008. stated right in the guideline. 24 THE COURT: Rather than have 24 Q. In here? 25 25 duplicates of the thing, if we can find the Page 185 Page 183 A. It's recommended that the blood tests be exhibit, let's just use the one that's admitted. taken on an annual basis. 2 MS. GUSSACK: PDR --3 MR. ALLEN: The book's not 3 Q. Annually. Okay. A. It doesn't exclude taking them more 4 admitted. 4 5 often. 5 THE COURT: You want to use the 6 Q. Now you said something in your answer. 6 whole book? 7 You said any doctor worth his salt; do you MR. BRENNER: Just so the record's 8 8 remember saying that? clear. 9 A. 9 MR. ALLEN: For identification Yes. 10 Q. Do you know Dr. Duane Hopson? 10 purposes, that's fine. 11 A. I don't know him personally, sir. 11 MR. BRENNER: I'm marking it for 12 O. You know of him? 12 identification as EL3909. 13 A. I believe he's here in Alaska. 13 THE COURT: 3909? 14 Q. You think he's worth his salt? 14 MR. BRENNER: Yes, sir. 15 A. I'm sure he is. 15 THE COURT: EL -- just so the Q. He's told us he changed his practice on 16 record is clear, 3909 is the entire 19---17 MR. ALLEN: 2008. blood monitoring recently, did you know that? 17 18 A. No. 18 THE COURT: -- 2008 PDR. 19 Q. Did you read his testimony? 19 REDIRECT EXAMINATION 20 20 A. No. (BY MR. BRENNER) Doctor? Q. 21 MR. ALLEN: Anything else? 21 A. Yes.

22

23

25

22

23

Tommy? Dave?

24 length. I'm normally not that long and I

25 appreciate your patience.

Thank you, sir, I apologize for the

Q. In his cross-examination, Mr. Allen

ever seen them in your practice.

asked you about a number of potential adverse

events with Zyprexa and asked you whether you'd

- 1 Do you recall that?
- 2 A. Yes.
- 3 Q. Have you seen hyperglycemia occur in
- 4 patients treated with Zyprexa?
- 5 A. Yes.
- 6 Q. And do you monitor their blood for that?
- 7 A. Yes, I do.
- 8 Q. And have you done that since 1996?
- 9 A. Yes.
- 10 Q. Doctor, has anybody from Eli Lilly and
- Company ever sought to minimize any side effect
- 12 to you?
- 13 A. No.
- Q. Has anybody from Eli Lilly and Company 14
- 15 ever told you that Zyprexa did not cause gain?
- 16 A. No.
- 17 Q. With respect to the consensus
- 18 guidelines, Doctor, do you have an estimate as
- to -- strike that.
- 20 For whom are the guidelines
- 21 intended?
- 22 A. Practicing psychiatrists.
- 23 Q. And were these guidelines actually
- 24 mailed out to practicing psychiatrists?
- 25 Yes, they were.

- 1 Q. As in all guidelines for practice,
- 2 correct?
- 3 A. Absolutely.
- 4 And Mr. Allen had you read part of this
- section that enumerates some of the limitations?
- 6 A. Yes.
- 7 Can you read for the jury, please, the Q.
- last two sentences? The one beginning "despite
- 9 this."
- 10 A. Yes. Despite this, the aggregation of
- 11 the universe of the expert opinion is often the
- 12 best tool we have to develop guideline
- 13 recommendations. Certainly, the quantification
- 14 of the opinions of a large number of experts is
- 15 likely to be much more trustworthy than the
- 16 opinions of any small group of experts or of any
- 17 single person.
- 18 Q. Is that one of the reasons why you and
- 19 your colleagues took the time to prepare and
- 20 promulgate these guidelines?
- 21 A. Precisely.
- 22 Q. Doctor, you were asked about a blood
- 23 test known as an SMAC. In your practice, is that
 - a type of blood test commonly used to monitor
- blood glucose levels?

Page 187

Page 189

- Q. Approximately how many?
- 2 A. I believe that this guideline was mailed
- 3 to the membership of the American Psychiatric
- Association, that mailing list essentially, which
- 5 would have been about 30,000 psychiatrists, if
- 6 I'm not mistaken.
- 7 Q. And so any psychiatrist in Alaska who
- was a member of the American Psychiatric
- Association would have this mailed to him or her?
- 10 A. Yes.
- 11 MR. BRENNER: Can I have internal
- page 9, please, the right-hand column, the
- 13 middle.
- 14 MR. ALLEN: Mr. Brenner, can I have
- the actual page? 15
- 16 MR. BRENNER: It's Page 8. Yes.
- 17 It'll always be one page behind the internal
- 18 page.
- 19 MR. ALLEN: Okay. Thank you.
- 20 Q. (BY MR. BRENNER) Doctor, you were asked
- this question about the portion of the
- guidelines. The first thing I'd like to ask you,
- 23 there are limitations to these guidelines,
- 24 correct?
- 25 A. Yes.

- 1 Α. Yes.
- 2 Q. In your practice is that type of blood
- 3 test commonly used to monitor lipid levels?
- 4 A. Yes.
- 5 Is there some special, you know, arcane
- 6 kind of blood test that doctors use to check
- 7 blood glucose levels?
- 8 A. No.
- 9 O. Or to check lipid levels?
- 10 A. No.
- 11 Q. Is that still a test you use today?
- 12 A. Yes, it is.
- 13 You were asked questions about tardive
- 14 dyskinesia yesterday.
- 15 Do you recall that?
- 16 A. Yes, I do.
- 17 Q. In your clinical experience, are rates
- of tardive dyskinesia higher in patients who get
- 19 first-generation antipsychotics or
- 20 second-generation?

- 21 The rates are higher in patients who get
- 22 first-generation antipsychotics.
 - MR. BRENNER: Mike, could we have
- 24 internal page 47 of EL3907, and item 19, please?
- 25 (BY MR. BRENNER) Doctor, could you tell

8

Page 192

Page 193

- 1 us what data are depicted in item 19 from the 1999 guidelines?
- 3 A. Yes. Item 19 is a -- I'll read the
- question. Rate the appropriateness of the
- different antipsychotic medications for a patient
- for whom it is important to avoid the following
- side effects. Give your highest ratings to --
- that would be 7, 8 or 9. Give your highest
- ratings to the drugs that are least likely to
- 10 cause these problems and assume that the patient
- 11 is receiving an average therapeutic dose of the
- antipsychotic medication.
- 13 O. And the issue here is one of
- 14 extrapyramidal symptoms?
- 15 A. Right, we listed a whole bunch of side
- 16 effects, when we asked the questions, we would
- 17 ask them in sequence and list the drugs under it,
- and they would be listed in alphabetical order. 18
- 19 Q. Just remind us briefly: What are
- 20 extrapyramidal symptoms?
- 21 A. Extrapyramidal symptoms are symptoms
- 22 such as -- drug-induced. Parkinsonism and
- 23 akathisia that we talked about yesterday.
- 24 Q. As a result of this survey to the
- experts with whom your group consulted, what were

