

REPORTER'S RECORD
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CAUSE NO. D-1-GV-04-001288

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STATE OF TEXAS,) IN THE DISTRICT COURT
ex rel.)
ALLEN JONES,)
Plaintiffs,)

VS.)

JANSSEN, LP, JANSSEN)
PHARMACEUTICA, INC.,) TRAVIS COUNTY, TEXAS
ORTHO-McNEIL)
PHARMACEUTICAL, INC.,)
McNEIL CONSUMER &)
SPECIALTY)
PHARMACEUTICALS, JANSSEN)
ORTHO, LLC, and)
JOHNSON & JOHNSON, INC.,)

Defendants.) 250TH JUDICIAL DISTRICT

JURY TRIAL

On the 18th day of January, 2012, the following
proceedings came on to be heard in the above-entitled
and numbered cause before the Honorable John K. Dietz,
Judge presiding, held in Austin, Travis County, Texas:

Proceedings reported by machine shorthand.

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I N D E X

DAILY COPY VOLUME 7

JANUARY 18, 2012

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1 Q. In any case, is there a space on this form
2 where there's a box with the heading next call objective
3 or OBJ?

4 A. Yes.

5 Q. And could you read that into the record,
6 please?

7 A. Yes. It's next call, "Discuss using Risperdal
8 Oral/M-Tab in adolescent and children patients. Review
9 autism study and discuss how Risperdal should be used in
10 his patient population."

11 Q. All right. And then -- and who would be the
12 individual responsible for making an entry like that in
13 a form like this?

14 A. The sales rep who made the call.

15 Q. In this case, Laura Haughn?

16 A. Yes.

17 Q. All right. Well, I was asking if the next page
18 relates to a call on Dr. George Groves.

19 A. Yes, it does.

20 Q. With a call date of March 29th, 2004?

21 A. The call date. Top -- oh, okay. I've got it.
22 Yes, April -- March 29th, 2004.

23 Q. All right. And would you read the entry that
24 Ms. Haughn made in the next call objective box as it
25 relates to Dr. George Groves?

1 A. "Review MOA of Risperdal M-Tab and why it's
2 ideal for children and adolescents."

3 Q. Now, if I understood you correctly, in the case
4 of both Dr. Hu and Dr. Groves, they treated both
5 children and adults in their practice; is that true?

6 A. Yes.

7 Q. In the entries that you've just read on these
8 two pages concerning the next call objective, does the
9 call objective appear to be focused on the kids or on
10 the adults?

11 A. It appears to be on the child and adolescent
12 patient type.

13 Q. I'm not going to go through all these with you,
14 Mr. Jones, but let me ask you to skip over a couple of
15 pages, and we see another physician's name, a Dr. Alice
16 Mao. And I'm looking at the page that has a number at
17 the bottom that ends with the three numbers 639. And at
18 the top of the middle of the page, do you see a call
19 date of April 12, 2004?

20 A. Yes.

21 Q. Do you know Dr. Alice Mao?

22 A. Yes.

23 Q. And who is she?

24 A. She is a psychiatrist here in the Houston area
25 that worked for Harris County MHMR and also had a

1 private practice.

2 Q. Does she treat children in her -- in her
3 practice?

4 A. She also treats children in her practice, but
5 when she's at the MHMR, Harris County MHMR, off
6 Navigation, she -- she saw adults there.

7 Q. All right. Do you see the box for the next
8 call objective relating to Dr. Mao?

9 A. Yes.

10 Q. "Discuss why Risperdal is better choice for
11 children and adolescents than Abilify. Point out weight
12 gain and side effects associated with Abilify. Get her
13 commitment to use Risperdal as first line treatment
14 choice for children and adolescents."

15 Did I read that correctly?

16 A. Yes.

17 Q. All right. And again, while Dr. Mao may treat
18 both children and adults in the course of her practice,
19 which population does it appear this note was focused
20 on?

21 A. Child and adolescent.

22 Q. Did Dr. Alice Mao serve as a speakers bureau
23 speaker for Janssen?

24 A. Mm-hmm. Yes.

25 Q. And when she did that, would she be compensated

1 for doing so?

2 A. Yes, honorarium, you know, fair market value
3 honorarium.

4 Q. Okay. Two pages. We're on now the page that
5 ends with the numbers 208. Do you see that page?

6 A. Yes.

7 Q. Now, the call date here is April 13th, 2004; is
8 that right?

9 A. Correct.

10 Q. The entry on the next call objective box reads
11 "Discuss autism indication and why Risperdal is best
12 choice in treating symptoms."

13 Did I read that sentence correctly?

14 A. Yes.

15 Q. Let me ask you to go to the next page after
16 that, the one ending in the numbers 594.

17 A. Okay.

18 Q. Here the doctor is in Beaumont, Dr. Enrique
19 Del Campo.

20 A. Yes.

21 Q. Was he a physician who treated children in the
22 course of his practice?

23 A. Yes, he had children and adults, correct.

24 Q. All right. The -- in looking at this note, it
25 starts the same, "Review why Risperdal is best choice

1 for bipolar in mixed episode patients. Go over why
2 Abilify shouldn't be used in kids (weight gain, side
3 effects and lack of dose efficacy) as a first line of
4 treatment. Review Risperdal's efficacy in treating
5 autistic children and adolescents."

6 Did I read that correctly?

7 A. Yes.

8 Q. First of all, can we agree that prior to the
9 first time Risperdal received an indication by the FDA
10 for use in children, that promoting Risperdal for use in
11 kids would be an off-label, not an on-label promotion;
12 is that true?

13 A. Correct.

14 Q. In the course of your work as a district
15 manager, was Laura Haughn the only one of your
16 salespeople who called on child and adolescent
17 psychiatrists?

18 A. No, she was not the only one.

19 Q. If I'm understanding you correctly, each sales
20 representative in each district gets a target list.

21 A. Correct.

22 Q. And a target list that's prepared by the
23 company?

24 A. Correct.

25 Q. And so in the case of Ms. Haughn and the

1 physicians she's called on here who practice child and
2 adolescent psychiatry, is it your belief that she was
3 calling on physicians she was instructed to call on?

4 A. Correct.

5 Q. But let me show you what has been marked
6 previously in this deposition -- I'm sorry, in this case
7 as Exhibit 1176. And I believe you'll see that this is
8 a call note with a call date of April 2, 2003; is that
9 correct?

10 A. Yes.

11 Q. And was Debra Crain a part of your team here in
12 Houston?

13 A. Yes.

14 Q. This particular call note is one that relates
15 to a call on a physician named Dr. Sonja --

16 A. Randle.

17 Q. Okay. And in the box headed next call
18 objective, let me read the entry, then I'll ask you some
19 questions about it. "Invitation to April 17 program -
20 encouraged her to use Risperdal oral solution for the
21 kids she is seeing."

22 Did I read that correctly?

23 A. Yes.

24 Q. Exhibit 388 is entitled on the front page of
25 this exhibit "Sales Training CNS"; is that right?

1 A. Yes.

2 Q. All right. Is -- do you believe this is a
3 document that you've seen before?

4 A. Yes.

5 Q. You testified earlier that -- I believe you
6 said it was about 1 percent of the population who had
7 been diagnosed with schizophrenia at any given time. Is
8 that -- did I understand you correctly?

9 A. Correct.

10 Q. Now, if one were seeking to expand the market
11 for Risperdal, if its only use is in patients with
12 schizophrenia -- schizophrenia as a diagnosis, whether
13 higher functioning or lower functioning, it's still
14 1 percent, true?

15 A. True.

16 Q. If all you're talking about is getting a bigger
17 chunk of the 1 percent, would you think that would --

18 A. Got it.

19 Q. -- constitute the fastest growing market for
20 this drug?

21 A. Can't be a \$2 billion product and 1 percent
22 marketing.

23 Q. Let me ask you, if you would, to skip over to
24 the page that ends in the numbers 495. Do you see on
25 this page what appear to me to be prints of information

1 from a slide presentation?

2 A. Yes.

3 Q. And the title of the presentation on these
4 pages is what, Mr. Jones?

5 A. "Child & Adolescent Physicians."

6 Q. Okay. The next bullet point under that says
7 "Provide treatment to patients who are under the age of
8 18." And those would be child and adolescent patients,
9 true?

10 A. Yes.

11 Q. The next bullet says, "Most are diagnosed with
12 a 'behavioral disorder,'" and that's in quotation marks,
13 "or a mood disorder."

14 Did I read that correctly?

15 A. Yes.

16 Q. Skipping over to the next page, the top slide
17 has as its first bullet "Key Issues" and below that in
18 all caps followed by several exclamation points "No
19 indication."

20 A. Mm-hmm.

21 Q. And what's that referring to?

22 A. Risperdal was not indicated for this patient --

23 Q. All right.

24 A. -- population.

25 Q. The next bullet point below that is called "Key

1 Strategies." Do you see that? "Key Strategies"?

2 A. Yes.

3 Q. All right. And the first of those is to "Sell
4 on symptoms not diagnosis."

5 Did I read that correctly?

6 A. Yes.

7 Q. And what does that mean to you?

8 A. Focus on the associated symptoms of
9 schizophrenia.

10 Q. What I understand you to be saying is that the
11 sales representatives calling on the physician who
12 primarily treats children and adolescents could talk
13 about treating the symptoms of those children if the
14 symptoms were ones that a schizophrenia patient might
15 have of a mood and anxiety type; is that what you're
16 saying?

17 A. Yes.

18 Q. Let me show you what's been marked as
19 Exhibit 2395, starting with Ms. Haughn's e-mail. And
20 again, Ms. Haughn is someone who was a member of your
21 team in Houston; is that correct?

22 A. Yes.

23 Q. And is this the same individual whose call
24 notes we were looking at earlier in the deposition?

25 A. Yes.

1 Q. And so do you gather from this e-mail that she
2 had attended an advanced sales training course?

3 A. Yes.

4 Q. And then had also somehow been in communication
5 with Dr. Alice Mao?

6 A. Yes.

7 Q. She goes on -- and I'm not going to go through
8 all of this information about Abilify, but if you'll
9 look at the second category under the Abilify
10 description, do you see where it says "Abilify's
11 Targets"?

12 A. Yes.

13 Q. And the first bullet point on that, let me read
14 it, and then I'll ask you a question about it.
15 "Children and adolescents (trying to niche this
16 market)."

17 Did I read that right?

18 A. Yes.

19 Q. The -- do you recall that in about this time
20 period that Abilify was a competitor product to
21 Risperdal?

22 A. Mm-hmm. Yes.

23 Q. Now, skipping over to the last page of this
24 exhibit, after all the bullet points Ms. Haughn says:
25 "I hope this information is helpful in your selling

1 efforts."

2 Did I read that correctly?

3 A. Yes.

4 Q. "Please contact me if you have any questions
5 about the information I provided."

6 "Don't use in selling situations, just for
7 your educational purposes."

8 Did I read all that correctly?

9 A. Yes.

10 Q. And there's a P.S. She says, "Let's beat the
11 everliving, everloving hell out of Abilify," exclamation
12 points.

13 A. Yeah.

14 Q. Did I get that right?

15 A. You got it.

16 Q. All right. When you then wrote your e-mail
17 dated the 25th of May of 2004, to whom -- to which group
18 were you addressing your e-mail?

19 A. To the management team.

20 Q. All right. And you copied Laura Haughn?

21 A. Yes.

22 Q. All right. And in your e-mail, did you
23 compliment her on doing a nice job?

24 A. I sure did.

25 Q. We looked at this organization chart early on,

1 and so we've got -- all the individuals that you
2 highlighted on Exhibit 2394 get involved in this e-mail
3 chain somewhere along the way if I'm reading it right;
4 is that right?

5 A. That's right.

6 Q. Okay. Mr. Meeks' e-mail says "RBD team."
7 That's the regional business directors; is that right?

8 A. Yes.

9 Q. "Here are some good tips regarding selling
10 Risperdal vs. Abilify from the Advanced Selling Skills
11 class."

12 "Abilify is gaining ground primarily with"
13 child and adolescent psychiatrists "and we need to make
14 sure Risperdal is growing with this customer segment.
15 Let's make it happen!"

16 Did I read that correctly?

17 A. Yes.

18 Q. At any point in this e-mail string did -- was
19 there any criticism leveled at the idea of targeting
20 child and adolescent psychiatrists?

21 A. No.

22 Q. With respect to speakers who -- to speak about
23 the drug Risperdal, was it ever part of your charge as a
24 district manager to talk with individuals about becoming
25 speakers on behalf of Janssen?

1 A. Yes.

2 Q. What was the process of training a speaker to
3 speak about Risperdal?

4 A. The process of training a speaker pretty much
5 was you identified the speaker. Obviously, you know,
6 you want someone that is credible within the
7 marketplace, has influence within the community, and
8 then they would go to speaker training that was led by
9 the brand marketing team, and sales would not be a part
10 of that though.

11 Q. Was there a time when speakers were tabbed to
12 interface with Texas Medicaid?

13 A. Yes.

14 Q. Did I understand you to say that they would
15 speak in Austin to individuals and in addition speak to
16 individuals at Texas Medicaid?

17 A. Yes.

18 Q. Were they ever asked to speak to either the --
19 to the P&T Committee?

20 A. Yeah. They -- they would go down to -- while
21 they're at the -- the -- in Austin for the speaker
22 program, then they would that morning be asked to go
23 talk in front of the DUR board on behalf of Janssen as a
24 high, you know, Medicaid prescriber and advocate for
25 Risperdal or for, you know... But they would do this,

1 you know, for other products as well.

2 Q. With respect to -- and -- and you talked about
3 the DUR board. Were there -- did they speak also to the
4 P&T committee or was it exclusively the DUR board?

5 A. On that Saturday morning it would just be the
6 DUR board. But, you know, some of the DUR board members
7 are also on the P&T committee, too.

8 Q. Was this something that was encouraged by other
9 levels of management within Janssen over you?

10 A. It was a strategic part of the way we would,
11 you know, operate in order to gain access for Risperdal
12 or for, you know, Janssen branded products, Invega,
13 you know, Risperdal CONSTA and so forth.

14 Q. Do you know the name Valerie Robinson?

15 A. Yes.

16 Q. Okay. Can you tell me, have you ever
17 participated in a conference call with management at
18 Janssen where her name was discussed?

19 A. Absolutely.

20 Q. And can you give us an instance where that
21 occurred?

22 A. Sure. The -- she was part of the P&T and also
23 the DUR board for Medicaid of the State of Texas. And
24 what we would try to do was try to get as much
25 information prior to the meeting to key people that sat

1 on the DUR board who help make the decisions, and so
2 none of the sales would make any calls on her; however,
3 what would -- like Peter Dorson, our MSL, would go and
4 visit with her just to give her, you know, product
5 updates and answer any questions that was needed within
6 lieu of trying to ensure that, you know, she would be an
7 advocate for access --

8 Q. Okay.

9 A. -- for Risperdal Oral.

10 Q. What were you specifically told to do from your
11 higher-ups with respect to contact of Valerie Robinson
12 by your -- by providers within your region?

13 A. Well, you know, it would -- you know, just if
14 you can get your providers to show any support,
15 you know, any phone call, written communication or any
16 type of communication just letting her know the need
17 for, you know -- you know, for our product.

18 Q. Why was Medicaid a target of your sales
19 efforts?

20 A. I mean, Medicaid is a -- a big payer in the --
21 you know, mental illness. And of all the payers --
22 you know, you have Medicaid and you have Medicare
23 Part D, third-party payers such as Aetna, United
24 Healthcare, so forth. I mean, Medicaid was -- was a
25 very targeted and -- you know, bucket of patients that

1 our patient volume would -- or patient population would
2 have high volume in terms of that payer, so that's where
3 we targeted our selling efforts.

4 Q. Was EPS a recognized side effect during the
5 time you were promoting Risperdal of Risperdal?

6 A. Yes.

7 Q. Okay. What were you told as far as messaging
8 to deliver regarding EPS as it relates to placebo?

9 A. That it was equal to placebo.

10 Q. Okay. Is that a message that you communicated
11 to doctors within your region?

12 A. Yes.

13 Q. Is that a message that was communicated by
14 sales representatives under you while you were a
15 district manager at Janssen?