- 1 Akathisia is best described as restless
- 2 legs, inability to sit still or hold still in one 3 place.
- Q. Okay. Am I correct that this question
- was soliciting views from the experts as to what
- drug you would use or switch a patient to if you
- 7 wanted to avoid akathisia?
 - A. Well, if a patient is on -- and the way
- 9 this question is phrased, if a patient is on a
- 10 high potency conventional antipsychotic at the
- 11 lowest dose that you believe will be effective --
- 12 just explain what that means. We are still in an
- era here where there were patients being treated
- 14 with first-generation antipsychotics. That's
- 15 what conventional means. The high-potency
- conventional antipsychotics were the ones that
- 17 were most frequently associated with akathisia.
- 18 Haldol would be the best known example.
- 19 So if a patient was being treated
- 20 with a high-potency conventional antipsychotic,
- for example, like Haldol, and you've lowered the
- dosage as much as you can, which would be the
- 23 first thing, you know, you would try to do within
- 24 the limits of what the patient still needs to
- 25 treat their psychosis, and they still have

Page 191

- 1 the drugs they found least likely to cause
- extrapyramidal symptoms?
- The drugs where the survey respondents
- fell within the first-line range as shown by the
- confidence intervals were in the following order,
- clozapine, quetiapine, olanzapine, and
- 7 ziprasidone.
- 8 Q. If you were wanted to avoid
- 9 extrapyramidal symptoms, this is what the experts
- 10 prescribed?

- 11 A. That's correct.
 - MR. BRENNER: Can I have the next
- 13 page, please, and item 23.
- 14 Q. (BY MR. BRENNER) Doctor, this -- these
- data address something called something 15
- akathisia, and I know you addressed yesterday.
- 17 Just remind us what akathisia is.
- 18 A. Yes, I'm sorry. It was on the wrong
- 19 page, pardon me.
- 20 Which is the internal page of the
- 21 document?
- 22 Q. It's one page additional.
- 23 Got it. Oh, here I am. Question 23, Α.
- 24 sorry.
- 25 O. Just remind us what akathisia is.

- 1 distressing akathisia, despite concomitant
- treatment with an anticholinergic,
- anti-Parkinsonian agent like the kind of antidote
- 4 I mentioned yesterday such as Cogentin. So
- they're on a high-potency drug. You've lowered
- the dosage. You've given them Cogentin, and
- 7 you've given that agent like Cogentin at the
- highest dosage that the patient can tolerate,
- 9 because you remember those have side effects too.
- 10 This is the setup. So they have
- 11 akathisia and you're stuck. Please rate each of
- 12 the following treatment strategies for this
- 13 problem. Then we gave them, you know,
- 14 alphabetical the whole list and this was the rank
- 15 ordering of how they were rated.
- 16 And olanzapine was the highest ranked?
- 17 Yes, 79 percent of the panel felt that
- 18 this would be their first-line intervention, to
- 19 switch the patient at this point from the
- 20 high-potency conventional drug to olanzapine.
- 21 And they would do that -- their
- 22 recommendation was to avoid or do away with this
- 23 akathisia side effect?
- Specifically because of the akathisia. 24
- 25 Okay. Doctor, in your practice do you

- 1 currently prescribe many first-generation
- antipsychotics?
- A. Very infrequently currently. 3
- 4 Occasionally, but not often.
- Q. Why don't you prescribe them very much?
- 6 A. Because of the neurological side
- 7 effects.
- 8 MR. BRENNER: Mike, can we go to
- 9 internal page 7, please?
- Q. (BY MR. BRENNER) Doctor, at the 10
- 11 beginning of the guidelines there's a list of a
- 12 lot of people to whom surveys were sent or who
- 13 were consulted in some way in generating these
- 14 guidelines, right?
- 15 A. Yes.
- 16 O. And there's a section called State
- 17 Medical Directors?
- 18 A. Yes.
- 19 MR. BRENNER: It's over to the
- 20 right-hand column, please. All the way over.
- 21 Q. (BY MR. BRENNER) And within the state
- 22 medical directors, is there a Carey Ozer,
- 23 O-z-e-r, M.D.?
- 24 A. Yes.
- 25 Q. And Dr. Ozer was from the Alaska

- 1 Department of Mental Health here in Anchorage?
- 2 A. That's right.
- 3 MR. BRENNER: Can I also have
- 4 internal page 8, please?
- 5 Q. (BY MR. BRENNER) Near the end of the
- 6 list of people consulted, Doctor, are
- representatives from an organization called -- or
- affiliated with an organization called NAMI,
- N-A-M-I? 9
- 10 A. Yes.
- 11 Q. What's that?
- 12 A. The National Alliance for the Mentally
- 13 III.
- Q. And there's a John F. Malone identified? 14
- 15 Yes. A.
- Q. And he is -- he was with the Alaska
- 17 Mental Health Trust Authority?
- 18 A. Yes. This is an aggregation of State
- 19 branches of this national organization, which is
- an advocacy group that advocates for the
- 21 appropriate care and resources for people with
- 22 mental illness.
- 23 MR. BRENNER: Could I have internal
- 24 page 57, please, item 38.
- Q. (BY MR. BRENNER) I think the jury's

- 1 probably seen this enough, Doctor. But very
- briefly, is weight monitoring and blood chemistry
- 3 screening recommended as screening measures that
- should be taken in connection with patients in
- maintenance treatment for chronic schizophrenia?
- 6 A. Yes.
- 7 Q. And that was certainly as of the time
- these data were derived in 1998 and 1999?
- 9 A. Yes.
- 10 Q. And that had been your practice since
- 1996? 11
- 12 A. Yes.
- 13 MR. BRENNER: And then at the
- 14 bottom of that page, if we could show item 39.
- 15 (BY MR. BRENNER) And 39 were the
- recommendations from the experts as to comorbid
- medical conditions and risk factors for which of
- those patients should be monitored?
- 19 A. Yes.
- 20 Q. And among those were obesity and
- 21 diabetes, correct?
- 22 A. Yes. Both viewed as -- by the majority
- 23 of experts as first-line areas of concern.
- 24 Q. Okay. Doctor, Mr. Allen read to you
- 25 from various parts of your report. I want to

Page 197

- 1 show you one other portion. The top paragraph.
- 2 Doctor, is it correct that one of
- 3 the things you noted in your report -- I'll just
- read it -- is discussion of weight gain and
- 5 metabolic issues relating to olanzapine has been
- 6 in the medical literature since at least the late
- 7 1990s, and information concerning these topics
- 8 has been set forth in the olanzapine product
- 9 labeling from the time of its launch. That
- 10 olanzapine can cause weight gain in some patients
- 11 has been well understood in the psychiatric
- 12 community, as are the potential consequences of
- 13 weight gain.
- 14 Have I read that correctly?
- 15 A. Yes.
- 16 Q. That was an opinion you held at the time
- 17 you prepared your report?
- 18 Α. Yes.
- 19 Q. Is it an opinion you hold today?
- 20 Yes, it is.
- 21 And do the potential consequences of
- 22 weight gain that you noted in your report, do
- 23 they include hyperglycemia?
- 24 A. Yes.
- 25 O. Hyperlipidemia?

Page 200 Page 198

- 1 A. Yes.
- 2 Diabetes? O.
- 3 Yes.
- 4 MR. BRENNER: Nothing further,
- 5 Your Honor.
- 6 RECROSS-EXAMINATION
- 7 Q. (BY MR. ALLEN) Okay. Let's go back to
- 8 your article.
- 9 First of all, you talked about
- 10 NAMI?
- 11 A. Yes.
- 12 Q. National Alliance for the Mentally Ill?
- 13 A. Yes.
- 14 Q. Financed and supported in part by Eli
- 15 Lilly, correct?
- A. I don't know to what degree. I don't 16
- know their sources of financing. 17
- 18 You don't know any of them?
- 19 A. No.
- 20 Q. Are you aware there's evidence in these
- 21 files that, in fact, the National Alliance for
- the Mentally Ill is financed in part by Eli
- 23 Lilly?

1

- 24 MR. BRENNER: Objection,
- 25 Your Honor.

- Q. Is this where the -- you said somebody
- 2 from Alaska was sent a survey?
- 3 A. Yes.
- 4 Q. Okay. The survey was not on medical
- issues, was it, sir?
- 6 A. That's correct.
 - Q. It was on public policy and the
- 8 financing of care of schizophrenia; is that
- 9 correct?

7

- 10 A. Yes, that's right.
- 11 And you understand that's who's hired me
- 12 to be here on their behalf in this case? Do you
- 13 understand that?
- Yes, I understand what you mean. 14 Α.
- 15 Right. So does that give you an
- indication of how they feel today?
- 17 MR. BRENNER: Objection,
- 18 Your Honor.
- 19 THE COURT: Sustained.
- 20 Q. (BY MR. ALLEN) Now, sir, on these
- guidelines -- tardive dyskinesia and akathisia,
- all right? You said in your deposition -- I can
- get it out if you want and I'm paraphrasing --
- 24 that the CATIE study is probably the most
- 25 important study that you've seen in a long time,

Page 201

Page 199

- THE COURT: Sustain that.
- 2 Q. (BY MR. ALLEN) Now, concerning the
- 3 experts for the medical questions --
- 4 A. Yes.
- 5 Q. -- that's page 4.
- 6 Yes.
- 7 Who's from Alaska?
- 8 MR. BRENNER: Objection; asked and 9 answered.
- 10 MR. ALLEN: No, he brought it back
- 11 up.
- 12 (BY MR. ALLEN) Who's from Alaska?
- 13 THE COURT: I'll allow this.
- 14 A. None of them are, sir.
- 15 Q. (BY MR. ALLEN) Yes, sir. Now, on the
- 16 issue of sending something to the people in
- 17 Alaska, that -- was in regard to policy experts
- 18 on page 5?
- 19 Sending something to people in Alaska? A.
- Well, this list --20
- 21 A. Participation in the survey you mean?
- Well, sir, I'm not trying to quibble. 22
- 23 No, no. I just wanted to be sure.
- Turn to page 5, please, sir. 24 Q.
- 25 Yes.

- 1 right?
- 2 Well, let's look at what I've said.
- 3 Looking at the expert report?
- Q. No, sir. I was actually looking at your
- 5 deposition.
- 6 A. Okay.
- 7 MR. BRENNER: Your Honor, are we
- 8 going to impeach him with deposition testimony or
- 9

14

15

- 10 THE COURT: I don't know what the
- 11 question is, so I have to wait to rule on an
- objection before I understand that. Right now
- 13 this is all preliminary to something.
 - MR. ALLEN: Yes.
 - Q. (BY MR. ALLEN) You remember being asked
- 16 questions about the CATIE study?
- 17 A. Boy, that was a year ago.
- 18 Yes, sir. Do you agree that the CATIE
- 19 study is quite relevant?
 - The CATIE study was a
- 21 widely-promulgated study. Studies such as CATIE
- 22 that received front-page national newspaper
- 23 attention and key articles in widely disseminated
- 24 journals are a very important component that
- 25 doctors take into account when they make

Page 204 Page 202

- 1 treatment decisions, and I would think -- and it
- would be. I think, a mistake to overlook an
- article with the impact of CATIE in talking about
- how doctors make decisions.
- 5 Yes. A.
- 6 Q. So you agree with that?
- 7 If I said that, I wouldn't revise it A.
- 8 now
- 9 Q. Okay. And --

10 THE COURT: And, again, Mr. Allen,

- 11 if you're going to read a deposition, you can
- 12 remind him of his testimony. You can impeach him
- if there's something to impeach, but if you're
- just going to read his testimony to him, what you
- 15 should just do is ask the question over again.
- 16 MR. ALLEN: Well, I'm sorry. I was
- 17 trying to speed this along, Your Honor.
- 18 O. (BY MR. ALLEN) How about this? Do you
- 19 agree the CATIE study is important and doctors
- 20 should pay attention to it?
- 21 A. Yes.
- 22 Q. Okay, sir. And didn't it look -- it was
- 23 independently sponsored. It wasn't sponsored by
- 24 a drug company; isn't that right?
- 25 A. That's right.

1 A. Yes.

- 2 O. What's been admitted into evidence in
- this case is Alaska 10147, Practical Treatment
- Information for Schizophrenia by Dr. Carol
- 5 Tamminga.
- 6 Are you familiar with that?
- 7 No. A.
- 8 Do you know Dr. Tamminga?
- 9 A. No.

13

15

18

- 10 Q. So you have not reviewed the treatment
- 11 guidelines -- by the way, it's published in the
- 12 American Journal of Psychiatry in April of 2006.
 - Have you reviewed that?
- 14 What's the title of the document?
 - Yes, sir. It's admitted into evidence.
 - It's AK10147, entitled Practical Treatment
- 17 Information for Schizophrenia.

Have you reviewed that?

- 19 The editorial that she wrote. At some
- 20 point I may have read it. I'd be glad to look at
 - parts of it again or look at the whole editorial
- 22 again if you wish.
- 23 Q. Yes, sir. My first question is: It's
- an editorial by one of the editors of the journal
- and one of their designated experts in this case.

Page 203

- Q. And it was by the National Institutes of
- Mental Health, right?
- 3 That's right.
- 4 They looked at neurologic side effects
- of second-generation and first-generation
- antipsychotics, did they not?
- 7 A. They compared second-generation
- antipsychotics with one middle potency
- first-generation. So it was singular
- 10 first-generation, an antipsychotic.
- 11 Q. Perphenazine?
- 12 Perphenazine.
- 13 Q. Perphenazine, I'm sorry, sir.
- 14 And they concluded -- this was the
- 15 NIMH -- there were no significant differences
- among the groups in the incidence of
- extrapyramidal side effects, akathisia or
- movement disorders, as reflected by rating
- 19 scale measures of severity, did they not?
- 20 A. The NIMH didn't conclude that, sir. The
- 21 authors of the study did.
- 22 Q. Who were not financed by drug companies?
- 23 A. That's correct.
- 24 You know, we were talking about
- 25 treatment guidelines, and yours were in '99?