16 A. Yes. And the doses that -- typically that was
17 referenced was that, you know, the dose is four
18 milligrams below because it had less dopamine occupancy,
19 so that was comparable to equal to placebo for the
20 patient on those doses, if I recall.

21 Q. During your tenure at Janssen Pharmaceutical,
22 were you ever told of a study that was internally coded
23 as RIS-INT-35?

24 A. No.

25 Q. All right. This, Mr. Jones, is something

1 that's been previously marked as 1917. Okay. And I'm
2 going to read some parts of it. First of all, the date
3 of the -- first, it's -- it's entitled the "Voicemail
4 Message Confirmation" and dated Friday, September 26,
5 2003; is that right?

6 A. Mm-hmm.

7 Q. Okay. And it says, "Good afternoon everyone.
8 This is Mike with a message to the entire CNS sales
9 force on Friday with copies to our sales and marketing
10 managements teams."

11 First of all, will you show us on the
12 exhibit that's been previously marked as 2394 where
13 Mr. Walsman sits on the Janssen psychiatry organization
14 chart?

15 A. He's right -- he and Jeff Bailey are national
16 sales directors for the east and west regions.

17 Q. Now, he says this is a message to the entire
18 CNS sales force. Would that have included you?

19 A. Yes.

20 Q. And let's go down to the second paragraph. "As
21 you know, the FDA recently sent us a request for a
22 Risperdal label revision to address the issue of
23 diabetes. This request was sent to all companies who
24 are currently marketing an atypical antipsychotic. We
25 continue to be in discussions with the FDA regarding

1 this issue and continue to believe the scientific
2 evidence shows a difference in the incidence of diabetes
3 among the different atypical antipsychotics."

4 Did I read that correctly?

5 A. Yes.

6 Q. The next sentence says, "The data does not show
7 an association between Risperdal and an increased risk
8 of diabetes."

9 And was that a message that you heard at
10 the time that this voicemail was sent by Mr. Walsman?

11 A. Yes.

12 Q. Okay. Was this a consistent message within
13 Janssen regarding the issue of diabetes during that
14 time?

15 A. Yes.

16 Q. It also goes on to say, "However, the data does
17 suggest a greater association with some of the other
18 products."

19 Was that also a message that was delivered
20 to you in September of 2003?

21 A. Yeah, we -- we would always want to
22 differentiate our safety profile from the competition.

23 Q. Including on the issue of diabetes?

24 A. Yes.

25 Q. Is that something that your sales staff

1 communicated within the Houston area to physicians here?

2 A. Mm-hmm.

3 Q. Is that a yes?

4 A. Yes.

5 Q. Okay. With respect to Risperdal being --
6 having a low risk of diabetes and -- and diabetic
7 ketoacidosis, was that a message that you were
8 instructed to deliver to doctors within your area or
9 region?

10 A. We had to deliver that on every call.

11 Q. And did you, sir, do so?

12 A. Yes.

13 Q. Now, I want you to pick back up the FDA letter
14 authored by Dr. Mahmoud, and that's Exhibit 686;
15 correct?

16 A. Yes.

17 Q. Now, approximately how -- how long after
18 Mr. Walsman's voice blast was that letter sent by
19 Ramy Mahmoud?

20 A. How long after?

21 Q. Yes, sir.

22 A. It was -- the voicemail was Friday,
23 September 26, 2003, and Ramy Mahmoud sent the letter
24 November 10, 2003, I mean. So Friday, September 26th,
25 2003, voicemail was out -- sent out by Mike Walsman, and

1 then two months after that the letter went out.

2 Q. How often did the issue of diabetes come up
3 with physicians within the Houston area during the
4 September to January 1st, 2004 time period?

5 A. On every call.

6 Q. Okay. Mr. Jones, this is an exhibit that's
7 previously been marked in the Laura Haughn deposition as
8 2110. What's the date of the -- what's the date listed
9 on this call note on the first page of Exhibit 2110?

10 A. May 7, 2004.

11 Q. Okay. And I want to ask you if you would,
12 please, to tell me who was the doctor that is referenced
13 there?

14 A. The doctor?

15 Q. Yeah, or the account.

16 A. Yeah, the account is Burke South.

17 Q. Okay. And what is Burke South, sir?

18 A. That's an MHMR in Lufkin, Texas.

19 Q. And can you read for me the substance of what's
20 listed in the next call objective portion?

21 A. It says, "Touch on how Risperdal addresses
22 symptoms head-on instead of just sedating products with
23 Seroquel and without weight gain or risk of diabetes
24 with Zyprexa."

25 Q. Is that a similar message to the one that

1 Mr. Walsman communicated early in September of '03?

2 A. Yes.

3 Q. Okay. I'm going to ask you to turn, if you
4 would, please, to -- go two pages back, if you would,
5 and ask you to identify what that document is, sir.

6 A. It's another call note from Seibel.

7 Q. And can you tell us who -- and what the date of
8 the call note is, sir?

9 A. The date of the call note is May 7, 2004.

10 Q. Okay. And let me ask you, if you would,
11 please, to read what's listed in the next call
12 objective.

13 A. "Touch on how Risperdal addresses symptoms
14 head-on instead of just sedating products with Seroquel
15 and without weight gain or risk of diabetes."

16 Q. Okay. So she's -- it appears that's the same
17 narrative as listed in the previous call objective,
18 correct?

19 A. Yes.

20 Q. Okay. I'm going to ask you to turn, if you
21 would, please, to the next document, which is 087, sir.

22 A. Okay.

23 Q. And I want to ask you who is the sales
24 representative listed there?

25 A. Laura Haughn.

1 Q. And can you tell me the physician she's calling
2 on there, please?

3 A. James Buckingham.

4 Q. Okay. And can you tell me the date of the
5 call?

6 A. May 7, 2004.

7 Q. And then if you could read for me the next call
8 objective portion.

9 A. "Touch on how Risperdal addresses symptoms
10 head-on instead of just sedating products with Seroquel
11 and without weight gain or risk of diabetes with
12 Zyprexa."

13 Q. Now, you mentioned that you've met with
14 Mr. Sweeten and Mr. Jacks four times before today; is
15 that correct?

16 A. Yes.

17 Q. What did y'all discuss during that meeting?

18 A. Just my background and also, you know, just
19 promotion of Risperdal.

20 Q. Okay. Well, why did you meet with them at all?

21 A. Well, why I met with them at all, because of
22 this situation with Risperdal and my, you know,
23 involvement with Janssen. That's pretty much, you know,
24 the reason. And when I received calls from the J&J
25 legal department, you know, I just -- didn't really know

1 where to go. They just felt more comfortable, you know,
2 in terms of what they wanted me to do compared to what
3 J&J was wanting me to do, if that makes sense.

4 Q. Well, what -- what did -- what did J&J want you
5 to do?

6 A. Well, from my understanding -- and I can't
7 remember the young lady's name I spoke with back in the
8 summer of 2009, but they wanted to meet with me and I
9 would -- to get compensated for my time, to discuss the
10 sales and marketing of Risperdal in the state of Texas.
11 And I thus have some, you know, lawyer friends and kind
12 of asked them, threw that, you know, on the wall to them
13 to see what they thought. It was like, well, you know,
14 you would probably be better off just not getting
15 represented by your former company.

16 So then I didn't do anything for a long
17 time. Didn't contact, you know, J&J legal or wasn't
18 contacted by this party either. So I just, you know,
19 went on in my day thinking, hey, good, cool, I won't
20 get -- I don't have to do anything with this. And then
21 I received a call possibly just to, you know, visit
22 about this opportu -- you know, what occurred and my --
23 learn more about my background and so forth.

24 Does that answer your question?

25 Q. I mean, you wouldn't have had any objection

1 meeting with me before your -- your deposition, would
2 you have?

3 A. For free, no. But, you know, just the way it
4 was presented, you know, in the first -- when it was --
5 the situation presented to me, it was more that I had to
6 do this and, you know -- if it could have been -- if it
7 would have -- was presented differently, that would have
8 been an opportunity.

9 Q. Okay.

10 A. But the way it was presented, to be honest with
11 you, it was quite offensive to the point where I had to
12 do something because I was formerly employed there.

13 Q. Uh-huh.

14 A. You know, just didn't align with what --
15 you know, how I wanted to handle the situation, so
16 that's why I showed up today as just me.

17 Q. Did you go over any documents with Mr. Sweeten
18 or Mr. Jacks?

19 A. No. Just, you know, answered, you know,
20 questions about Risperdal, about promotion, my
21 background. Pretty much that was the gist of our
22 discussions.

23 Q. First of all, I think it's been your consistent
24 testimony, but you tell me if I've got this wrong, that
25 you as a sales agent and the sales agents who worked

1 under you never delivered any message to customers that
2 weren't approved by the company; is that true?

3 A. Correct.

4 Q. All right. Now, you and I went over some but
5 not nearly all of the call notes in Exhibit 2113
6 containing Ms. Haughn's call notes; is that correct?

7 A. Correct.

8 Q. Now, in this next call objective, the statement
9 appears: Go over why Abilify shouldn't be used in kids.
10 Review why Risperdal is best choice for children and
11 adolescent patients. Review Risperdal Oral Autism
12 indication and 72 milligram Concerta dose.

13 Did I read all of that correctly?

14 A. You did, yes.

15 Q. All right. I want to move from that call note
16 to the next one just behind it, the page that ends with
17 the numbers 567. And here the call date is May 3rd,
18 2004 with an updated date of May 15th, 2004; is that
19 right?

20 A. Correct.

21 Q. Specifically the statement is "Go over why
22 Abilify isn't the best option for treating kids and why
23 Risperdal is the first line choice."

24 Did I read that right?

25 A. Yes.

1 Q. The next mention of Abilify that I see is about
2 three pages beyond, and this is a call note -- the page
3 number -- or the last three numbers are 103. Are you
4 with me?

5 A. Yes.

6 Q. And the physician here is Dr. Del Campo in
7 Beaumont; is that right?

8 A. Dr. Del Campo, yes, sir.

9 Q. "Identify why Abilify isn't the best option for
10 treating children and adolescents due to negative side
11 effect profile and unpredictable efficacy."

12 Did I read that sentence correctly?

13 A. Yes, you did.

14 Q. Now, the call notes that I just went over with
15 you from Ms. Haughn that mentioned Abilify all had a
16 call date in April or May of 2004; is that right?

17 A. Correct.

18 Q. In Dave Meek's message in late May of 2004 to
19 the regional business directors, he's forwarding to them
20 some tips regarding selling Risperdal versus Abilify
21 from the advanced selling skills class, true?

22 A. Correct, yes.

23 Q. Is there anything in Mr. Meek's e-mail to the
24 regional business directors that suggests that he
25 disapproves of selling Risperdal against Abilify in the

1 child and adolescent population?

2 A. No.

3 Q. When he says, "We need to make sure Risperdal
4 is growing with this customer segment; let's make it
5 happen," does that suggest approval or disapproval of
6 promoting Risperdal against Abilify to child and
7 adolescent psychiatrists?

8 A. It approves.

9 Q. And Mr. Meek, if I recall the organization
10 chart, was the field sales director; is that right?

11 A. Correct.

12 Q. You said and you've testified in response to
13 questions Mr. Scott Jones asked you, and you repeated it
14 several times, that you did what the company asked you
15 to do and your sales representatives did the same. Did
16 I hear that testimony correctly?

17 A. Correct.

18 Q. Does it appear to you in looking at these call
19 notes that we've just gone over of Mrs. Haughn's in
20 which she's selling and promoting Risperdal versus
21 Abilify for use in the child and adolescent population
22 in 2004?

23 A. Correct. Yes.

24 Q. And if in fact it was September 2006 when
25 Risperdal first received approval from the FDA -- when

1 Janssen first received approval from the FDA to have an
2 indication for the use of Risperdal in children, then
3 all these call notes we've just gone over would be ones
4 selling outside instead of inside the label; is that
5 true or not?

6 A. Based on the dates of approval, yes.

7 Q. Did you ever get the idea based on your
8 communications with the district managers who attended
9 those meetings that the sales representatives who worked
10 in your district were doing anything significantly
11 different in their selling practices from the sales
12 representatives who worked for other district managers
13 in other parts of the country?

14 A. No, there was no difference.

15 Q. Was there an effort to see that the messaging
16 was consistent throughout the country?

17 A. Yes, i.e., through directors, through managers
18 down to the reps.

19 *(Video stopped)*

20 MR. MELSHEIMER: That concludes our
21 presentation of the testimony of Mr. Tone Jones.

22 MR. McCONNICO: Your Honor, the defendants
23 have a presentation.

24 *(Video played as follows:)*

25 **CROSS-EXAMINATION**

1 Q. We've looked at several documents, compilation
2 exhibits consisting of call notes.

3 A. Yes.

4 Q. Do you remember seeing those? We've seen some
5 call notes by Laura Haughn?

6 A. Yes.

7 Q. Debra Crain?

8 A. Yes.

9 Q. And were these both sales representatives who
10 reported to you during your tenure as manager?

11 A. Yes.

12 Q. And in preparing for your deposition, have you
13 talked to any of them?

14 A. No.

15 Q. Have you reviewed their deposition testimony in
16 this case?

17 A. No.

18 Q. So do you know what their explanation was as
19 far as the substance that they've typed in the next call
20 objective box?

21 A. No.

22 Q. So you don't know one way or the other whether
23 or not they're reporting what they said or what somebody
24 else said during a particular sales call?

25 A. Correct.

1 Q. Do you feel like you instructed your sales
2 representatives who reported to you to promote
3 off-label?

4 A. No, I would -- no, I did not ask them to
5 promote off-label.

6 Q. In your experience as a sales representative
7 and district manager at Janssen, did you ever experience
8 doctors telling you that they prefer perphenazine over
9 Risperdal?

10 A. No.

11 Q. How about Haldol? Preferring Haldol over --
12 over Risperdal?

13 A. No.

14 Q. How about Thorazine? Was it your experience
15 that doctors would communicate to you that they
16 preferred Thorazine over Risperdal?

17 A. No.

18 Q. Well, putting aside the quantity of sales, do
19 you think that sales representatives who reported to you
20 acted responsibly in their promotion of Risperdal?

21 A. Yes. They would always execute upon company
22 direction how we were trained to do and how they were
23 trained.

24 Q. Did you ever express any criticism about the
25 direction you received from the company in the -- in the

1 sale of Risperdal?

2 A. No.

3 Q. If you felt that you were being asked to say or
4 do something that was unlawful, would you speak up about
5 it?

6 A. Yes.

7 *(Video stopped)*

8 MR. McCONNICO: Your Honor, that is the
9 end of our tender.

10 MR. MELSHEIMER: Your Honor, at this time,
11 may it please the Court, we'd like to publish to the
12 jury Plaintiffs' Exhibit 1067, which is in evidence as
13 an e-mail between several of the people that Mr. Jones
14 talked about in his deposition.

15 THE COURT: Okay.

16 MR. MELSHEIMER: Thank you, Your Honor.

17 All right. Start at the bottom. This is
18 an e-mail from Debra Crain sent Saturday, January 29th,
19 2005, 6:58 p.m. to Tone Jones, Omar Chivers, Christin
20 Hopkins, Geff Gandy, Joaquin Croslin and Debra Crain.
21 Subject: Concerta 2005 Objectives and Strategy.

22 Houston M Reps, The following attachment
23 contains highlights from the Concerta slides that should
24 have been presented during the district breakout session
25 at the recent national meeting. Due to a time crunch,

1 we did not get to discuss these points. Please take a
2 moment to read through the attachment. As a district
3 tactic, please determine who your top five Concerta
4 targets are (cross-match high APS/ADHD targets). Each
5 time you call on those top five doctors, present
6 Concerta in last position. In other offices, support
7 the efforts of your McNeil Consumer, quote, Concerta
8 rep, unquote, by plastering the office with new
9 promotional materials. Got the picture? Make sure that
10 your focus is in selling Risperdal first, Concerta last.
11 Just a few targets can make a tremendous difference.
12 Partner with your Concerta lead rep as often as you
13 can ... support their efforts ... utilize coupons and
14 support materials to fullest extent ... then get back to
15 selling Risperdal. Got the picture? If questions,
16 please give me a call, Debra Crain, Janssen
17 Pharmaceutica, Senior Psychiatry Division
18 Representative.