- 1 Have you read it?
 - MR. BRENNER: Objection, Your

Page 205

- 3 Honor. I don't believe Dr. Tamminga is an
- 4 expert.

- 5 MR. ALLEN: She was designated.
- 6 THE COURT: Well, whether she was
- 7 or she wasn't, just rephrase the question.
- 8 Q. (BY MR. ALLEN) Have you read this?
- 9 A. I believe I may have read it.
- 10 O. Yes. And, in fact, it has more
- 11 up-to-date guidelines, of course, since it was
- published in April of 2006 than your 1999 report;
- 13 wouldn't you agree?
- 14 Α. Yes.
- 15 In fact, she identifies two specific
- 16 drugs. And let's read it together: The
- 17 metabolic and other somatic effects of olanzapine
 - and clozapine also have implications for
- 19 psychiatric practice. As long as psychotropic
- medications were considered relatively free of
- 21 side effects, psychiatrists could practice in
- 22 settings appropriate to other mental health
- 23 counselors. However, medication treatments with 24 high side-effect burdens demand clinical settings
- 25 that are capable of detecting and managing

Page 206 Page 208

- 1 serious side effects.
- 2 Did I read that correctly?
- 3 A. Yes, you did.
- 4 Q. This knowledge means that a clinician's
- 5 office needs to be equipped to efficiently
- 6 monitor antipsychotic drug side effects, blood
- 7 pressure cuffs, scales, body tape measures, a
- 8 process for plasma chemistry monitoring, and
- 9 electrocardiograms, and qualified consultants for
- 10 medical questions -- let's see -- qualified
- 11 consultants for medical questions become
- 12 important components of practice. Dynamic
- 13 information of drug side effects needs to take a
- 14 prominent place in a patient's psychiatric chart.
- 15 Medical consequences of psychiatric drugs are
- 16 real, preventable and require focused monitoring.
- 17 Clinicians will need to have systems for the
- 18 effective monitoring of drug side effects to
- 19 maintain and promote physical health among
- 20 patients as well as psychiatric health. That
- 21 these studies were NIMH-funded increases our
- 22 confidence that they are as free from marketing
- 23 or other bias or spin as possible.
- 24 Did I read that correctly?
- 25 A. Yes, you did.

1 the document he's being shown is what number?

MR. ALLEN: 10 -- sorry -- AK10147.

3 Let me make sure.

Yes, sir, Your Honor, AK10147.

- A. So your question to me, sir? I'm sorry.
- 6 Q. (BY MR. ALLEN) I can't even remember 7 anymore.
 - Do you agree with these guidelines?
- 9 A. Sir, this is a long article. I can't
- 10 tell you that I agree or disagree with an entire
- 11 article.

2

4

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13

- 12 Q. Thank you, sir.
 - A. And it's not a guideline.
- Q. Let me see if I can find it -- I thought
- 15 the exact words they used. Let me put it back
- 16 up.
- Doesn't she, in fact -- by the way,
- 18 this is Carol Tamminga --
- 19 THE COURT: Is he reviewing the
- 20 Tamminga editorial, or is he reviewing the CATIE
- 21 study? I thought he was reviewing --
- MR. ALLEN: He's reviewing the
- 23 editorial following the CATIE study, which has
- 24 been admitted into evidence.
- MR. BRENNER: The document speaks

Page 207

drug 1 for itself.

2

THE COURT: I thought it was the

Page 209

- 3 CATIE study, that was following this and that
- 4 that's the number that -- which article -- are
- 5 you looking at the CATIE study?
- 6 THE WITNESS: No, I'm looking at
- 7 the editorial published in a different journal
- 8 from the journal that the CATIE study was
- 9 published in.
- in opinion on that, sir. | 10 THE COURT: Okay.
 - 11 Q. (BY MR. ALLEN) Yeah. And this was
 - 12 following the CATIE -- actually, CATIE had three
 - 13 parts, did it not? 1, 2 and 3?
 - 14 A. In terms of the way that the research
 - 15 proceeded.
 - 16 Q. Yes, sir.
 - 17 A. Yes.
 - 18 Q. Didn't it have three parts?
 - 19 A. Yes.
 - 20 Q. And I didn't know -- just so we can look
 - 21 right here. She talks -- the reason this article
 - 22 is written -- and if you can read any part of it,
 - 23 it's following the CATIE analysis; isn't that
 - 24 right?

25

MR. BRENNER: Your Honor, I don't

- Q. And there's been a problem with the drug
- 2 industry putting spin on medical recommendations 3 prior to 2006, wasn't there?
- 4 MR. BRENNER: Objection,
- 5 Your Honor.
- 6 THE COURT: I'll let the doctor 7 answer the question, if he's able to.
- 8 Q. (BY MR. ALLEN) Hasn't there been a 9 problem with spin and bias?
- 10 A. I wouldn't have an opinion on that, sir.
- Q. Okay. Did you see in these new practice
- 12 guidelines that Dr. Tamminga identifies clozapine
- 13 and olanzapine as the two worst drugs following
- 14 CATIE?
- 15 A. This is not a practice guideline, sir.
- 16 I see that she makes the statement.
- 17 Q. Okay. Do you disagree with her
- 18 statement?
- 19 A. Could I see the context? I haven't
- 20 reviewed the whole article.
- 21 Q. I'll let you have my highlighted and
- 22 starred copy. I don't know if I have another
- 23 one.
- 24 A. Sure.
- 25 THE COURT: Just for the record,

Page 210 Page 212 1 recommendation -- you know, the question was

1 think he can testify to why an article was written.

3 MR. ALLEN: It's reflected in the 4 article and the article is in evidence.

5 MR. BRENNER: It speaks for itself. 6 THE COURT: He may or may not be able to. If the document explains it, then he probably can reflect it, and if he can't, he

9 can't. 10 Q. (BY MR. ALLEN) Let's just read it

11 together since everybody -- we were at a point where we can ask which among the multiple

antipsychotic treatments are best for

effectiveness, efficacy and tolerability.

15 Do you see that?

16 Α. Sure, I'm sorry. Which --

17 Right on the first page.

18 First page. Yes, I see it, second

19 paragraph.

20 Q. I'll quit reading. And we're talking

21 about CATIE, right?

22 A. Yes.

23 Q. And then you go to the last page, which

is the part I read, and it talks about the

metabolic and somatic effects of two drugs,

asked: What would you do for annual monitoring?

3 And, you know, annually you would certainly check

these things. And then let me be precise about

the answer -- pardon me for a moment.

6 Then it says: Routinely monitoring 7 for comorbid medical conditions, and routinely is 8 not defined.

9 THE COURT: Okay. What did you do 10 when you said that you monitored in 1996?

11 THE WITNESS: Sure.

12 THE COURT: What did you do?

THE WITNESS: Well, certainly, as I

14 said, you know, annually you would have patients

15 get a basic check-up and look for common health conditions that might occur, some of which we

know patients with schizophrenia are at higher

18 risk for. So we'd be watching for those and

19 making sure that if they were not fully able to

adhere with all of our recommendations, as any of

us might, that we would make sure that at least

our patients got focused evaluation for certain

problems. And that would include the kind of 23

24 blood tests we talked about before.

In terms of routine monitoring,

Page 211

13

25

1 when you see a patient develop signs or symptoms

of hyperglycemia, you would step up your

3 vigilance, get a blood test at that point. If

4 you see a patient gaining weight at any point,

you begin to do things like check their thyroid

function, look to see if they've developed

7 altered lipids or blood sugars. These are things

that you do in the course of seeing patients who

you might be seeing every few weeks, every month,

10 every few months, but at those intervals when you

see them, you're observing for changes in their

health status and then asking them to have

appropriate evaluations based on the changes that 13

14 you see.

23

24 25

15 THE COURT: So how often would you 16 take blood? When you saw them gaining weight, 17 you'd take blood?

18 THE WITNESS: Yeah. If you see a 19 patient gaining weight and they've put on --

20 THE COURT: How much weight would they have to gain to --

21 22 THE WITNESS: I'm sorry.

THE COURT: How much weight would they have to gain to do the blood tests?

THE WITNESS: You know, there's not

Zyprexa and clozapine, right? 2 That's right. 3 Thank you, sir. 4 MR. ALLEN: I have no further 5 questions. 6

MR. BRENNER: If I may, Your Honor. 7 REDIRECT EXAMINATION 8 Q. (BY MR. BRENNER) Doctor, in connection

9 with the 1999 guidelines that have been

10 discussed, was it recommended that there be blood

monitoring and monitoring for diabetes among

patients being treated for schizophrenia?

13 A. Yes.

14 Q. Would that be your recommendation today 15 as well?

16 A. Yes.

18

17 MR. BRENNER: Thank you.

THE COURT: I'm actually going to

19 follow that question up. 20

What was the blood monitoring that

21 was recommended in 1999? Was it once a year?

Was it every six months? Was it every two weeks? What was -- what was that recommendation intended

24 to recommend? 25

THE WITNESS: Okay. The

- 1 a strict cutoff point there. I'd say when you
- 2 look at someone and, you know, they're moving
- 3 up -- a woman is moving up a couple dress sizes,
- 4 a man's belt is -- you know, people have to get
- 5 new clothes, you're putting on 5 percent of your
- 6 body weight, you know. It's hard to say exactly.
- But people know when they're gaining a
- significant amount of weight out of the usual
- 9 fluctuation of what they experience. You know it
- 10 as a doctor; the patient knows it. Sometimes
- 11 they can gain a small amount, and it's going to
- 12 be unusual for them.
- 13 I've had patients where, you know,
- 14 if they gain three or four pounds, it's a big
- 15 change because they usually have very stable
- 16 weights. Other patients whose weights go up and
- 17 down, they come back from a Carnival Cruise
- 18 vacation and they've put on ten pounds. But when
- 19 they're taking medication, if I see someone put
- 20 on anything in the order of, you know, ten pounds
- 21 over the course of a portion of the year, I'm
- going to be concerned about them, and I'm going
- 23 to step up my monitoring. I'm going to have them
- 24 diet and exercise more. If I see them gaining
- more weight, I'm going to be checking their

Page 215

- bloods, as I said, periodically monitoring
- thyroid function. And I may lower their dosage
- or change their treatment.
- 4 MR. ALLEN: Can I ask a question
- now, Your Honor?
- 6 THE COURT: You may.
 - RECROSS-EXAMINATION
- 8 Q. (BY MR. ALLEN) We're not talking
- 9 Carnival Cruise Line gaining weight here, are we,
- 10 sir?

7

- 11 A. I'm talking about the range in weight
- 12 fluctuation that people experience. And the
- 13 threshold for medical evaluation depends on the
- 14 individual. Certainly there's a point of a lot
- 15 of weight gain where you're going to be concerned
- about a higher risk of diabetes or
- hyperlipidemia. You're going to check bloods in 17
- the course of the year. 18
- 19 Q. And to answer the judge's question --
 - MR. BRENNER: If Your Honor please.
- 21 If Your Honor has other questions, Your Honor can
- 22 ask them.

20

- 23 THE COURT: I'll let both sides
- 24 follow up to when I ask questions. I think it's
- 25 only fair.

Q. (BY MR. ALLEN) 38, please rate the

- appropriateness of including each of the
- following tests as part of an annual routine
- screening for patients in maintenance treatment
- for chronic schizophrenia. That's the list we
- 6 went down, dental check-up and everything else, 7 right?
- 8 THE COURT: Again, he answered that 9 question to me, and I understand that.
 - MR. ALLEN: All right. Yes, sir?
- 11 THE WITNESS: I'm sorry. Did you
- 12 want me to --

10

- 13 MR. ALLEN: No, the judge told me
- 14 not to answer -- not to ask it.
- 15 Q. (BY MR. ALLEN) Now, are you aware -- I
- 16 think you said yesterday, and implied to
- 17 Your Honor a minute ago, that you've seen less
- 18 than a handful of patients with diabetes related
- 19 to Zyprexa?
- 20 A. Developing frank clinical diabetes, I've
- 21 seen a handful of patients.
- 22 Are you familiar with the fact that
- 23 doctors had informed Eli Lilly in November of
- 24 1999 --

25

7

THE COURT: This isn't a follow-up

Page 217

Page 216

to my question.