19 And then the top e-mail is from Shane
20 Scott on January 31st, 2005, a couple days later.
21 Blake -- to Susan Blake, Kirk Burgess, John Gaston, Todd
22 Pletcher, Larry Sears, Clifford Smith and Connie
23 Whitworth. Attachments: The Concerta 2005 Objectives
24 and Strategy. Subject: Forwarding Concerta 2005
25 Objectives and Strategy.

1 Team SA, here is a good recap of the
2 Concerta information passed on by Debra Crain in the
3 Houston district, Shane T. Scott, Janssen Psychiatry.

4 Your Honor, at this time, may it please
5 the Court, we'd turn up the lights if the Court pleases
6 and we would call to the stand Mr. Billy Milwee.

7 Your Honor, my colleague Mr. Sweeten from
8 the Attorney General's Office will be examining
9 Mr. Milwee.

10 THE COURT: Mr. Milwee, may I get you to
11 raise your right hand for me, please, sir.

12 THE WITNESS: Yes, sir.

13 *(The witness was sworn)*

14 THE COURT: I appreciate it. There's a
15 front door. And then everybody be quiet while Della
16 adjusts the microphone.

17 Okay, Patrick.

18 MR. SWEETEN: Thank you, Your Honor.

19 **BILLY MILWEE,**
20 having been first duly sworn, testified as follows:

21 **DIRECT EXAMINATION**

22 BY MR. SWEETEN:

23 Q. Good morning.

24 A. Good morning.

25 Q. Would you introduce yourself to the jury,

1 please?

2 A. Yes, I can. My name is Billy Milwee. I serve
3 as the State Medicaid and Children's Health Insurance
4 Program director.

5 Q. And what does that mean?

6 A. I'm responsible for management of the State
7 Medicaid and Children's Health Insurance Program in
8 Texas.

9 Q. Can you tell the jury briefly a little about
10 yourself, where you're from?

11 A. Sure. Well, I was originally born in
12 Jacinto City, Texas. I grew up in Big Spring, Texas.
13 And now I live in Henly, Texas, a little town right
14 outside of Dripping Springs.

15 Q. So Henly's close to Dripping Springs. Do you
16 have -- do you have kids, grandkids?

17 A. I have children and I have grandchildren. I
18 have three grown children. My oldest daughter lives in
19 Baltimore, and we have three grandchildren with her. My
20 other daughter lives here in Austin, and I have one, my
21 granddaughter. She's nine years old and is kind of
22 the -- has a strong place in her heart, naturally. And
23 my son, he's our youngest. He's married and lives in
24 San Antonio.

25 Q. Let's talk about you. You grew up in

1 Big Spring?

2 A. Yes, sir, I did.

3 Q. Okay. And when did you leave Big Spring?

4 A. I left Big Spring in 1971.

5 Q. Okay. What did you do when you left in '71?

6 A. Well, after high school I joined the Air Force.

7 Q. Okay. How long were you -- did you serve in
8 the United States Air Force?

9 A. A little over 20 years.

10 Q. Okay. And where were you stationed during that
11 time?

12 A. I was stationed in Thailand, in Texas,
13 North Dakota, Greenland and Colorado. And Okinawa, I
14 forgot about that one.

15 Q. Okay. Can you tell us a little bit about what
16 you did while you were in the Air Force?

17 A. Sure. Originally -- when I originally came
18 into the Air Force, I was trained as a medic and I flew
19 rescue for a number of years. Then I had the
20 opportunity to go to officer training school and became
21 a United States Air Force officer, became a missile
22 combat crew commander and later became a logistics
23 management officer.

24 Q. After you left the Air Force, can you tell us
25 about what was your first job after you served?

1 A. I went to work for Hospital Corporation of
2 America. South Austin HCA Medical Center was what it
3 was called at the time, and I was the business office
4 manager.

5 Q. Okay. And what was your next position after
6 being a business office manager at Hospital Corporation
7 of America?

8 A. Well, I went to work for the State. I believe
9 that was in 1993. And I served as a trauma systems
10 planner.

11 Q. Have you worked at the State of Texas since
12 1993?

13 A. Yes, sir, I have.

14 Q. Okay. After you were a trauma systems manager,
15 can you tell us what you did after that?

16 A. Well, I worked in the immunization division to
17 develop tools to assess immunization system
18 effectiveness around the state. And then in 1995, I
19 believe it was, I moved to the Early Periodic Screening
20 and Diagnosis and Treatment Program. That's a long
21 word. That means the Children's Health Insurance
22 Program within Medicaid.

23 Q. And can you -- can you tell us again, what is
24 your current position?

25 A. I'm currently the State Medicaid and Children's

1 Health Insurance Program director.

2 Q. Okay. And -- let's see. In 2004 you became
3 the director of Managed Care Operations; is that
4 correct?

5 A. Yes, sir, that's correct.

6 Q. Okay. And then when did you become the State
7 Medicaid director?

8 A. January 1st, 2010.

9 Q. Okay. So how many years total have you worked
10 with the Texas Medicaid Program?

11 A. About 15 years, I believe.

12 Q. Are you familiar with the policies and
13 procedures of the Texas Medicaid system that have been
14 in place during your time?

15 A. Yes, sir, I am.

16 Q. How many people work for you at the State of
17 Texas?

18 A. About 300.

19 Q. And how large is the budget that you're
20 responsible for as the Medicaid director?

21 A. It's about \$30 billion.

22 Q. Do you know what percentage of the entire state
23 budget is represented by that amount?

24 A. Yes, I do. The Texas Medicaid budget is
25 approximately 25 percent of the total state budget.

1 Q. Okay. I want to take a step back, and I want
2 you to tell the jury, if you would, what is Medicaid?

3 A. Okay. Medicaid is a joint venture between the
4 state and federal government. It's operated in the
5 state by the State, and every state has a state Medicaid
6 Program. We serve primarily the very poor and also the
7 aged and disabled.

8 Q. Now, you say you serve the very poor and the
9 aged -- aged and disabled.

10 A. Yes, sir.

11 Q. Can you tell me -- can you give us an idea of
12 what level of income you would qualify to be covered by
13 Medicaid?

14 A. Well, let's take, for instance, a family of
15 four. They would have to make -- we call it the federal
16 poverty level, but they would have to be at a certain --
17 100 percent of the federal poverty level. And what that
18 means is a family of four would have to earn about \$1800
19 a month in order to qualify for Medicaid.

20 Q. Can you tell us, how is Medicaid different than
21 Medicare?

22 A. Medicaid and Medicare are very different.
23 Medicare provides services for people age 65 and above.
24 Medicaid is primarily for women and children and the
25 disabled. We do cover some older folks, but it's only

1 because of the associated disability.

2 Q. And which state agency runs the Texas Medicaid
3 Program?

4 A. The Health and Human Services Commission.
5 Sometimes you'll hear it referred to as the HHSC. We
6 use a lot of acronyms.

7 Q. Okay. And that's where you're the state
8 Medicaid director now?

9 A. Yes, sir, that's correct.

10 Q. Okay. How many people that are covered by the
11 Medicaid Program -- how many are covered by the Medicaid
12 Program in this state?

13 A. 3.5 million people are in the Medicaid Program
14 today.

15 Q. And what percentage of those covered by Texas
16 Medicaid are children?

17 A. Well, 70 percent of the people in the Medicaid
18 Program are pregnant women and children, and the
19 remaining 30 percent are disabled.

20 Q. Can you tell the jury, how do those children or
21 disabled adults -- how do they receive healthcare
22 benefits from Medicaid?

23 A. Well, they receive their healthcare benefits
24 from Medicaid through a network of enrolled providers.
25 We have about 40,000 providers around the state enrolled

1 in the program, and they're providers like you or I
2 might see. They happen to enroll with our program and
3 they receive services through our program, and we -- we
4 reimburse those providers directly.

5 Q. Do you -- do Medicaid recipients -- do they get
6 a direct check from the government?

7 A. No, sir, there's no exchange of cash between
8 the -- or check between the client and the Medicaid
9 Program, but rather the network of the providers that we
10 provide services through.

11 Q. Okay. You talked about providers. How does
12 one become a Texas Medicaid provider?

13 A. Well, in order to become a Medicaid provider,
14 you must enroll in the program, and you do that through
15 completion of a provider agreement.

16 Q. Okay. And tell us what a provider agreement
17 is.

18 A. It's basically we capture information about
19 your location and what kind of provider you are, and
20 then there's rights and responsibilities and some
21 assurances that we capture in that agreement process.

22 Q. Okay. And is that true with pharmacies and
23 with physicians that they have to sign a provider
24 agreement?

25 A. Yes, sir. When I say 40,000 providers, I'm

1 talking about physicians, pharmacies, home health
2 agencies, durable medical equipment providers, a host of
3 medical types.

4 Q. Okay. This case is particularly about
5 prescription drugs, so I want to focus in on that
6 particular Medicaid benefit, okay? Can you tell the
7 jury how a Medicaid patient actually gets a prescription
8 drug that he or she has been -- when he or she has been
9 provided a prescription by a doctor?

10 A. Certainly. The way a Medicaid client receives
11 a drug is not unlike how you and I get a drug when we go
12 to the doctor. A Medicaid client goes to a
13 Medicaid-enrolled physician. They're seeing -- and a
14 physician provides them with a prescription. They then
15 take that to a pharmacy, a Medicaid-enrolled pharmacy.
16 Walgreen's, CVS, many of the drug stores we use are also
17 Medicaid-enrolled pharmacies. They give that
18 prescription to the pharmacist who then submits it to
19 the Medicaid Program electronically, and usually one of
20 two things will happen. The drug is either approved for
21 purchase and then we reimburse -- agree to reimburse the
22 pharmacist and the Medicaid client leaves with the drug
23 or it may be denied for several reasons.

24 Q. So when presented to the pharmacy, a claim can
25 either be accepted or rejected?

1 A. Correct.

2 Q. If -- why would a claim be rejected if
3 presented at the -- at a Medicaid provider pharmacy?

4 A. Well, if the drug were not on our formulary.
5 The formulary is basically a list of the drugs that
6 Medicaid covers. And so if a drug were not on that
7 formulary, then we would reject it.

8 Q. Okay. What percentage of retail pharmacies in
9 the state of Texas are Medicaid eligible pharmacies?

10 A. We have about 4500 pharmacies enrolled in the
11 program, and that's 80 to 90 percent of the total
12 pharmacies in the state.

13 Q. Okay. Now, I want to talk about how a drug
14 gets on the Texas Medicaid formulary. Can you tell me
15 what -- can you tell the jury about that process?

16 A. Sure. There are basically three things that
17 must happen in order for a drug to get on the Medicaid
18 formulary. The first thing is the drug must be approved
19 by the FDA. The second thing is the manufacturer has to
20 have a rebate agreement in place with the federal
21 government. A rebate agreement is kind of a discounting
22 process. And then the third thing is kind of unique to
23 Texas, but state law requires that the manufacturer
24 complete a Vendor Drug Program application.

25 Q. Does every state have this same formulary

1 application process?

2 A. Well, you know, there's a saying that if you've
3 seen one Medicaid Program, you've seen one Medicaid
4 Program. They vary. And I think Texas may be unique in
5 that respect.

6 Q. How do manufacturers apply to get on the
7 formulary itself?

8 A. They submit an application.

9 Q. Okay. And are there laws and regulations that
10 relate to that?

11 A. Yes, sir, there are. Those are laws outlined
12 in the Texas Administrative Code.

13 Q. Okay. I'm going to have Mr. Barnes put up
14 Plaintiffs' Exhibit 2302.

15 MR. McDONALD: Your Honor, defendants
16 again object to this being displayed to the jury. It's
17 law. It's outside the scope of the Texas Rules of
18 Evidence. We believe the Court should admonish the
19 witness and instruct the jury to disregard --

20 THE COURT: Overruled.

21 MR. McDONALD: Can I please have a running
22 objection on this exhibit --

23 THE COURT: You may.

24 MR. McDONALD: -- as well as his
25 testimony?

1 THE COURT: You may.

2 MR. McDONALD: Thank you.

3 Q. (BY MR. SWEETEN) And Mr. Milwee, can you tell
4 me what this provision -- what this provides?

5 A. Well, this basically is our -- the Texas
6 Administrative Code that governs the operation of the
7 many parts of the Vendor Drug Program, and it requires
8 the drug company must complete the questionnaire
9 provided by the Commission to request the addition of a
10 drug to the TDCI. The TDCI is basically the Medicaid
11 formulary. All questions on the questionnaire must be
12 answered and all statements must be complete. And
13 that's the requirement within the tag.

14 Q. Does state law require a drug company to fill
15 out a VDP application?

16 A. Yes, sir, it does.

17 Q. Can you tell us generally, what sorts of
18 questions are on the Vendor Drug Program application?

19 A. Questions are generally about clinical
20 information, pricing information. With the application
21 we also ask for a package insert, the FDA approval
22 letter, and then we require a certification or
23 attestation.

24 Q. When the manufacturer submits this application
25 to Texas Medicaid, does the company certify anything to

1 Texas Medicaid?

2 A. Yes, sir, the company does.

3 Q. Okay. And can you tell us -- can you give us
4 an idea what the certification provides?

5 A. Sure. On the Vendor Drug Program application,
6 we ask for a certification that the company is in
7 compliance with all state and federal laws and also that
8 they will notify us within 15 days of any change in
9 status.

10 Q. Okay. Did the defendants in this case ever
11 submit a Vendor Drug Program application to Texas
12 Medicaid?

13 A. Yes, sir, they did.

14 Q. And can you tell us how many applications they
15 submitted?

16 A. There were eight applications submitted.

17 Q. Why would a manufacturer submit more than one
18 application to the Vendor Drug Program?

19 A. Perhaps a change in product, change in dosage,
20 administration, any number of -- a change in the product
21 composition.

22 Q. Okay. Formulations, is that --

23 A. Yes.

24 Q. Okay.

25 A. Or strength, yes.

1 Q. All right. Now, can you tell me whether all
2 eight applications they submitted were approved by Texas
3 Medicaid?

4 A. Yes, sir, they were.

5 Q. Now, let's go ahead and take a look at some of
6 these VDP applications. And the first one I want to
7 show you is Plaintiffs' Exhibit 1713.

8 A. Yes, sir.

9 Q. And can you tell us what this packet of
10 information is in 1713?

11 A. This is a -- basically the cover letter for a
12 Vendor Drug Program application package.

13 Q. And what is the date of the letter on the top
14 of this exhibit?

15 A. February 2nd, 1994.

16 Q. And can you tell to whom this letter has been
17 addressed?

18 A. This letter is addressed to Flora Bryant,
19 Senior Information Coordinator, Janssen Pharmaceuticals
20 Incorporated.

21 Q. And who wrote this letter?

22 A. Martha McNeill, Product Manager of Vendor Drug
23 Program.

24 Q. And what appears to be the significance of this
25 letter?

1 A. Well, they're advising Flora Bryant that the
2 drug Risperdal has been added to the list of products
3 for which the Texas Vendor Drug Program will provide
4 reimbursement.

5 Q. Okay. I'm going to ask you to turn -- or
6 Mr. Barnes to turn to Page 848 of the document, the last
7 three digits. And can you tell us briefly what this
8 next page is?

9 A. This is also part of a Vendor Drug Program
10 application, and this is the submission of the
11 application for consideration.

12 Q. And can you tell us where this application
13 submission came from?

14 A. It came from Flora Bryant, Senior Information
15 Coordinator.

16 Q. Can you go to the top of the page?

17 A. With Janssen Pharmaceutica.

18 Q. Okay.

19 MR. SWEETEN: I want to ask you now,
20 Mr. Barnes, if you would turn to 807.

21 Q. (BY MR. SWEETEN) I want you to look at that,
22 Mr. Milwee. And what is this?

23 A. This is information about the drug.

24 Q. Okay. Is this the actual application itself?

25 A. Yes, sir, it is. It's the Vendor Drug Program

1 application.