- 2 MR. ALLEN: Okay. I'll withdraw.
- 3 THE COURT: Do any of the members
- 4 of the jury have any questions?
- 5 Can counsel please approach?
- 6 (Bench discussion.)
 - THE COURT: I think there's a
- 8 little bit of confusion, but I'll ask him.
- 9 Doctor, the question from the juror
- 10 is: If blood monitoring is recommended for all
- 11 schizophrenic patients, why didn't you start
- 12 doing it until 1996?
- 13 THE WITNESS: Oh, I didn't mean to
- 14 leave that impression. I think I said yesterday
- I've been doing blood monitoring of patients from 15
- the time that I began practicing psychiatry
- 17 certainly as part of a baseline evaluation of
- 18 every patient. Certainly recommending that my
- 19 patients with schizophrenia have annual health
- 20 monitoring just as I would recommend it for
- 21 anyone who didn't have schizophrenia.
- 22 And certainly from the time that
- 23 I've been seeing patients in psychiatry, I've
- been using drugs that cause weight gain, lithium,
- 25 Depakote, conventional antipsychotics of the

Page 220 Page 218 1 first generation, newer antipsychotics of the and we'll get started. second generation. This has been a recognized 2 Again, I would remind you, please do not discuss this case with anyone or let problem with psychiatric medications for many years, that weight gain occurs with not all of anyone discuss it with you. Please try to keep them, but a number of them. And from the time an open mind until you've heard all of the that I've been practicing this type of medical evidence in this case. Please, as I've 7 monitoring, I think it's been part of the care previously instructed you, please do not listen that my colleagues and I deliver to our patients. to or watch any media that might concern the 9 I didn't mean to leave the 9 subject matter of this case. 10 10 impression that this was new in 1996. I'll see everybody tomorrow at THE COURT: Do we have another one? 11 8:30. 11 12 Counsel, please approach. 12 (Jury out.) 13 THE COURT: Please be seated. 13 (Bench discussion.) THE COURT: I think this is outside 14 We're outside the presence of the 14 jury. Just for the record, I think I may have 15 his expertise, but maybe not. neglected when the jury came back around our noon 16 MR. ALLEN: If he wants --17 MR. BRENNER: I think we'll -break and Mr. Brenner resumed with his redirect, 18 I may have neglected to state for the record that 18 (End of bench discussion.) 19 19 THE COURT: I think this is outside all members of the jury were present. So the 20 record should just reflect that all members of 20 the doctor's area of expertise, so I'm not going 21 to ask this question. 21 the jury have been present throughout the trial 22 22 part of the case. Thank you, Doctor. I think you're 23 23 done. Where are we and what other issues 24 Who is Lilly's next witness? 24 do we have? And I want to talk to the parties 25 MR. LEHNER: Your Honor, if we again about jury instructions, because I would Page 219 Page 221 could just approach briefly to talk about it. 1 really like to at least start thinking in my own 2 THE COURT: Please. mind about jury instructions. And so I really 3 (Bench discussion.) need something by close of business tomorrow so 4 that I can use the weekend productively. MR. LEHNER: Just on a matter of 5 scheduling. We had intended to start playing the 5 MR. LEHNER: I think that's our intention, to certainly get you some material, if deposition of Dr. Beasley. It's rather long. By 6 7 7 not sooner. the time we set up the screen, we're probably 8 8 going to have 15 minutes or so left. And there's I just want to raise --9 9 a couple of other matters that -- it's up to you. THE COURT: Just so that there's no 10 THE COURT: Let's take up the other 10 doubt about it, if the parties are going to 11 submit any additional jury instructions, I want 11 matters and then we'll put --12 MR. LEHNER: -- with respect to 12 it by close of business tomorrow. 13 some of our witnesses that Dave has raised so --13 MR. FIBICH: And we will comply 14 THE COURT: Well, we'll do it. 14 with that request, Your Honor. 15 15 MR. LEHNER: Thank you, Your Honor. (End of bench discussion.) 16 THE COURT: Ladies and gentlemen of 16 One matter with respect to our next 17 17 live witness. Dave, I don't have the slides here the jury, my understanding is that the next 18 in front of me -- I was just going to raise with 18 witness that Lilly would present is a long 19 deposition witness. By the time we set up the 19 the judge. We'd provided the -- certain 20 screen and in order to get everybody out of here 20 demonstratives that we anticipated using with Dr. 21 at 1:30, we don't have much time left. 21 Baker. Dr. Baker is an employee of Lilly. 22 So what I'm going to do is send you 22 Product safety -- and he was going to be coming 23 23 home early and take up some matters with the to testify about work that he does. And we had 24 attorneys to use up the rest of the time. I 24 prepared some demonstratives that would would like you to be here again at 8:30 tomorrow 25 illustrate some of the material that he would be

Page 222 Page 224

1 talking about. And I think Mr. Suggs suggested that he was concerned that these would be expert opinions. I don't want to mischaracterize what you were saying. 5

MR. SUGGS: Yes.

MR. LEHNER: I think these are matters here. I think those are the ones you identified to me that you had concerns about.

9 Dr. Baker was deposed in this 10 litigation extensively by Mr. Suggs. He has talked about a number of these matters, and 11

12 certainly these matters have been well-known to

13 the Plaintiffs. These are about the various

14 Lilly submissions -- the various submissions

15 Lilly made to the FDA. These reflect Lilly's

16 conclusions about those submissions. And I think

17 it's certainly proper testimony in light of the

prior deposition, in light of his position at the

company, in light of the work that he does on

20 Zyprexa. And he would be explaining using

21 those --

6

22 THE COURT: This is a witness who

23 is going to testify as to the views of Lilly on

24 these submissions, or on these studies and why

25 Lilly -- this is my word -- discounted them or

25

Page 223

1

1 didn't feel that they were -- said what they said 2 or --

3 MR. LEHNER: I think your first question is proper. He's going to testify as to what Lilly's view of what these studies say and reflect and the conclusions that Lilly drew from

7 these studies, exactly.

8 THE COURT: Okay. And what's the 9

10 MR. SUGGS: Your Honor, our objection is he's a fact witness. We have no 11 report from him. These --12

13 THE COURT: I understand what the 14 fact is, is he's going to say Lilly --

MR. SUGGS: Your Honor, I have no 15 16 objection --

17 THE COURT: -- looked at the GPRD

study and this is what they thought about it, and 18

Lilly looked at the Allison clinical trial 19

analysis and felt that there -- this is what 20

21 Lilly felt that it showed.

22 MR. SUGGS: Your Honor, if, in

23 fact, the questions are phrased that way and this

24 is what we told the FDA about, you know, what our

conclusions were about the study, I've got no

problem with that. But I don't want him, you

2 know, with a mantle of an expert that, you know, 3

these studies show --

6

4 THE COURT: Well, he's not going to 5 be offered as an expert, for one thing, correct?

MR. LEHNER: No, he's not being

7 offered as an expert. He's --

8 THE COURT: So I'm not going to 9 announce to the jury, as I am asked to do with experts, that I recognize him as an expert in 10

11 anything. You can certainly cross-examine to the

12 extent you need to do that. So I'm not sure -- I

understand what you're worried about, but I

really am not seeing it as something that can't

15 be handled with cross-examination or other 16 clarification.

17 MR. SUGGS: Okay. Very well. 18

THE COURT: And particularly to the

19 extent that you feel that this is going beyond

20 him being a fact witness and giving the Lilly

21 point of view as to these studies or submissions,

then you can come on up and we'll discuss what to

23 do, whether it's going too far over to give the

24 false impression that he's an expert.

MR. LEHNER: Thank you, Your Honor.