2 Q. Next to the number one at the top of the page,
3 what is the name of the drug for this application?

4 A. Risperdal.

5 Q. Next to No. 4, what is the description of the
6 drug listed there?

7 A. Dosage form, tablets, strength one milligram,
8 two milligram, three milligram, four milligram. Formula
9 refers to the package insert. The recommended daily
10 dose refers to the package insert. The maximum daily
11 dose refers to the package insert.

12 Q. Okay. Let's go to the second page of the VDP
13 application itself. And I want to turn your attention
14 to answer No. 12 of that application. And can you tell
15 me the names of the representatives listed as covering
16 Austin on that first VDP application?

17 A. Yes, sir, I can. Armando Sanchez and Jeffrey
18 Dunham.

19 Q. Okay. Now, can you tell me looking at -- let's
20 scroll down to No. 14. And I want to ask you whether
21 the package insert and materials for physicians for the
22 drug are required to be submitted with this application.

23 A. Yes, they are.

24 Q. All right. Let's now turn to Page 809. And
25 I'm going to direct your attention to the third

1 paragraph which Mr. Barnes has highlighted, and I want
2 to ask you to read that first sentence to the jury,
3 please.

4 A. Certainly. "I certify that the information
5 submitted is correct to the best of my knowledge and
6 that this product is not now in violation of either
7 federal or state law. I also agree to inform the Texas
8 Department of Human Services, in writing, of any changes
9 in formulation, product status, price or availability as
10 herein described, within 15 days of such change."

11 Q. And what's being certified to here?

12 A. Well, the certification kind of -- it means
13 what it says, that is, that if the company is out of
14 violation of law -- in violation of either state or
15 federal law, they're attesting that they are not, and
16 that if there's any change in the product status, that
17 they'll notify us within 15 days.

18 Q. And can you tell me on that second sentence,
19 what does it mean on the VDP application where it says
20 you'll inform the department of any changes in product
21 status?

22 A. Well, any time that status changes. That might
23 include a change by the FDA or any kind of
24 communications with the FDA that would affect that
25 drug's status at all, any kind of changes in status.

1 Q. Can you determine the name and the title of the
2 person that signed this first VDP application, sir?

3 A. Flora Bryant, Senior Information Coordinator.

4 MR. SWEETEN: And can we page down on the
5 title.

6 Q. (BY MR. SWEETEN) Okay. And can you say what
7 the company name is listed as?

8 A. Sure. Janssen Pharmaceutica Incorporated.

9 Q. Now, to your knowledge, has Johnson & Johnson
10 or Janssen ever informed Texas Medicaid that Risperdal
11 was in violation of any state or federal law?

12 A. No, sir, it has not.

13 Q. To your knowledge, has Johnson & Johnson or
14 Janssen ever updated Texas Medicaid as to any change in
15 Risperdal status with respect to whether it was in
16 violation of state or federal law?

17 A. No, sir, they have not.

18 MR. SWEETEN: Can you please turn to the
19 Page 027, Mr. Barnes.

20 Q. (BY MR. SWEETEN) And can you tell me what that
21 appears to be on this first VDP application?

22 A. I believe that's the package insert.

23 Q. Okay. Let's turn to another exhibit, which is
24 Exhibit 1719, Plaintiffs' Exhibit 1719. And can you
25 tell me what Plaintiffs' Exhibit 1719 is, sir?

1 A. Yes, sir. This is part of a Vendor Drug
2 Program application package. It's a letter to Flora
3 Bryant from Martha McNeill.

4 Q. What is the date of this letter?

5 A. August 8th, 1996.

6 Q. And on whose letterhead was this written?

7 A. The Texas Department of Health.

8 Q. Okay. Let's go to the second page. And can
9 you tell us what this document is?

10 A. This is also part of a Vendor Drug Program
11 application, and it's the transmittal letter for the
12 Vendor Drug Program application.

13 Q. And what form of Risperdal is this application
14 being submitted for?

15 A. Risperdal oral solution.

16 Q. And this letter again came from Flora Bryant;
17 is that correct?

18 A. Yes, sir, it is.

19 Q. Flipping through the next several pages of the
20 application, I just want you to go to Page 967. And
21 again, can you read the certification?

22 A. Certainly. "I certify that the information
23 submitted is correct to the best of my knowledge and
24 that this product is not in violation of either federal
25 or state law. I also agree to inform the Texas

1 Department of Health, in writing, of any changes in
2 formulation, product status, price or availability as
3 herein described, within 15 days of such change."

4 Q. Who signed this document?

5 A. Flora Bryant, Senior Business Coordinator,
6 Janssen Pharmaceutica.

7 Q. Okay. Let's go to Plaintiffs' Exhibit 1714.
8 And can you tell me what Plaintiffs' Exhibit 1714 is,
9 sir?

10 A. Yes, sir. This is also part of a Vendor Drug
11 Program application, a letter to Flora Bryant from
12 Martha McNeill.

13 Q. And what's the date on it?

14 A. August 4th, 1999.

15 Q. Can you tell me for what formulation and
16 dosage -- and I think we want to turn to Page --
17 actually, it's right there on the first one. What
18 formulation and dosage is this application submitted
19 for?

20 A. This application was for Risperdal tablets,
21 0.25 and 0.5 milligrams.

22 Q. Can you turn to Page 752, please. And this was
23 submitted by Flora Bryant of Johnson & Johnson again?

24 A. Yes, sir. It's a transmittal letter submitting
25 the Vendor Drug Program application.

1 Q. Okay. We'll look at one more page on this VDP
2 application, which is 757. Is this the same
3 certification we've talked about on the other VDP
4 applications?

5 A. Yes, sir, it is.

6 Q. Was this signed?

7 A. Yes, sir, it is.

8 Q. We'll go to another VDP application, which is
9 1715. And can you tell us, sir, what is this document?

10 A. This is again a part of the Vendor Drug Program
11 application package, and it's a letter to Flora Bryant
12 from Martha McNeill.

13 Q. If you could turn to 694, please. And can you
14 tell me the product name and drug strength this was
15 submitted for?

16 A. Yes. The product name is Risperdal M-Tab and
17 the drug strength is .50 milligrams.

18 Q. If we could go to Page 697. Same certification
19 on this VDP application?

20 A. Yes, sir, it is.

21 Q. And what is the date of this certification,
22 sir?

23 A. May 22nd, 2003.

24 Q. All right. Let's look at Plaintiffs'
25 Exhibit 1716. And can you tell us what this document

1 is?

2 A. Certainly. This is a letter to Flora Bryant
3 from Martha McNeill and also part of the Vendor Drug
4 Program application package.

5 Q. If we could turn to 630, please. And can you
6 tell us, what is this document?

7 A. This is the transmittal document submitting the
8 Vendor Drug Program application from Janssen
9 Pharmaceutica and part of the Vendor Drug Program
10 application package.

11 Q. And was this letter signed?

12 A. Yes, sir, it was.

13 Q. And who signed this letter?

14 A. Flora Bryant, Business Coordinator to Health
15 Policy & Issues.

16 Q. All right. I want to ask you to turn to
17 Page 637, here. Is this the same certification?

18 A. Yes, sir, it is.

19 Q. And who's listed underneath? Whose name and
20 title is on it?

21 A. Flora Bryant, Health Policy & Issues Management
22 Business Coordinator II, Johnson & Johnson.

23 Q. Okay. And on this VDP application, it appears
24 there's not a signature on the signature line. Do you
25 see that?

1 A. Yes, sir, I do.

2 Q. And as Medicaid director, can you tell me
3 whether that somehow invalidates the certification or
4 holds any significance?

5 A. No, sir, I don't believe it does. It has -- we
6 have the transmittal letter clearly communicating the
7 intent, a signed transmittal letter.

8 Q. Okay. I've got two more of these documents to
9 look at. One is Plaintiffs' Exhibit 1717. And can you
10 tell me for what formulation and dosage of Risperdal
11 this application was submitted?

12 A. This was submitted for Risperdal M-Tab three
13 milligram and four milligram.

14 Q. And as I understand it, Plaintiffs'
15 Exhibit 1717 is two VDP applications, correct?

16 A. Yes, sir, you're correct.

17 Q. Flipping through the next several pages of the
18 application, I'll have you turn to Page 618, if you
19 would, please. And is this a certification exactly the
20 same as the others we've been looking at?

21 A. Yes, sir, it is.

22 Q. And is this signed?

23 A. Yes, sir, it is.

24 Q. What's the date of this one?

25 A. March 17th, 2006.

1 Q. Who signed this one?

2 A. Elizabeth Raney, Business Coordinator II,
3 Johnson & Johnson.

4 Q. Okay. And then I'll have you turn to Page -- I
5 think we're at 619. And can you tell us what this
6 document is?

7 A. Yes. This is part of the Vendor Drug Program
8 application.

9 Q. And what's the product name and drug strength
10 listed here?

11 A. Risperdal M-Tab and the drug strength is four
12 milligrams.

13 Q. And we'll turn to Page 622 of this document.
14 And can you tell us who signed -- by the way, is the
15 certification the same as the others?

16 A. Yes, sir, it is.

17 Q. Who signed this certification?

18 A. Elizabeth Raney, Business Coordinator II,
19 Johnson & Johnson.

20 Q. And then there's one more we want to look at,
21 which is 1718. Can you tell us what this is?

22 A. Yes, sir. This is also part of a Vendor Drug
23 Program application. It's a letter to Elizabeth Raney
24 from Don Valdes.

25 Q. And what formulation and dosage of Risperdal is

1 this application submitted for?

2 A. Risperdal CONSTA injectable 12.5 milligram
3 vial.

4 Q. Okay. And finally, as to these documents, if
5 we would go to Page 504. And Mr. Milwee, is this the
6 same certification as is on the other VDP applications?

7 A. Yes, sir, it is.

8 Q. Who signed and certified this?

9 A. Elizabeth Raney, Business Coordinator II,
10 Johnson & Johnson.

11 Q. Okay. Have we gone over all eight of the VDP
12 applications related to Risperdal?

13 A. Yes, sir, I believe we have.

14 THE COURT: Mr. Sweeten.

15 MR. SWEETEN: Yes, Your Honor.

16 THE COURT: We're taking a break.

17 MR. SWEETEN: Okay.

18 THE COURT: See y'all back in about ten
19 minutes or so.

20 *(Recess taken)*

21 *(Jury present)*

22 THE COURT: Thank y'all. Be seated.

23 Mr. Sweeten.

24 Q. (BY MR. SWEETEN) Okay. Mr. Milwee, we were
25 talking prior to the break about the eight VDP

1 applications signed by Janssen or Johnson & Johnson.

2 A. Yes, sir.

3 Q. Okay. Now, can you tell me, who is it that
4 processes all these VDP applications and reviews the
5 information on them?

6 A. Staff in our formulary division.

7 Q. And how many employees are there in the
8 formulary section of the Vendor Drug Program or VDP?

9 A. There's five or six. Right now I believe we
10 have six people working in there.

11 Q. And approximately how many drugs are on the
12 Texas Medicaid formulary?

13 A. We have 17,000 drugs on the Medicaid formulary.

14 Q. All right. And let me ask you, is Risperdal
15 one of those drugs currently?

16 A. Yes, sir, it is.

17 Q. Are the conventional antipsychotics on the
18 formulary?

19 A. Yes, sir, they are.

20 Q. Is Haldol on the formulary?

21 A. Yes, sir.

22 Q. Perphenazine?

23 A. Yes.

24 Q. Mellaril?

25 A. Yes, sir.

1 Q. The VDP formulary staff, is it five or six
2 people that are in charge of supervising the over 17,000
3 drugs that are on the formulary, the VDP applications
4 associated with those?

5 A. Yes, sir, that's correct.

6 Q. And how --

7 THE COURT: And may I -- I'm sorry to
8 interrupt. May I see y'all briefly over here?

9 *(Discussion off the record between the*
10 *Court and counsel)*

11 Q. (BY MR. SWEETEN) And Mr. Milwee, Abilify is
12 also on the formulary, correct?

13 A. Yes, sir, it is.

14 Q. Okay. And is that a second generation
15 antipsychotic?

16 A. I believe so.

17 Q. How does the VDP staff ensure that all the
18 information supplied by manufacturers about the drug is
19 complete and accurate?

20 A. Well, we're reliant upon the information
21 reported by the manufacturer, the accuracy of the
22 information reported on the Vendor Drug Program
23 application.

24 Q. Why is that?

25 A. Well, one, it's a requirement of our state law

1 to submit the application. And another is we simply
2 don't have the resources to validate all the application
3 information given the 17,000 drugs on the formulary.

4 Q. What happens if a manufacturer fails to submit
5 complete and accurate information about their drug on
6 VDP applications and the VDP staff is aware of these
7 deficiencies?

8 A. Well, because of the state law in the Texas
9 Administrative Code, we submit that -- return that
10 Vendor Drug Program application back to the
11 manufacturer.

12 MR. SWEETEN: And I'm going to ask
13 Mr. Barnes to show the next exhibit, which is PX 2303.

14 MR. McDONALD: Your Honor, we have the
15 same objection as with the last exhibit.

16 THE COURT: That's correct, that there
17 will be a running objection to any testimony concerning
18 the Texas Administrative Code.

19 MR. McDONALD: Thank you, Your Honor.

20 THE COURT: You're welcome.

21 Q. (BY MR. SWEETEN) Mr. Milwee, Rule 354.1923,
22 Mr. Barnes has highlighted Section B and 1. Can you
23 read those to the jury, please?

24 A. Certainly. B is the commission returns a
25 questionnaire for any one of the following reasons:

1 Discovery of false, erroneous or incomplete information
2 or documentation on the questionnaire.

3 Q. Okay. Can VDP, or the Vendor Drug Program,
4 take action on inaccuracies or missing information that
5 it's not aware of?

6 A. No, sir, we cannot.

7 Q. Getting back to the process, once an
8 application has been completed, submitted to VDP and is
9 approved, what happens next?

10 A. The drug is then placed on the formulary and it
11 becomes available for prescription.

12 Q. Is being placed on the Texas Medicaid
13 formulary -- is that a benefit for manufacturers of a
14 drug?

15 A. Yes, sir, it is. Once placed on the formulary
16 and it's available by prescription, then the drug is
17 available for -- through pharmacies and available to
18 be -- to be sold basically. It's an opportunity for
19 revenue.

20 Q. Okay. And what does that mean with respect to
21 Medicaid's reimbursement of that drug?

22 A. Well, pharmacists will purchase it and have it
23 available so that they could be reimbursed by the
24 Medicaid Program for it.

25 Q. Are you familiar with the term open formulary?

1 A. Yes, sir, I am.

2 Q. Okay. And what does that term mean?

3 A. Open formulary simply means that a drug is
4 listed on the Medicaid formulary.

5 Q. And does open formulary mean that once a drug
6 is on the Texas Medicaid formulary, that there's no way
7 to restrict its use?

8 A. No, sir, it does not.

9 Q. And can you tell the jury why not?

10 A. Once a drug is on the formulary, it's available
11 for prescription, but limits can be placed on that drug.
12 For instance, we can require a prior authorization.
13 That means that a physician, before they can prescribe
14 that drug, they'd have to contact the Medicaid Program
15 to get that drug approved, or we can place edits on that
16 drug that might deny it under certain circumstances.

17 Q. Does the State of Texas Medicaid Program
18 monitor and manage the use and utilization of drugs that
19 are on the Medicaid formulary?

20 A. Yes, sir, we do. And we're required to do so
21 by our federal government.

22 Q. What are the ways that Texas Medicaid monitors
23 and manages the use of drugs?

24 A. Well, let me talk a little bit about the
25 Omnibus Reconciliation Act of 1990, also referred to as

1 OBRA-90. It created a requirement for all state
2 Medicaid programs to operate a Drug Utilization Review
3 program.

4 Q. And what is a Drug Utilization Review program?

5 A. You look at drugs and how they're used and
6 consider it for any kind of policy or other
7 interventions that might be required associated with
8 their safe and effective use.

9 Q. Did Texas Medicaid set up a committee based
10 upon the Drug Utilization Review process?

11 A. Yes, sir. As a result of OBRA-90, we created
12 in 1992 the Drug Utilization Review Board.

13 Q. Okay. And first of all, who's on the DUR or
14 Drug Utilization Review Board?

15 A. The board consists of six physicians and six
16 pharmacists appointed by the governor to advise the
17 Medicaid Program on Drug Utilization Review.

18 Q. And what does the -- what is the function of
19 the DUR board? What do they do?

20 A. They review the utilization and safety and
21 effectiveness of drugs used in the Medicaid Program.

22 Q. Can you tell the jury what information does the
23 DUR board rely upon when it's doing its review of drugs?

24 A. The DUR board relies upon -- primarily upon
25 peer-reviewed scientific literature, testimony from

1 providers and testimony from advocates and clients.

2 Q. How does the board ensure the accuracy and
3 completeness of all the information they review in
4 journal articles, for example?

5 A. Well, they're dependent upon the integrity of
6 that process. So the peer review by its nature implies
7 that it's subject to a certain level of integrity and
8 peer review.

9 Q. In doing its review, can the DUR board consider
10 information that it is not provided or that is not
11 available?

12 A. No, sir, it cannot.

13 Q. I want to talk about something called
14 intervention letters. Can you tell the jury what that
15 is, what those are?

16 A. Sure. Intervention letters are sent to
17 providers identified that may have a -- be utilizing
18 drugs in a way that we might find -- might not best fit
19 some clinical criteria or that might be a more
20 cost-effective drug, and so we send those intervention
21 letters. And I would describe them more as an
22 educational kind of letter, as an education process
23 rather than an absolute prohibition on using a
24 particular drug.

25 Q. And why are these educational letters sent?

1 A. To affect the utilization of that particular
2 drug.

3 Q. And what typically happens after these letters
4 are sent?

5 A. The desired effect is generally achieved. We
6 get some feedback from physicians, and as a result, the
7 utilization of that particular drug declines.

8 Q. Does that save the state money typically?

9 A. Yes, sir, it does.

10 Q. Let's talk about clinical edits. You mentioned
11 something about clinical edits earlier. What are
12 clinical edits?

13 A. Clinical edits are put into place to defer a
14 potentially bad outcome. For example, you might have a
15 clinical edit in place to avoid a drug-to-drug
16 interaction. You might have an edit put in place that
17 says this drug is not consistent with this diagnosis.
18 Those kind of things that, in my mind, they're a
19 question mark that says, hey, should this drug really be
20 used with this condition?

21 Q. If a clinical edit is placed upon a drug,
22 what's the effect of that?

23 A. Well, it might reduce the overall utilization
24 of that drug.

25 Q. If an age restriction, say, for example, is put

1 in as a clinical edit, what would be the effect of that?

2 A. It would restrict that drug from being used in
3 a certain age group.

4 Q. Can you tell the jury what prior authorization
5 is?

6 A. Sure. That's basically -- prior authorization
7 is we have -- the physician must obtain a prior
8 approval, if you will, call in, get some approval before
9 we'll honor that service or that particular drug as a
10 Medicaid covered service.

11 Q. Has the DUR board always -- and by the way,
12 what's the effect if you put prior authorization on a
13 drug?

14 A. Well, any time you put prior authorization on a
15 drug, you typically see the utilization of that drug
16 come down.

17 Q. Has the DUR board always had clinical edits
18 that they could put on a drug?

19 A. Yes, sir.

20 Q. Have they always had the tool of intervention
21 letters?

22 A. Yes, sir.

23 Q. Has -- since their inception, have they always
24 had the tool of prior authorization?

25 A. Yes.

1 Q. Does it benefit a manufacturer to avoid these
2 type of restrictions on their drugs?

3 A. Yes, sir. Any of those restrictions would
4 impact the use of that particular drug.

5 Q. Are there -- can you give me an example of DUR
6 imposing some of these restriction tools in the past?

7 A. Yes, I can. Human growth hormone has been
8 restricted by age group for a number of years as has
9 certain ages restrictions placed on the attention
10 deficit disorder drugs.

11 Q. What happened when restrictions were placed on
12 these drugs?

13 A. Utilization declined.

14 Q. And what did -- what was the effect on the
15 State's expenditures for these drugs?

16 A. The consequential cost for those drugs went
17 down.

18 Q. Apart from the DUR program, does Texas Medicaid
19 have any other means to which it can manage its
20 expenditures for pharmaceuticals?

21 A. Yes, sir. We have a preferred drug list.

22 Q. And who manages the preferred drug list?

23 A. There's a group called the Pharmacy and
24 Therapeutics Committee.

25 Q. Can you tell us what the Pharmaceutical and

1 Therapeutics Committee does?

2 A. Sure. Well, they're similar in composition to
3 the Drug Utilization Review Board. It consists of
4 physicians and pharmacists that are appointed by the
5 governor to serve on that board. They review drugs for
6 safety, efficacy and cost-effectiveness and will make
7 recommendations about what drugs should be put on the
8 preferred drug list.

9 Q. And what happens when the P&T Committee reviews
10 drugs for these factors?

11 A. They look at the -- the published literature on
12 those drugs. And similar to the DUR, the Drug
13 Utilization Review Board --

14 THE REPORTER: I didn't get that.

15 A. Similar to the Drug Utilization Review process,
16 the P&T Committee will review the published literature
17 about the drug and also take testimony from providers
18 and advocates.

19 Q. (BY MR. SWEETEN) Does the P&T Committee
20 conduct its review in-house only?

21 A. No, sir. We con -- we have a contract where we
22 contract with a group known as Provider Synergies.

23 Q. Okay. Were you present for defense counsel's
24 opening statement in this case?

25 A. Yes, sir, I was.

1 Q. And did you hear defense counsel describe
2 Provider Synergies as a third party that provided
3 reports to the Legislature and came in and debunked
4 everything that's being claimed in this case?

5 A. I do recall that.

6 Q. Okay. Is that what the State of Texas
7 contracts with the Provider Synergies to do?

8 A. No, sir. Provider Synergies doesn't provide
9 any reports to our legislature. Provider Synergies
10 provides the reports to the Pharmacy and Therapeutics
11 Committee, and it's really -- they don't do independent
12 research. They don't do clinical trials. They review
13 the body of literature and the professional journals and
14 provide a summary of that information for the Pharmacy
15 and Therapeutics Committee members.

16 Q. Okay. Do they -- does their review -- is it
17 limited to publicly available resources?

18 A. Yes, sir, it is.

19 Q. Does Provider Synergies receive information
20 from time to time from drug manufacturers?

21 A. Yes, sir, they do.

22 Q. Can information or data that is not published
23 or provided to Provider Synergies be utilized in their
24 review?

25 A. No, sir, it cannot.

1 Q. And for that matter, can information that is
2 not provided to the P&T Committee be used in making
3 their decisions about a drug?

4 A. No, sir, it cannot.

5 Q. Now, was Risperdal ever placed on the preferred
6 drug list?

7 A. Yes, sir, it was.

8 Q. For what period of time?

9 A. It was placed on the preferred drug list in
10 2004 and continued until 2009.

11 Q. Is it currently on -- is Risperdal currently on
12 the preferred drug list?

13 A. No, sir, it's not.

14 Q. Okay. And is there a generic equivalent on the
15 preferred drug list now?

16 A. Yes. Yes, there is.

17 Q. Now, yesterday we heard testimony that this
18 drug during its patented phase was 45 times more
19 expensive than Haldol. Let me ask you, the generic form
20 of risperidone, how is it priced with Haldol now?

21 A. The generic form is within pennies of the price
22 of Haldol.

23 Q. What -- going back to the preferred drug list,
24 what does it mean for a drug to be placed on the
25 preferred drug list?

1 A. When a drug is on the preferred drug list, it
2 means that it doesn't have to have that prior
3 authorization, prior authorization being that extra step
4 a physician would have to take to get approval for that
5 drug, so it skips that process. If it's not on the
6 preferred drug list, then it would require that step be
7 taken.

8 Q. Is being on the preferred drug list a benefit
9 for drug manufacturers?

10 A. Yes, sir, it is.

11 Q. Why?

12 A. Well, because there's no obstacle towards
13 prescribing that drug. There is no prior authorization
14 requirement.

15 Q. I want to go back to defense counsel's opening
16 statement. Is it true today that Provider Synergies has
17 debunked the idea that Risperdal was no better than
18 conventionals?

19 A. Well, the most recent thing I've seen from
20 Provider Synergies was that it was no -- correct, it's
21 no better than the conventionals.

22 Q. I'm going to ask -- I'm going to show you
23 Plaintiffs' Exhibit 1166, sir. And I want to ask you if
24 you can identify what this document is, sir.

25 A. Yes. It's Antipsychotics Review prepared by

1 Provider Synergies.

2 Q. And I'm going to ask if we could turn to
3 Page 30 of this document, which is 063. And we've
4 already highlighted a section on first generation
5 antipsychotics. I'll read this for you, and I want to
6 ask you a question about it.

7 "Multiple studies have been performed
8 between the first and second generation agents, but the
9 results are not clear when considering the aggregate of
10 available information. Although the second generation
11 antipsychotics are commonly associated with superior
12 effectiveness against the negative symptoms of psychotic
13 disorders, most studies have not sought to prove that
14 point."

15 Further down, "Results from trials that
16 evaluated oral olanzapine (Zyprexa) and risperidone
17 (Risperdal) do not give results consistent with this
18 claim. In general, there is inconclusive evidence that
19 the overall effectiveness of second generation
20 antipsychotics is better than that for first generation
21 agents in terms of meeting primary outcomes of changes
22 in rating scale scores."

23 Did I read that accurate?

24 A. Yes, sir, you did.

25 THE COURT: May I interrupt? May I see

1 y'all down here a second?

2 MR. SWEETEN: Yes, sir.

3 *(Discussion off the record between the*
4 *Court and counsel)*

5 Q. (BY MR. SWEETEN) Based upon your review of
6 this paragraph that's been highlighted, does it suggest
7 to you that Provider Synergies thinks that Risperdal is
8 better than the conventionals?

9 A. No.

10 Q. Let me ask you if you would turn to Page 4064
11 if we could, please. The last sentence there is "All of
12 these issues cloud the issue of the presence of a
13 detectible difference between first and second
14 generation antipsychotics."

15 Does that suggest to you that they think
16 Risperdal as a second generation is better than the
17 conventionals?

18 A. It suggests that they do not believe that the
19 second generations are any better than the
20 conventionals.

21 Q. Defense counsel also suggested that Risperdal
22 was on the PDL. Is it?

23 A. It's not on the PDL today.

24 Q. You mentioned a couple of times the State is
25 dependent upon manufacturers to supply complete and

1 accurate information about their drugs in order for the
2 VDP, the DUR and the P&T processes to work. Do you
3 recall those discussions?

4 A. Yes, sir, I do.

5 Q. Now, I'm going to ask you some questions about
6 the information that Texas Medicaid might need in order
7 to make fully informed decisions. Would it be important
8 for Texas Medicaid to know whether a manufacturer was
9 promoting their patented drug as superior to a
10 generically available drug if the FDA had not -- had
11 specifically prohibited this act?

12 A. Yes, it would.

13 Q. Why?

14 A. Well, that would violate the certification in
15 the Vendor Drug Program application if they were
16 operating outside of federal and state law if they were
17 off-label marketing their drug or doing something
18 outside of the provisions for which the FDA approved
19 that drug. They also potentially could pose a safety
20 and health risk to the population that we serve.

21 Q. Would it be important for Texas Medicaid to
22 know whether or not a manufacturer's drug was being
23 off-label promoted to, for example, children?

24 A. Yes, sir, it would.

25 Q. Why?

1 A. Well, that off-label marketing would be a
2 violation of state and federal law and also potentially
3 place at risk the lives that we're charged with caring
4 for.

5 Q. Would it be important for Texas Medicaid to
6 know whether a manufacturer had held back the
7 publication of studies revealing side effects of their
8 drug?

9 A. Yes, sir, it would.

10 Q. Why?

11 A. Without complete information, we can't make the
12 decisions that we need to make around coverage and
13 utilization for that drug.

14 Q. Would it be important for Texas Medicaid to
15 know if the manufacturer was making payments to mental
16 health advocates who then testified before the P&T
17 Committee or DUR board?

18 A. Yes, sir, it would.

19 Q. Why?

20 A. Many times the most powerful testimony you
21 receive are people that are directly affected by your
22 program, advocates and clients. So if that testimony is
23 tainted by some financial transaction, that might flavor
24 the way in which you accept that testimony.

25 Q. Let me ask you, changing subjects, as state

1 Medicaid director, could you take an honorarium from a
2 drug company and give a talk or attend a pharmaceutical
3 event?

4 A. No, sir, I couldn't. Besides being a violation
5 of state law, that would violate all the ethics in the
6 Health and Human Services arena that we're trained and
7 counseled and literally is part of our blood, if you
8 will, about not accepting gratuities or honorarium.

9 Q. Do you recall a discussion in defense counsel's
10 opening about a TMAP audit conducted in 2004?

11 A. Yes, sir, I do.

12 Q. And are you familiar with that audit?

13 A. Yes, sir, I am.

14 Q. Can you tell me, was that -- what did the audit
15 time period cover?

16 A. 2004.

17 Q. And was it an -- was it an investigation or an
18 audit?

19 A. No, sir. It was an audit of agreed-upon
20 procedures.

21 Q. Did this -- did the time period of the audit
22 cover the time of the TMAP conception, 1996?

23 A. No, sir, it did not.

24 Q. Did it cover 1997?

25 A. No, sir, it did not.

1 Q. '98?

2 A. No.

3 Q. '99?

4 A. No.

5 Q. What year did it cover?

6 A. 2004.

7 Q. Also, we're going to have a witness testify at
8 a later time, Ms. Sharon Dott. Did I ask you at some
9 point to check to see if she was at any point a Medicaid
10 provider for the State of Texas?

11 A. Yes, you did.

12 Q. And is Ms. Dott a Medicaid provider?

13 A. She is an enrolled Medicaid provider.

14 MR. SWEETEN: Pass the witness.

15 **CROSS-EXAMINATION**

16 BY MR. McDONALD:

17 Q. Good morning, Mr. Milwee. I see it's still
18 morning.

19 A. Good morning.

20 Q. We met just a little bit ago at the last break.

21 A. Yes, sir.

22 Q. I understand you've been working with the
23 Medicaid Program for a number of years, right?

24 A. Yes, sir, I have.

25 Q. But in truth, you've only had dealings with the

1 pharmaceutical benefit portion of Medicaid for just a
2 very few years, right?

3 A. I have been the Medicaid director since
4 January 2010.

5 Q. Okay. So you've only been involved with
6 pharmaceutical benefits since January of 2010?

7 A. Yes, sir.

8 Q. Okay. So you had no involvement prior to
9 January of last year?

10 A. I wouldn't characterize it as no involvement.
11 I would say it's within the Medicaid Program where I've
12 been in a senior management position, so tangential
13 involvement, so it's not though I have been silo.

14 Q. You were never involved in decisions about
15 approval of the applications that you discussed with
16 your lawyer, right?

17 A. That's correct.

18 Q. Okay. Had you ever seen an application before
19 January of last year?

20 A. Yes, sir, I have.

21 Q. Okay. You talked a little bit about the P&T
22 Committee, the Pharmacy and Therapeutics Committee.

23 A. Yes, sir.

24 Q. You've never attended one of those meetings,
25 right?

1 A. I have not.

2 Q. Okay. And you've never actually been on that
3 committee, right?

4 A. I am not on that committee.

5 Q. Okay. Also talked about the Drug Utilization
6 Review Board.

7 A. Yes, sir.

8 Q. You've never been a member of that board,
9 right?

10 A. No, sir, I'm not a member of that board.

11 Q. And you've attended, I think in your deposition
12 you told us, two meetings?

13 A. Yes, sir.

14 Q. Okay. And it's the Drug Utilization Review
15 Board, right?

16 A. Yes, sir.

17 Q. So they look retrospectively in the past, not
18 in the future, right?

19 A. I believe that's an accurate characterization.

20 Q. Okay. You talked about the DUR board sending
21 out intervention letters.

22 A. Yes, sir.

23 Q. Okay. The DUR board actually has no authority
24 to impose or tell a doctor what to do through one of
25 those intervention letters, correct?