Page 225

The next matter. I think, concerns

Dr. Cavazzoni. We have given Plaintiffs some

deposition designations for Dr. Cavazzoni -- it

doesn't appear that she's going to be able to

come live now -- to play in the case. Not to mischaracterize Mr. Suggs' position, but he

7 mentioned to me earlier this morning that because

her deposition was not noticed in the Alaska

9 proceedings, that he would object to our using

10 deposition designations in our case, correct? 11 I'm not sure that I understand that

12 objection, because as the State of Alaska noted

13 earlier on, that they expect to rely on documents

produced in depositions taken in the MDL. Alaska

15 has absolutely no desire to reinvent the wheel or

create unnecessary work for itself or Lilly. And

17 I think it was generally agreed that matters

18 taken in the MDL would be used in this

19 proceeding. She was deposed twice. I think

20 Mr. Allen, in fact, was there at her second

21 deposition. And we would intend to play those

22 deposition designations here.

23 MR. SUGGS: Your Honor, her

24 deposition was not -- Alaska was not noticed in 25 that deposition. At that point in time, I think

Page 226 Page 228

this case was -- was filed in June -- herdeposition was taken in June, was it not, June of2006?

MR. LEHNER: Her deposition was taken twice and I don't remember the dates they were taken. But certainly the other deposition --

8 MR. SUGGS: The latest one -- well, 9 her first one was taken before the State of Alaska even filed suit. The second one, I think. 10 11 was filed about the -- was about the same time. 12 At that point, this case was like in the 13 netherworld, I think, in the federal district 14 court here. It ultimately got remanded back 15 here. The State of Alaska was not represented at that deposition. Mr. Allen was there, but was 17 not representing the State of Alaska. And absent 18 the --

THE COURT: The State wasn't
represented or wasn't -- before you can use a
deposition, doesn't a party who is on the other
side of the particular case you're using it in
have to be represented in some particular way?

MR. LEHNER: Well, Your Honor, I
think -- Your Honor, I think the understanding,

1 recollection of it being noticed.

2

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8

I told Mr. Lehner if there was some agreement, you know, about this that would cover this, I'd be happy to look at it. He also mentioned he thought Your Honor has issued an order about this previously. And I said, look, I'd be happy to look at that too. But I'm not aware of any agreement -
THE COURT: Again, I won't decide

9 10 this now. If the parties -- if you want to use the deposition in this proceeding and it wasn't 11 noticed for this proceeding, if there's an 13 agreement, if I issued an order, if there's 14 anything like that that permits it, then I'll 15 allow you to do it. But you're going to have to convince me that there's some basis for Alaska 17 having either waived any objection they have that 18 it wasn't noticed for that proceeding, or that 19 they were noticed and -- for the proceeding. And 20 so why don't you give me something in the

21 morning.
22 MR. LEHNER: That's why I raised
23 it, so we could know and prepare something for
24 you, and we will.

THE COURT: Yes.

Page 227

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Page 22/

1 if I'm not mistaken, was that the work that had

been done in the MDL, in part because these

3 attorneys have been involved in this work from

4 the very beginning, would be used here so there

wouldn't be a need to reinvent the wheel. Andthe fact that the State of Alaska, I don't think,

wasn't participating in the depositions of Mr. --

wasn't participating in the depositions of Mr. --Dr. Beasley and the other depositions that have

been played here. We certainly were there as

10 Lilly, of course. But I think it would be -- I

11 think it was clearly the understanding --

THE COURT: But what's the process of noticing these depositions in the MDL? Do you designate there what it's being used for and in which cases?

which cases?
 MR. SUGGS: Your Honor, the cover
 page of her deposition transcript -- I don't have

18 it here. Do you have it here? It lists all the parties that are represented there. And -- and,

20 in fact, Lilly did notice -- cross-notice

on fact, Lilly did notice -- cross-notice

21 depositions in State court actions where you can

22 tell right on the front of the deposition

23 transcript that these are the ones where their

24 notice was filed. There is Alaska -- I'm told --

25 is not listed on there at all. We have no

MR. SUGGS: Your Honor, I'd also

Page 229

point out that Dr. Cavazzoni was not on the

3 original deposition designations which were due,

4 like, a month ago as well.

5 MR. ALLEN: And there's one other 6 thing, since it's on the record that I attended.

7 Your Honor, I think I had been hired by Mr. Ken

8 Bailey in Houston, Texas approximately two weeks

9 before that to assist him with his personal

10 injury matters. I wasn't hired by the State of 11 Alaska until like -- I can't -- you know.

11 Alaska until like -- I can't -- you know, 12 whatever day you signed the pro hoc --

THE COURT: I understand. The

14 question is going to be -- I mean, the rule15 allows depositions to be used under certain

16 circumstances, but one of the critical things is

17 that the other side gets to be present and

18 participate at the deposition. And what I'm

19 hearing is, at least on that initial threshold,

20 that wasn't met in this case. Whether there were

21 other orders, I don't remember, and whether -- or

22 whether there were other agreements, I don't

23 know, and so you can let me know if that's the

24 case.

I guess the second question, which

Page 230 Page 232

1 probably I'll just let everybody know, if you meet the first threshold, the noticing of the deposition -- the of the deposition probably isn't going to bother me that much.

MR. LEHNER: That's why I raised it, Your Honor. Thank you. We'll prepare you something.

THE COURT: So we'll -- I'll just wait and see what you give me on that.

7 8

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And then as to these documents, I think we'll -- I'll allow them subject to what 11 12 we've just discussed.

13 And then I'll get jury instructions tomorrow. We're going to start with Dr. Baker tomorrow -- or we're going to start with --15

16 MR. LEHNER: We're going to start 17 with some deposition --

THE COURT: Depositions tomorrow. 18 19 And then go to --

20 MR. LEHNER: Dr. Baker.

21 MR. ALLEN: Your Honor, since we

22 have time -- do you have anything? I'm sorry.

23 MR. LEHNER: I do not have anything 24 else.

25 MR. ALLEN: Okay. I want to offer

Page 231

25

1

1 an exhibit into evidence, Your Honor. I would offer 3860, Your Honor, which I've used with

their witness. It's a Lilly document, from their

files, and I'd like to offer 3860.

MR. LEHNER: Your Honor, I thought the State had closed its case. I don't think

it's time to be offering any evidence. I haven't

seen that document. It wasn't on, I think, their initial exhibit production, but it may or may not

10 have been. But the real point is that the case

11 is closed on the State's side.

THE COURT: Well, can't the witness in cross-examination offer a document? But the

14 question is, you don't have cross-examination 15

here; you're just offering the exhibit. So it's

16 not like you're using this for cross-examination

purposes and offering it and having authenticated

it. You're just giving us an extra exhibit,

19 which kind of is your case in chief. 20

MR. ALLEN: Well, you know, I'm --

21 Your Honor, I tend to disagree with you on this 22 level. But you and I just don't see eye to eye

23 on this, and I think I've been over it with you.

24 THE COURT: Yeah. I mean, I will

25 tell you, and I don't think we see eye to eye. I do have somewhat of an aversion to sort of like

2 just giving jurors documents where we haven't had

3 any witness to testify about the documents.