1 A. That's correct.

2 Q. It's just a recommendation?

3 A. It's education.

4 Q. Okay. You also talked about clinical edits
5 that you say the DUR board had the authority to
6 implement.

7 A. Yes, sir.

8 Q. Do you recall that? Now, in 2003, 2004 time
9 period, that's when the P&T Committee came into
10 existence, correct?

11 A. Yes, sir, in 2004.

12 Q. And at that time the preferred drug list was
13 created, right?

14 A. Yes, sir.

15 Q. And there were a number of drugs after the
16 creation of the preferred drug list that were prior
17 authorized or that had clinical edits for prior
18 authorization, correct?

19 A. Correct.

20 Q. Now, that was the first time that the State of
21 Texas had a fulsome prior authorization program,
22 correct?

23 A. I believe we had some -- a limited number of
24 drugs on prior authorization even before that, as I
25 recall.

1 Q. Right, and that's what I want to focus on.
2 Prior to 2003 and 2004, there were just one or two or a
3 handful of drugs that had prior authorization, correct?

4 A. Yes.

5 Q. Okay. You talked about TMAP for a little bit
6 at the end. TMAP is part of -- or came from the Texas
7 Department of Mental Health and Mental Retardation,
8 right?

9 A. Correct.

10 Q. It's not part of the Medicaid formulary, right?

11 A. It's not part of the Medicaid formulary.

12 Q. Risperdal has been on the Medicaid formulary
13 since before TMAP was created, right?

14 A. Yes, it was.

15 Q. Okay. We looked at a number of these
16 applications. And again, you didn't have anything to do
17 with the approval of any of these applications that you
18 looked at, right?

19 A. No, sir, I personally did not approve those
20 applications.

21 Q. Okay. And do you know when this application
22 form came into existence?

23 A. I believe it was in the early '90s. It's been
24 around a very long time.

25 Q. And do you know what communications the

1 Medicaid Program has had with manufacturers about what
2 they're supposed to do with this form?

3 A. I don't. I don't.

4 Q. Okay. I want to look at one of these -- and
5 let's just look at the last one, Plaintiffs'
6 Exhibit 1718. It's the last one we looked at.

7 MR. McDONALD: If you can pull this up,
8 Chris. Go to the first page, please, so we can all just
9 see what it is.

10 Q. (BY MR. McDONALD) Okay. This is -- the first
11 page of Exhibit 1718 is a letter from Don Valdes, and
12 you know Mr. Valdes?

13 A. Yes, sir, I do.

14 Q. He runs the Vendor Drug Program at Medicaid?

15 A. He works in the Vendor Drug Program, yes, sir.

16 Q. Okay. He took Martha McNeill's place?

17 A. Yes, sir.

18 Q. She ran the Vendor Drug Program formulary for
19 many, many years?

20 A. Yes, sir.

21 Q. Okay. And her name -- we saw her name on the
22 approval of almost all of these applications?

23 A. Yes, sir.

24 Q. Okay. This is in June 14th of 2007 when
25 Mr. Valdes tells Ms. Raney that the application for

1 Risperdal CONSTA has been approved?

2 A. Yes.

3 Q. Okay.

4 MR. McDONALD: Now, let's look at the
5 certification, if you would, please, Chris. Can you
6 blow that up for us, please?

7 Q. (BY MR. McDONALD) This is a certification that
8 we looked at a minute ago -- or you looked at with
9 Mr. Sweeten. And this certification is essentially the
10 same on every one of the applications; is that what you
11 testified to?

12 A. Yes, sir.

13 Q. Okay. And it says, "I certify that the
14 information is correct to the best of my knowledge and
15 that this product is not now in violation of either
16 federal or state law," right?

17 A. Correct.

18 Q. And it says, I also agree to inform HHSC, in
19 writing, of any changes in formulation, product status,
20 price or availability, and goes on from there, right?

21 A. Correct.

22 Q. Okay. And you testified that product status
23 means that if a drug is found to be in violation of
24 state or federal law, that means that the manufacturer
25 is supposed to tell the Vendor Drug Program?

1 A. Correct.

2 Q. When was that communicated to pharmaceutical
3 manufacturers?

4 A. I don't know when it was communicated to
5 pharmaceutical manufacturers.

6 Q. In fact, you don't know that that's ever been
7 communicated to pharmaceutical manufacturers, do you?

8 A. Well, I know that pharmaceutical manufacturers
9 submit letters to us when something changes in the
10 status of their drug.

11 Q. Right. For example, an example that we've
12 probably all heard of is, for example, Merck's Vioxx.
13 When it was taken off the market by the FDA, they should
14 tell the Vendor Drug Program, hey, our drug's been taken
15 off the market by the FDA, right?

16 A. Or if there were a black box warning added to
17 the drug.

18 Q. Okay. Have you ever had a manufacturer tell
19 the Vendor Drug Program that they had received a warning
20 letter from the FDA?

21 A. Not to my knowledge.

22 Q. Now, this lawsuit that we're here about today
23 was filed -- was filed in May of 2004. Do you
24 understand that?

25 A. Yes, sir, I do.

1 Q. Years before this application was made. Do you
2 understand that?

3 A. Yes, sir.

4 Q. And it's alleged in the lawsuit that my client
5 is in violation of state or federal law, and the
6 allegations are being made that my client is engaged in
7 off-label promotion. Do you understand that?

8 A. Yes, sir, I do.

9 Q. And yet three years after this lawsuit was
10 filed, Mr. Valdes approved this application, right?

11 A. Correct.

12 Q. Okay. Thank you. You mentioned that Medicaid
13 is a network of providers that are made up of doctors
14 and pharmacies, right?

15 A. Correct.

16 Q. My client's not a provider in the Texas
17 Medicaid, right?

18 A. Your client would be a manufacturer supplier
19 for the Medicaid Program.

20 Q. Okay. Not a provider, right?

21 A. No, sir, they're not enrolled in the
22 traditional sense.

23 Q. And my client doesn't receive Medicaid benefits
24 from Texas Medicaid, does it?

25 A. Yes, it does.

1 Q. What benefits do my client -- what Medicaid
2 benefits does my client receive?

3 A. We have your client's drug covered in our
4 formulary. And as a result of having it on the
5 formulary, your client's drug is available for sale
6 through the Medicaid Program and available through
7 pharmacies and available to physicians to prescribe.

8 Q. I understand you believe that that's a
9 financial benefit that my client receives, right?

10 A. Yes.

11 Q. But in the traditional sense of benefits, that
12 is, services received by a Medicaid beneficiary, my
13 client doesn't receive benefits from the State of Texas,
14 does it?

15 A. Well, not in the same way that a Medicaid
16 client would receive a benefit.

17 Q. Right. My client's not a Medicaid beneficiary,
18 is it?

19 A. Your client's not on Medicaid, correct.

20 Q. Okay. They're not a beneficiary, right?

21 A. Well, your client's --

22 MR. SWEETEN: Objection, Your Honor --

23 A. -- not enrolled in Medicaid.

24 MR. SWEETEN: -- asked and answered.

25 Q. (BY MR. McDONALD) So we've established that

1 Risperdal has been continuously on the Medicaid
2 formulary since the first application we saw, and that
3 was approved in early February of 1994, right?

4 A. Yes, sir.

5 Q. So nearly 17, 18 years ago?

6 A. Yes, sir.

7 Q. Okay. And so to be clear, sitting here today,
8 a doctor can write a prescription for Risperdal and
9 Medicaid would pay for it?

10 A. Yes, they would.

11 Q. Okay. Has Texas Medicaid ever tried to remove
12 Risperdal from the Medicaid formulary?

13 A. No, sir, we have not.

14 Q. Has Texas Medicaid ever returned one of the
15 applications we looked at to my client and said, this is
16 wrong, the certification is false?

17 A. No, sir, we have not.

18 Q. To be on the Medicaid formulary, it's true,
19 isn't it, Mr. Milwee, that a medicine does not need to
20 be the safest in its class?

21 A. That's true. The three conditions are the FDA
22 approval, the federal rebate agreement and the
23 completion of the Vendor Drug Program application.

24 Q. All right. And it doesn't need -- so it
25 doesn't need to be the safest, the most effective, the

1 best side effect profile. None of that has anything to
2 do with whether or not it's on the formulary, correct?

3 A. Correct.

4 Q. Okay. It also doesn't have to be the cheapest?

5 A. Correct.

6 Q. Doesn't have to be better than the older
7 cheaper generic drugs out there to be on the formulary,
8 right?

9 A. Correct.

10 Q. Okay. We've heard a bit about cost in this
11 case. Risperdal, when it was a branded drug, was not
12 the most expensive second generation antipsychotic, was
13 it?

14 A. I don't know if it was or wasn't, sir.

15 Q. Okay.

16 MR. McDONALD: Let's pull up Exhibit 227,
17 please.

18 Q. (BY MR. McDONALD) Do you recognize this memo
19 from Brian Flood? You've seen this before, right?

20 A. I have seen this memo.

21 Q. Okay.

22 MR. McDONALD: Let's look at Page 6 of
23 this document, please, Chris.

24 Q. (BY MR. McDONALD) This is part of Mr. Flood's
25 memo, and it's from ACS. Can you explain to the jury

1 who ACS is?

2 A. ACS is Affiliated Computer Systems. They are a
3 contractor with the State.

4 Q. So they were a vendor for the State working for
5 Texas Medicaid?

6 A. Yes.

7 Q. Okay. Now, let's look at what ACS has in here.
8 Do you see that they have antipsychotic drug summary
9 report for July through August of 2004?

10 A. Yes, sir.

11 Q. Okay. And you see the paid per claim?

12 A. Yes, sir.

13 Q. Okay. And Risperdal, according to ACS, was
14 \$191.41. Do you see that?

15 A. Yes, sir.

16 Q. And Seroquel, you know that Seroquel is another
17 second generation atypical antipsychotic, right?

18 A. Yes, sir.

19 Q. And it's -- the paid amount per claim is higher
20 than Risperdal, right?

21 A. Yes, sir.

22 Q. And Abilify is another second generation
23 antipsychotic, right?

24 A. Correct.

25 Q. And it's nearly twice as expensive as

1 Risperdal, right?

2 A. Yes, according to this.

3 Q. And Zyprexa is another second generation
4 antipsychotic, right?

5 A. Yes.

6 Q. Again, nearly twice as expensive as Risperdal?

7 A. Correct.

8 Q. Geodon, another second generation
9 antipsychotic?

10 A. Yes.

11 Q. More expensive than Risperdal?

12 A. Correct.

13 Q. And Symbyax, another second generation
14 antipsychotic?

15 A. Yes.

16 Q. And it again is more expensive than Risperdal,
17 right?

18 A. Correct.

19 Q. Okay. Thank you. Now, you talked a little bit
20 about off-label promotion with Mr. Sweeten. Texas
21 Medicaid doesn't monitor promotion of drugs by
22 pharmaceutical manufacturers, does it?

23 A. No, sir, we don't.

24 Q. Has Texas Medicaid ever removed a drug from a
25 formulary because of alleged off-label promotion?

1 A. Not to my knowledge.

2 Q. I think Mr. Sweeten asked you also about
3 misbranding of a drug. Texas Medicaid doesn't monitor
4 misbranding of drugs, does it?

5 A. No, sir, we don't.

6 Q. And has Texas Medicaid ever removed a drug from
7 its formulary because of alleged misbranding?

8 A. No, sir, we have not.

9 Q. We talked a little bit about the preferred drug
10 list, and that was formulated in the late 2003, early
11 2004 time period, correct?

12 A. Yes, sir, 2004.

13 Q. And Risperdal was on the preferred drug list
14 until about a -- nine months or a year after it went
15 generic, right?

16 A. Yes, sir.

17 Q. And it went -- it's still on the list, but you
18 have to have prior authorization to get the branded
19 Risperdal, right?

20 A. Correct.

21 Q. But the generic Risperdal, there's no prior
22 authorization for that, correct?

23 A. Correct.

24 Q. Okay. And the reason that the brand went to
25 prior authorization and the generic was not is just from

1 a price standpoint, correct?

2 A. Well, I believe that was one of the reasons.

3 Q. Sure.

4 A. Yes.

5 Q. The State wants to encourage pharmacies and
6 doctors to use generic drugs because they're cheaper
7 than brands?

8 A. Correct.

9 Q. Didn't have anything to do with this lawsuit?

10 A. Not to my knowledge.

11 Q. Because the generic Risperdal is essentially
12 the same as the brand Risperdal?

13 A. Correct.

14 Q. Okay. You looked at a document with
15 Mr. Sweeten from Provider Synergies. You've seen these
16 before, right?

17 A. Yes, sir, I have.

18 Q. Okay. And Provider Synergies is this outside
19 consultant that the State of Texas has contracted with,
20 correct?

21 A. Correct.

22 Q. You paid them millions of dollars a year to
23 help you run this program, right?

24 A. I'm not sure how much we pay them, but yes, we
25 do pay them to help us manage the program.

1 Q. And you rely upon their independence and their
2 judgment in reviewing information to make
3 recommendations to the P&T Committee about who should be
4 on the PDL, right?

5 A. Well, I wouldn't want to characterize that as
6 they're doing independent clinical work. What we're
7 relying upon them is to do the literature reviews and
8 provide us with the research on the literature.

9 Q. Independent of anything some pharmaceutical
10 company may tell you?

11 A. Right.

12 Q. They're giving you their independent review and
13 their independent judgment about what they think you
14 should do?

15 A. Right.

16 Q. Okay. And Mr. Sweeten showed you a review from
17 them that is dated January 22nd of 2010. Do you recall
18 that?

19 A. Yes, sir, I do.

20 Q. Okay. Now, Provider Synergies gives the State
21 of Texas these types of reports on a pretty regular
22 basis, right?

23 A. Correct.

24 Q. And prior to January -- or yeah, January of
25 2010, Provider Synergies was telling the State of Texas

1 that second generation antipsychotics were preferred to
2 first generation antipsychotics, right?

3 A. Correct.

4 Q. So years after this lawsuit was filed, years
5 after the CATIE study, just only a year ago did Provider
6 Synergies for the first time make the statements that
7 Mr. Sweeten went over with you, correct?

8 A. Correct.

9 Q. If you'll bear with me, I'm trying to cut out
10 some of this and make this a little faster for you.

11 Now, let's go back to Exhibit 227. Now,
12 this is a memorandum from Brian Flood who's with the
13 Inspector General's Office at Texas Health and Human
14 Services Commission. And you've seen this memo before?

15 A. Yes, I have.

16 Q. All right. And it's dated October 7th of 2004,
17 correct?

18 A. Correct.

19 Q. And Mr. Flood had -- did an investigation where
20 he made some recommendations to Medicaid about the use
21 of antipsychotics in kids, correct?

22 A. I believe that's what the memo captured, yes,
23 sir.

24 Q. Okay. And we'll look at the third page of this
25 document. And Mr. Flood's specific recommendation, and

1 it's again in October of 2004, to Texas Medicaid was to
2 develop and implement a prior authorization edit for the
3 antipsychotic drug class for children under the age of
4 18, right?

5 A. Correct.

6 Q. And Texas Medicaid ignored Mr. Flood's
7 recommendation and did not implement that prior
8 authorization, right?

9 A. Well, no -- no prior authorization was
10 implemented as a result of Mr. Flood's notification.

11 Q. And there's never been a prior authorization
12 for this drug class for children under the age of 18,
13 correct?

14 A. Correct.

15 Q. Okay. Even though in October of 2004 it would
16 have been off-label for antipsychotic drugs to be
17 prescribed to children under the age of 18?

18 A. Correct.

19 Q. The State of Texas Medicaid Program does not
20 restrict off-label use of drugs, right?

21 A. Correct.

22 Q. When Texas Medicaid pays a benefit to a -- to
23 one of its beneficiaries and reimburses the pharmacy for
24 a drug, it knows the age of the beneficiary, right?

25 A. Correct.

1 Q. And so at the time of the approval to the
2 pharmacy to pay for the drug, Texas Medicaid knows that
3 the beneficiary is 18 or under?

4 A. Yes, we do.

5 Q. Okay. Now, having just looked at Mr. Flood's
6 memo in October of 2004, and his recommendation was not
7 implemented, I want to look at Exhibit Defendants' 346.
8 Have you seen this before?

9 A. I believe I have.

10 Q. And the first -- the cover page of it -- of
11 Exhibit 346 is an e-mail from Charles Bell dated
12 February 15th of 2005. Do you see that?

13 A. Yes.

14 Q. And can you -- we've all seen a lot of names,
15 and it's probably easier for the lawyers than the jury.
16 Can you tell us, who is Charles Bell?

17 A. Charles Bell at that time was the deputy
18 executive commissioner with the Health and Human
19 Services Commission.

20 Q. And within your position at the Health and
21 Human Services Commission, where would he fit in?

22 A. He would have been my boss.

23 Q. Okay. And so -- then the subject of this man,
24 who is a senior official at the department -- is that
25 fair to say?

1 A. Yes, sir.

2 Q. All right. He only reports to the
3 commissioner?

4 A. Yes, sir, he reports to the executive
5 commissioner.

6 Q. One person above him. The subject is the DSHS
7 Psychotropic Medication Guidelines. Do you see that?

8 A. Yes, sir, I do.

9 Q. And one other thing I want to point out:
10 Mr. Bell is an actual -- he's an MD?

11 A. Yes, sir, he is.

12 Q. And I -- you're not?

13 A. No, sir, I'm not.

14 Q. And you're not a scientist?

15 A. No, I'm not.

16 Q. Okay. I'm not either, so I'm not disparaging
17 you by any means.

18 Okay. Let's look at what this is that
19 Mr. Bell is sending around, if you'll look at the second
20 page. This is a memorandum to healthcare providers in
21 the state of Texas, right?

22 A. Yes, it is.

23 Q. And it says, "The Texas Department of State
24 Health Services has coordinated the creation of the
25 accompanying best practice guidelines, *Psychotropic*

1 *Medication Utilization Parameters for Foster Children."*

2 Do you see that?

3 A. Yes, I do.

4 Q. And Mr. Bell and -- actually, if we'll go to
5 the bottom of this, this particular memo is from Eduardo
6 Sanchez, who's actually the commissioner; is that --

7 A. Eduardo Sanchez at this time was the
8 commissioner of the Texas Department of Health -- or the
9 Department of State Health Services.

10 Q. And so was he Mr. Bell's boss?

11 A. No, he was not.

12 Q. Okay. Different position, but Mr. Sanchez is
13 an MD as well, correct?

14 A. Yes.

15 Q. Okay. Let's go back up. And Mr. Sanchez is
16 telling providers these guidelines are based on the most
17 current evidence-based medical literature, right?

18 A. Correct.

19 Q. And in the fourth paragraph, they're intended
20 as a resource for physicians and clinicians, correct?

21 A. Correct.

22 Q. And again, this is in February of 2005 --

23 A. Correct.

24 Q. -- right? And if we'll look on what the State
25 of Texas told practitioners --

1 MR. McDONALD: If you'll look on Page 5,
2 Chris, it ends in 665. And again, this is for -- if
3 you'll look at -- blow up the antipsychotics at the
4 bottom.

5 Q. (BY MR. McDONALD) This is the use of drugs in
6 children and adolescents, and the State of Texas is
7 making a recommendation for my client's drug, Risperdal,
8 of what the dosing should be in children and
9 adolescents, right?

10 A. Yeah. I haven't read the entire memo, but
11 that's what it appears to say --

12 Q. Sure.

13 A. -- is the dosage recommendations.

14 Q. And the jury has heard, and I don't think it's
15 disputed, that at the time of this memorandum, Risperdal
16 did not have an FDA indication for the use of the drug
17 in children and adolescents, and yet the State of Texas
18 is telling doctors what dose they should use for the
19 drug in children and adolescents, right?

20 A. I don't know. I haven't looked at the memo.
21 I'd suggest it's saying if they're going to use it, that
22 might be the dosage.

23 Q. Okay. Thank you. If we can look at
24 Exhibit 1348. Now, this is a clinical edit that was
25 finally implemented by Texas Medicaid for the use of

1 antipsychotics in children, correct?

2 A. Correct.

3 Q. And this edit was implemented --

4 MR. McDONALD: If you'll look at the
5 bottom, Chris.

6 Q. (BY MR. McDONALD) -- on October 13th of last
7 year?

8 A. Yes, sir.

9 Q. And if we'll go to Page 7 of this document, the
10 edit that was finally implemented by the State of Texas
11 for all antipsychotics -- not just Risperdal, right?

12 A. Correct.

13 Q. -- is for children under the age of three?

14 A. Yes.

15 Q. So two and under is the restriction that Texas
16 Medicaid implemented in October of last year?

17 A. Yes, under the age of three.

18 Q. I want to look at one other document, and then
19 I think I will be done. I'M going to warn you, it might
20 take us a while. Exhibit 360. We looked at this some
21 yesterday. And you're familiar with this report,
22 correct?

23 A. I've seen the report, yes, I have.

24 Q. Sure. And this is a report from the Texas
25 Health and Human Services Commission to the Legislature,

1 right?

2 A. Correct.

3 Q. And again, the Texas Health and Human Services
4 Commission is who you work for?

5 A. Correct.

6 Q. And that's Medicaid, right?

7 A. Medicaid is one part of the Health and Human
8 Services Commission.

9 Q. And so essentially -- and this lawsuit's about
10 Medicaid fraud, right?

11 A. Correct.

12 Q. The State of Texas Medicaid is claiming that my
13 client committed fraud?

14 A. Yes, we are.

15 Q. And so essentially, the same people that are
16 claiming my client committed fraud created this report,
17 right?

18 A. Well, the Medicaid Program didn't create this
19 report.

20 Q. The Medicaid Program --

21 A. The Health and Human Services Commission
22 created the report, part of the HHSC.

23 Q. Okay. Let's look at the executive summary on
24 Page 5. Now, I want to put this report in context.
25 It's not just something that HHSC did willy-nilly,

1 right? It was required by the Legislature that they do
2 this report?

3 A. Correct.

4 Q. And so in the 2009 session, the Legislature
5 ordered HHSC to do this report and to do a study on the
6 use of these drugs in the Medicaid Vendor Drug Program,
7 correct?

8 A. Correct.

9 Q. Did you have any involvement in this report?

10 A. No, I did not.

11 Q. You knew it was going on?

12 A. I believe so, yes.

13 Q. And it's fair to say that HHSC did its very
14 best to be accurate and tell truthful information to the
15 Legislature?

16 A. Well, I think the report kind of in that second
17 paragraph describes its review of the professional
18 research, literature and state and federal national
19 public information, so I wouldn't characterize this as
20 original research.

21 Q. HHSC did -- certainly did everything in its
22 power to give accurate information to the best of its
23 ability to the Legislature?

24 A. Correct.

25 MR. McDONALD: Chris, if you'll go to the

1 next page, please, under Summary of Findings on
2 Appropriateness and Safety.

3 Q. (BY MR. McDONALD) So outside the context of
4 this lawsuit, the plaintiff gives these summaries to the
5 Legislature. And if you'll look on the fourth
6 paragraph, please, it says, "Based on the legal measure
7 of 'standard of care,' antipsychotics have been used in
8 youth for a long time and physicians are trained and
9 expected to use them for certain indications in children
10 and adolescents by their professional colleagues."

11 Do you see that?

12 A. Yes, I do.

13 Q. And is that an accurate statement to the
14 Legislature, to the best of your knowledge?

15 A. To the best of my knowledge, I suspect it
16 reflects what the literature stated at the time.

17 Q. And the people writing this report, their
18 knowledge?

19 A. Right, yes.

20 Q. Okay.

21 MR. McDONALD: The next paragraph, Chris,
22 if you would, that begins in "Off-label."

23 Q. (BY MR. McDONALD) "Off-label prescribing is
24 the norm in all pediatric care, with a recent study
25 showing that approximately 62 percent of all pediatric

1 prescriptions are prescribed off label. This is an
2 artifact of the historical FDA drug approval process.
3 It does not occur at higher rates in pediatric
4 psychiatric care than in general pediatrics."

5 Did I read that correctly?

6 A. Yes, sir, you did.

7 Q. And that's a truthful statement?

8 A. Based on the research from the report, yes.

9 Q. Okay.

10 A. I didn't write the report.

11 MR. McDONALD: Let's go to the next page,
12 Chris. I want to go to that paragraph that begins
13 "Options for Texas Medicaid."

14 Q. (BY MR. McDONALD) And so HHSC is telling the
15 Legislature we're doing this report, this is the options
16 for Texas Medicaid, et cetera. It says HHSC "agencies
17 have already taken steps to encourage the appropriate
18 prescribing of antipsychotic medications, particularly
19 among children in foster care who are known to be
20 prescribed these medications at a significantly higher
21 rate than other children in Medicaid," right?

22 A. Correct.

23 Q. And we saw in fact the memo from Dr. Bell that
24 gave dosing suggestions to kids in foster care, right?

25 A. Correct.

1 Q. Okay. And then it goes on to say, "A newly
2 released study of 16 states highlighted 36 practices
3 that states have undertaken to encourage appropriate
4 prescribing of antipsychotic medications for children
5 and adolescents."

6 "While the study was not released in time
7 for HHSC's analysis of the 36 practices included, one of
8 the practices noted as a promising practice is Texas'
9 *Psychotropic Medication Utilization Parameters for*
10 *Foster Children,*" which is the thing we looked at,
11 right?

12 A. Correct.

13 Q. "These parameters were initially released in
14 February of 2005." Again, that was the memo we looked
15 at, right?

16 A. Correct.

17 Q. "And have been periodically updated to guide
18 utilization review of psychoactive medications for the
19 foster care population."

20 Again that's a truthful statement to the
21 Legislature, right?

22 A. Well, again, sir, I didn't write the report,
23 and it's based on the literature that was reviewed at
24 the time, I suppose.

25 Q. Well, as the head of Medicaid, Texas Medicaid,

1 do you have any reason to doubt the truthfulness of this
2 option for Texas Medicaid in this report?

3 A. No, sir, I don't.

4 Q. Okay. Let's go to the next page. "Conclusions
5 and options for Texas Medicaid." Again, this is your
6 department, right?

7 A. Yes, it is.

8 Q. "What We Know." Second bullet point,
9 "Antipsychotic medications have legitimate therapeutic
10 uses in children and adolescents for schizophrenia,
11 bipolar disorder, autism, tic disorders, and
12 aggression." And that's something that Texas Medicaid
13 knows, right?

14 A. Correct.

15 MR. McDONALD: Let's go to the third
16 bullet point from the bottom, please, Chris.

17 Q. (BY MR. McDONALD) Again, what Texas Medicaid
18 knows. "The second generation antipsychotics have a
19 fairly large and growing high quality clinical trial
20 evidence base. The first generation antipsychotics do
21 not, and they have been only evaluated via comparison
22 studies during the ten-year review period."

23 Again, that's something Texas Medicaid
24 knows, right?

25 A. It was in the literature in 2004 when the

1 report was developed.

2 Q. And the last bullet point, what Texas Medicaid
3 knows and told the Legislature. "Risperidone,"
4 Risperdal, my client's drug, right?

5 A. (Nods head affirmatively).

6 Q. "Has the largest clinical trial evidence base
7 of all the antipsychotics in the under 18 age
8 population." True?

9 A. That's what the report indicated.

10 Q. You don't have any reason to doubt it, do you?

11 A. No, sir.

12 MR. McDONALD: All right. If you could go
13 to Page 34, please, Chris. If you could blow up that
14 top paragraph, please.

15 Q. (BY MR. McDONALD) "By a wide margin," again,
16 what Texas Medicaid knows, "more pediatric clinical
17 trials have been published about risperidone than have
18 been published about any of the other antipsychotics.
19 Over the ten years of the review period, risperidone has
20 been intensively studied in autism and disruptive
21 behavior disorders with only five trials being devoted
22 to other diagnostic categories."

23 MR. McDONALD: And then there's a summary
24 chart, if we can pull that up.

25 Q. (BY MR. McDONALD) And we can see all these

1 Risperdal or risperidone clinical trials, right?

2 A. Correct.

3 Q. And you don't have any -- again, any reason for
4 doubting the accuracy of these statements to the
5 Legislature by your department, right?

6 A. No, sir, I don't.

7 Q. So, again, Mr. Milwee, this lawsuit was filed
8 in 2004, almost ten years ago, right?

9 A. Correct.

10 Q. The vendor -- the Texas Medicaid Vendor Drug
11 Program is still reimbursing for this drug?

12 A. Correct.

13 Q. The Texas Medicaid Vendor Drug Program has
14 never taken any type of action to remove my client's
15 drug from its formulary, right?

16 A. Correct.

17 Q. Never tried to restrict the use of my client's
18 drug, right?

19 A. Well, it's no longer on the PDL.

20 Q. After it went generic.

21 A. Correct.

22 Q. And the only clinical edit ever placed on
23 Risperdal -- these guys have me saying Risperdal --
24 Risperdal was for all antipsychotics that was instituted
25 in October of last year for children under the age of

1 three?

2 A. Correct.

3 Q. Thank you.

4 THE COURT: Ladies and gentlemen, let's
5 take our lunch break. I'll see y'all back at 1:30.
6 We're in recess.

7 *(Lunch recess taken)*

8 *(Jury not present)*

9 THE COURT: Thank y'all. Be seated.
10 Bring the jury in.

11 *(Jury present)*

12 THE COURT: Thank y'all. Be seated.

13 John, you had passed, had you not?

14 MR. McDONALD: I have, Your Honor.

15 THE COURT: And Patrick, you were doing
16 the examination, right?

17 MR. SWEETEN: Yes, Your Honor.

18 THE COURT: Okay.

19 **REDIRECT EXAMINATION**

20 BY MR. SWEETEN:

21 Q. Okay. Mr. Milwee, I'm going to go over a few
22 issues that Mr. McDonald discussed with you. The first
23 is I'm going to ask that we pull up Defendants'
24 Exhibit 346. Do you recall discussing this with
25 Mr. McDonald?

1 A. Yes, sir, I do.

2 Q. At the time -- and this discusses the foster
3 care children's guidelines that were sent in '05,
4 correct?

5 A. Yes, sir.

6 Q. Okay. At the time these were sent, did your
7 agency have access to an internal Janssen business plan?

8 A. No, sir, we did not.

9 Q. Had -- and the jury watched the deposition of
10 Tone Jones earlier today. Had that deposition been
11 taken?

12 A. No, sir, I don't believe it had.

13 Q. Did you have access to the deposition of
14 Tiffany Moake?

15 A. No, sir.

16 Q. Did you have access to the back to school
17 bashing programs?

18 A. No, sir.

19 Q. I want to ask you, if you would, to turn to the
20 second page, please, of -- which is 660, and I want to
21 focus on the last paragraph of this letter. And when
22 they're transmitting these, it indicates that questions
23 about the guidelines that are being disseminated may be
24 directed to Steve Shon, Medical director of Mental
25 Health Services, Texas Department of State Health

1 Services. Did I read that correctly?

2 A. Yes, sir, you did.

3 Q. I want to clarify a point. You remember
4 defendants' counsel asked if pharmaceutical companies
5 were, quote, providers, and you said not in the
6 traditional sense. Can you tell us what you meant by
7 that?

8 A. Certainly. Not in the traditional sense that
9 they're physicians or pharmacies, but in the sense that
10 they provide services for the Medicaid programs by
11 listing their drugs on the formulary and those in turn
12 are used in the Medicaid Program.

13 Q. You told us that -- during your direct
14 examination that the DUR and P&T Committee look at three
15 major factors. Can you tell us what those are again?