4 MR. ALLEN: Right. Right. But, 5 obviously, I mean, you and I have agreed 6 to dis- --

7 THE COURT: That may be my little 8 quirk, but --

9 MR. ALLEN: Right. You know, 10 Your Honor, I respect this Court. You know I do.

11 But when a witness such as Dr. Kahn

gets up there and testifies about weight gain

being widely known, and he's been hired by the

14 Defendants and given, quote, every relevant

15 document, and then I'm able to show that he

16 wasn't given this document, it goes to

17 impeachment of the witness and it is directly --

18 and it goes to the credibility of the Defendants.

19 He's testified -- he prepared a report, spent 30

20 hours, was paid \$18,000, and they didn't give him

21 that document.

22 THE COURT: Again, as I recall the 23 testimony, he couldn't really say whether this

24 document was given to him.

MR. LEHNER: Exactly.

Page 233

THE COURT: I do agree with you.

The fact that a specific document, that he can

say, I wasn't given this document, that would

make it at least relevant for that purpose.

5 MR. ALLEN: What if he said he was given the document? If he was given the

document, it would be relevant. And so by giving

the middle answer, which I don't know one way or

9 the other. You escape -- if he says he was given

10 it, you're entitled to show it. If he says he

11 wasn't given it, you're entitled to show it. But

12 if he gives the middle answer, which is I don't

13 know, I can't show it? That doesn't make -- I

14 mean, with all due respect to the Court, it

15 doesn't make any sense.

16 THE COURT: I understand your

17 point, and let me hear from Mr. Lehner. 18

MR. LEHNER: Well. Your Honor, I 19 think that's the ultimate sort of point about the

20 laying a foundation and authenticating the

21 document. He says, I don't know. If he says, I 22

wasn't given the document, then it really goes to 23 whether or not it was relevant and whether or

not -- you know, you can bring any document and 24

25 say, I wasn't given this and then try to move

Page 236 Page 234

1 that into evidence here. You know, he was not able to sort of say whether I've seen this 3 document or not. It was an honest answer, and it has no bearing -- it doesn't lay any basis for which to make it now part of their case and enter it into evidence.

7 THE COURT: I'm going to keep this 8 document out for the time being. Again, if 9 there's some Lilly witnesses that are Lilly people that we actually hear from live, then 10 we'll see what happens. 11

12 MR. ALLEN: Your Honor, can I mark 13 it and make it a bill?

THE COURT: You can. You 14 15 definitely can do that.

16 MR. ALLEN: I want to mark this and 17 make -- just so the record is clear -- because I may have missed something, but I thought this man 18 19 was up here talking about weight and he had known 20 it since college or medical school. And the 21 document, 3860, was handling weight. And the

page that I'm interested in is Eli Lilly training 23 their sales reps, which Ms. Gussack said on 24 opening statement -- here's what it says: Weight gain with Zyprexa is due to increased appetite,

1 that these people are not telling the truth. I

respect the lawyers, but I'm talking about the

3 company. The State of Alaska hired me to prove 4 that. And when this document proves it, this man

5 looked at three folders of, quote, marketing

documents, and he gets away with saying I don't

7 know one way or the other. If he says yes, I get it in; if he says no, I get it in --

9 THE COURT: I think you got in the 10 discussion of -- you didn't get in the document

11 yet, but you've gotten in the questions about

what was on the document, as I recall.

13 MR. ALLEN: Well, that's one thing and a series of questions as opposed to a 14 15 document I can show the jury at closing.

16 THE COURT: I understand what

17 you're saying, but for now I'm keeping it out. 18 MR. ALLEN: All right. Let me mark

19 it.

20 THE COURT: You may, though -- this 21 is totally without prejudice to renewing your

motion at the end of the day. And even if we

23 don't have a Lilly witness, I'll let you ask me

24 one more time when the case is --

25 MR. ALLEN: Yes, sir. I appreciate

Page 237

Page 235

1 not in metabolic response, i.e., the pill does

not equal weight gain. Now, he's testified he

asked for everything remotely related to this

topic. He testified that he reviewed those documents in 30 hours. The Court has indicated,

and I respect this Court, that if he had said, I have not reviewed it, I could get it in. If he

8 said he --

9 THE COURT: For that purpose. 10

MR. ALLEN: Right. If he says he 11 reviewed it, I could get it in as a basis of his 12 opinion. But I guess if I'm unlucky enough

13 to have the man say, I don't know one way or the

14 other, that keeps it out. I just don't believe

that's the evidence rule. I can't believe if he 15

says no, it comes in; if he says yes, it comes

17 in; if he says I don't know, it doesn't come in.

18 THE COURT: Well, again, to the

19 extent -- you're not just really offering it for 20 I've known about weight gain since law (sic)

21 school. You want to get in very specific things

22 and we both understand that. And I --

23 MR. ALLEN: I want to go get in the 24 very fact that he's not telling the truth and the 25 company's not. That's my position in this case,

1 it.

2

12

25

THE COURT: -- close to going to

3 the jury.

4 MR. ALLEN: Right. 3860, I'm going

to mark AK3860. That's what it says, right?

6 MS. RIVERS: Yes.

7 MR. ALLEN: And I'm going to submit 8 it to the Court and have it rejected at this time

9 and I want the Court to have it for the record.

10 THE COURT: I will -- the number is 11 3860?

MR. ALLEN: Yes, sir.

13 THE COURT: Okay. 3860 for the

14 time being is not admitted; it is offered.

15 Again, you can renew that if there's an

appropriate witness to renew it with, and I will

17 also let you take another crack at me at the end 18 of the case, depending on who the witnesses are

19 that have shown up.

20 MR. ALLEN: You've been -- thank 21 you, Your Honor. We disagree, but you've been 22 very patient and I appreciate your patience.

That's it. That's all I have.

23 24 THE COURT: Anything else?

MR. LEHNER: No. Thank you, Your

	- 222	
	Page 238	
	Honor.	
2	THE COURT: Then, we'll be off	
3	record.	
4	THE CLERK: Please rise. Superior	
5	Court in the State of Alaska is off record.	
6	(Trial adjourned at 1:26 p.m.)	
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	Page 239	
1	REPORTER'S CERTIFICATE	
2		
3	I, SANDRA M. MIEROP, Certified Realtime	
5	Reporter and Notary Public in and for the State of Alaska do hereby certify:	
6	That the proceedings were taken before me at	
7	the time and place herein set forth; that the	
8	proceedings were reported stenographically by me	
9	and later transcribed under my direction by computer	
10	transcription; that the foregoing is a true record	
11 12	of the proceedings taken at that time; and that I am	
13	not a party to, nor do I have any interest in, the outcome of the action herein contained.	
14	IN WITNESS WHEREOF, I have hereunto subscribed	
15	my hand and affixed my seal this 20th day of March,	
16	2008.	
17		
18		
19	SANDRA M. MIEROP, CRR, CCP	
20	Notary Public for Alaska	
	My commission expires: 9/18/11	
21	-	
22		
23		
24		
25		