16 A. Certainly. Those are safety, efficacy and
17 cost.

18 Q. Does a drug company marketing outside of an FDA
19 approval impact any of these issues?

20 A. Yes, sir, I believe it could impact all three.

21 Q. And without full and accurate information, can
22 a full review be done as to these issues?

23 A. No, sir, it cannot.

24 Q. Do the certifications that the defendants
25 signed require disclosures by a drug company if they're

1 in violation of a federal law?

2 A. Yes, sir, they do.

3 Q. You heard questions about off-label promotion.
4 Does Texas Medicaid rely on manufacturers to not violate
5 state or federal law?

6 A. Yes, sir, we do.

7 Q. Do they rely on their certifications as to
8 these issues?

9 A. Absolutely.

10 Q. We talked about the eight VDP applications that
11 were signed, and I think one went from 1994. And
12 Mr. McDonald showed you the one that had been entered in
13 2007, correct?

14 A. Yes, sir.

15 Q. So during this time period, Janssen
16 Pharmaceutical or Johnson & Johnson certified to Texas
17 Medicaid eight times that they were not in violation of
18 federal or state law; is that right?

19 A. Yes, sir, that's correct.

20 Q. Does Texas Medicaid have the manpower or the
21 resources to figure out if a drug company has marketing
22 plans or is promoting the drug off label?

23 A. No, sir, we do not.

24 Q. And in the face of that, what do you rely upon?

25 A. Well, we rely upon the honesty and integrity of

1 the people who submit information to us.

2 Q. Did Janssen Pharmaceutical or Johnson & Johnson
3 ever come to Texas Medicaid and tell them about the back
4 to school bashing programs in San Antonio?

5 A. No, sir.

6 Q. Did Janssen or Johnson & Johnson ever come to
7 Texas Medicaid and tell them of call notes relating to
8 M-Tabs, pushing M-Tabs for children?

9 A. No, sir.

10 Q. With respect to the Provider Synergies issue,
11 was there any way to know about Janssen's publication
12 plans or what they chose to or not publish?

13 A. No, sir. Provider Synergies can only use what
14 has been published and is in the public domain.

15 Q. I want to ask you about the Flood memo, which
16 was DX 227. Do you recall discussing this document?

17 A. Yes, sir, I do.

18 Q. Does the Flood memo do an analysis of just
19 Risperdal use?

20 A. No, sir, it does not.

21 Q. Does the Flood memo do an analysis of just
22 antipsychotic use?

23 A. No, sir.

24 Q. In fact, what are the classes of medications
25 that this addresses?

1 A. Antipsychotics as well as antidepressants.

2 Q. Did the Flood memo provide any sort of analysis
3 as to the root cause of why these prescriptions of these
4 three drugs were what they were?

5 A. No, sir, it did not.

6 Q. Did the Flood memo discuss -- provide an
7 analysis of marketing efforts by pharmaceutical
8 companies?

9 A. No, sir, it did not.

10 Q. I want to ask you -- I want to ask --

11 MR. SWEETEN: Jason, if you'd pull up
12 PX 1819, please.

13 Q. (BY MR. SWEETEN) Mr. McDonald showed you these
14 guidelines from HHSC, correct?

15 A. Yes, sir, he did.

16 Q. Okay. He read some portions from the HHSC,
17 quote, guidelines, right?

18 A. Yes, sir.

19 Q. Okay. I'm going to ask if we can turn to
20 page -- the bottom of Page 35. And on the -- the second
21 to the last sentence starting with "Risperidone," all
22 the way until right before "Prolactin." Can you read
23 that for me, Mr. Milwee?

24 A. Certainly. "Risperidone, similar to other
25 antipsychotics, has not been shown to be effective in

1 treating the core social deficits in autism. Weight
2 gain consistently occurs in clinical trials with
3 risperidone. The most rapid weight gain occurs early on
4 and is not associated with a change in nutritional
5 balance. Higher blood lipid levels are also seen as
6 well as higher levels of prolactin."

7 Q. Okay.

8 MR. SWEETEN: I want to turn to the bottom
9 of Page 56 if we would, please. And starting -- if we
10 could highlight the paragraph on the bottom, "Recent
11 research in adults."

12 Q. (BY MR. SWEETEN) Can you read that to the
13 jury, please?

14 A. Certainly. "Recent research in adults has
15 shown that the older antipsychotics, the first
16 generation, are as effective as the much more expensive
17 second generation medications. Growing literature in
18 youth verifies the same finding."

19 Q. Now, this document was a -- what was this
20 document?

21 A. In my mind, this document could be
22 characterized as a report to the Legislature that's
23 based on a review of the literature, available
24 literature.

25 Q. Thank you. Is this considered official HHSC

1 policy?

2 A. No, sir, it is not.

3 Q. Was any criticism lodged in some quarters about
4 the findings of this document?

5 A. Yes. Public comments were received criticizing
6 the document.

7 Q. Were public comments appended to the report?

8 A. I believe so, sir.

9 Q. Do the passages that either I or Mr. McDonald
10 read to you have any bearing whatsoever on the question
11 of whether Janssen marketed in violation of federal or
12 state law?

13 A. No, sir.

14 Q. Did the clinicians who authored this HHSC
15 report have access to Janssen business plans?

16 A. No, sir, they did not.

17 Q. Knowledge of Janssen's marketing efforts in
18 children?

19 A. Not to my knowledge, sir.

20 Q. You heard the suggestion that Texas is not
21 active. Do you remember that?

22 A. I remember that, yes, sir.

23 Q. Okay. And I want to ask you, is that a true
24 statement?

25 A. That's not a true statement.

1 Q. What has Texas Medicaid done with respect to
2 the drug Risperdal?

3 A. Well, I think we've taken the most profound
4 step that we can take in a civilized society, and that's
5 why we're here in court today, seeking relief under the
6 Texas Medicaid Fraud Prevention statute. Secondly, the
7 TMAP no longer exists. That TMAP has been pulled down.
8 It's no longer embraced by any state agency; and
9 instead, PORT guidelines are used. The PORT guidelines
10 are based on the, excuse me, National Institute of
11 Mental Health standards, and those guidelines put the
12 first generation and second generation antipsychotics on
13 a level basis. There's no preference given. Thirdly,
14 we have an age edit in place now for antipsychotics in
15 children, children under three. And we no longer have
16 Risperdal on the preferred drug list.

17 Q. Does this lawsuit to your knowledge seek to
18 remove Risperdal from the formulary?

19 A. No, sir, it does not.

20 Q. What is your understanding of this lawsuit?

21 A. My understanding of the lawsuit is that but for
22 some off-label marketing and some claims about --
23 comparative claims relative to the conventional
24 antipsychotics, marketing for children and adolescents
25 and some problems associated with diabetes, probably the

1 drug would not have been used to as great an extent as
2 it was, and Medicaid would not have incurred as great a
3 cost as it did in honoring prescriptions for this
4 product.

5 MR. SWEETEN: No further questions. Thank
6 you.

7 **RECROSS-EXAMINATION**

8 BY MR. McDONALD:

9 Q. Probably the drug would not have been used to
10 the extent as possible. Those were your words you just
11 used. In fact, you have no idea what would happen and
12 what doctors would have done, right?

13 A. I would say the drug would not have been used
14 to the extent as it has been had the off-label marketing
15 not occurred.

16 Q. So tell me the name of any doctor that wrote a
17 Medicaid prescription to a Medicaid recipient as a
18 result of something my client did.

19 A. I can't give you that name, sir.

20 Q. You can't tell me a single name, can you?

21 A. No, sir, I can't.

22 Q. You can't identify a single prescription that
23 was written by a Medicaid doctor to a Medicaid patient
24 as a result of anything my client did, can you?

25 A. I can't identify a single prescription.

1 MR. McDONALD: Pull up, Chris, please,
2 Defendants' Exhibit 227.

3 Q. (BY MR. McDONALD) This is the Flood memo we
4 looked at before.

5 A. Yes, sir.

6 Q. And if we'll look at Page 6 again, please.

7 MR. McDONALD: If you'll blow up that
8 chart, Chris.

9 Q. (BY MR. McDONALD) This is the information that
10 we looked at about the price paid per claim by Medicaid
11 for Risperdal as well as other second generation
12 antipsychotics, right?

13 A. Yes, sir.

14 Q. And if a Medicaid doctor would have written a
15 prescription to another second generation antipsychotic
16 instead of Risperdal, the State of Texas would have paid
17 more money, right?

18 A. Yes, if the reimbursement rate were higher,
19 correct.

20 Q. And, for example, in the case of Zyprexa, if a
21 doctor would have written a prescription for Zyprexa
22 instead of Risperdal, it would have cost the State of
23 Texas nearly twice as much, right?

24 A. Yes, sir, it would have.

25 Q. Mr. Sweeten asked you about the -- sorry, I got

1 a little disorganized here.

2 Exhibit 346, these are the psychotropic
3 medication guidelines. Do you recall that?

4 MR. McDONALD: Defendants' 346, Chris,
5 please.

6 Q. (BY MR. McDONALD) Now we have the right one,
7 right?

8 A. Yes, sir.

9 Q. Okay. These came out after this lawsuit was
10 filed, correct?

11 A. Correct.

12 Q. After the allegations had been made against my
13 client regarding TMAP and off-label use and all kinds of
14 other things, correct?

15 A. Correct.

16 Q. These guidelines have been updated over time,
17 correct?

18 A. I believe so.

19 Q. And the State of Texas has continued to tell
20 doctors what dose of Risperdal should be used in
21 children, correct?

22 A. I'm not a clinician, but I believe the memo
23 suggests the dosage if they were to use it in children
24 in these 2005 guidelines.

25 Q. Thank you. One of the things on the

1 applications that is submitted by my client as well as
2 all other pharmaceutical manufacturers is the price of
3 the drug, right?

4 A. Yes, sir.

5 Q. And there's no allegation in this case that the
6 price that was given by my client was ever wrong, is
7 there?

8 A. I don't believe so.

9 Q. Okay. Thank you. The State of Texas has never
10 rejected an application or returned an application to a
11 manufacturer because of alleged off-label marketing,
12 right?

13 A. No, sir, not for off-label marketing.

14 Q. Or violation of any federal law, have they?

15 A. I'm not aware of any, sir.

16 Q. Okay. And despite the fact that this lawsuit's
17 been around for ten years, been over 100 people deposed,
18 my client's produced over five million pages of
19 documents, you've taken no action to remove Risperdal
20 from the formulary, have you?

21 A. Well, there never was a move to take Risperdal
22 off the formulary.

23 Q. And you've never returned the applications to
24 my client rejecting the applications, have you?

25 A. No, sir.

1 Q. In fact, we saw an application that was -- that
2 was approved after this lawsuit was filed, right?

3 A. Yes, sir.

4 MR. McDONALD: That's all I have. Thank
5 you.

6 MR. SWEETEN: I've got a few more.

7 THE COURT: Let me see y'all down here.

8 *(Discussion off the record between the*
9 *Court and counsel)*

10 THE COURT: Thank you for your testimony.
11 I'd get out of here if I were you.

12 Call your next witness, please.

13 MR. MELSHEIMER: Your Honor, may it please
14 the Court. We call Dr. Valerie Robinson by video
15 deposition.

16 THE COURT: Do y'all need to set the TV
17 back up again?

18 MR. MELSHEIMER: We need a few moments.
19 May it please the Court.

20 THE COURT: If y'all don't mind going back
21 to the jury room or y'all can stay here, whichever.

22 MR. MELSHEIMER: It won't take long.

23 THE COURT: Why don't y'all relax while
24 they set up the TV.

25 *(Discussion off the record)*

1 THE COURT: They're talking about tilting
2 it toward where the jury can see. Watch this fellow
3 down here on the first -- he'll give you all
4 instructions you'll need.

5 Would y'all like to watch a different show
6 than the one we've been watching? I'm thinking Judge
7 Judy or something.

8 *(Video played as follows:)*

9 **VALERIE ROBINSON,**
10 having been first duly sworn, testified as follows by
11 videotaped deposition:

12 **DIRECT EXAMINATION**

13 Q. Can you state your full name for us, please?

14 A. Valerie Ruth Robinson.

15 Q. And we're at the Texas Health Science Center
16 here in Lubbock, Texas?

17 A. Yes.

18 Q. And is this where you work?

19 A. Yes.

20 Q. And how are you employed?

21 A. I'm an associate professor in the department of
22 psychiatry, which will actually be official in
23 September.

24 Q. And prior to becoming associate professor here
25 at the Texas Health Science Center, what -- what was

1 your position?

2 A. Assistant professor in the department of
3 psychiatry.

4 Q. And can you --

5 A. And I'm clinical director of child and
6 adolescent psychiatry.

7 Q. But you are a medical doctor, correct?

8 A. That's correct.

9 Q. And you are a medical doctor that specializes
10 in psychiatry; correct?

11 A. Child psychiatry.

12 Q. In child psychiatry?

13 A. Right. Child and adolescent, uh-huh.

14 Q. And what did you do in Fort Worth, Texas?

15 A. I was in private practice. I also worked for
16 Cook Children's Physicians' Network, which is a
17 children's hospital in Fort Worth, and I worked for Lena
18 Pope Home.

19 Q. And what is that?

20 A. Lena Pope Home is an agency that helps foster
21 care families with their children, and they also help
22 with the regulations of therapeutic foster homes. They
23 help children with adoption issues.

24 Q. And at some point, you left Fort Worth to come
25 to Lubbock, correct?

1 A. That's correct.

2 Q. And that was in 2003?

3 A. That's right.

4 Q. And in addition to all that in 2003, you also
5 became a member of the State's P&T Committee, correct?

6 A. That's correct.

7 Q. Which stands for the Pharmaceutical and
8 Therapeutics Committee?

9 A. That's right.

10 Q. And you have served on the State's P&T
11 Committee continuously since 2003?

12 A. That's correct.

13 Q. Through today?

14 A. That's right.

15 Q. And you currently also sit on the State's Drug
16 Utilization Review Board; is that correct?

17 A. That's correct.

18 Q. Can you describe for us generally what the
19 State's P&T Committee does?

20 A. It's made up of a committee of various
21 physicians, backgrounds, and pharmacists. And it is to
22 look at, for State Medicaid, various drug classes,
23 keeping in mind safety, efficacy, cost and coming up
24 with a preferred drug list.

25 Q. Is what is a preferred drug list?

1 A. These would be the medications that would be
2 preferred by the physicians and patients so that they
3 wouldn't have to necessarily ask for a prior
4 authorization.

5 Q. Do you personally have any -- any knowledge of
6 any information of anything Janssen has said that you
7 believe to be misleading about Risperdal?

8 A. What year are you talking about?

9 Q. Any year.

10 A. Yes --

11 Q. Okay.

12 A. -- I do.

13 Q. And what would that be?

14 A. In the mid '90s, I worked for Cook Children's
15 Physicians' Network, which is a Fort Worth-based
16 children's hospital, 18 and under. I practiced there as
17 an employee of the physicians' network services. I
18 maintained an outpatient practice. I also did inpatient
19 and partial hospitalization work and consult work for
20 the pediatricians.

21 I remember a Janssen rep, pharmaceutical
22 rep, visiting me numerous times with information about
23 Risperdal. However, at that time, there was no
24 indication for children for its use, but he would leave
25 pharmaceutical studies that I didn't even know existed

1 or had in my possession whether -- these were adult
2 trials. These would be adult indications for children.

3 I never practiced or saw adults as a child
4 psychiatrist and treated them other than as the parent
5 of a child. So I had -- what I mean by that, the parent
6 of the child has to give me history, background
7 information and permission to treat their child before I
8 can do so, but I never treated adults during that time
9 frame. My practice was exclusively child and
10 adolescent.

11 Q. What in that information did you find to be
12 misleading?

13 A. Why would a pharmaceutical rep who did not have
14 an indication for childhood disorders come and see me,
15 first off? I don't understand that.

16 Q. What did you find about that information to be
17 false or misleading?

18 A. There was no childhood indication for the use
19 of Risperdal in child -- child psychiatric conditions,
20 and that's what I was, a child and adolescent
21 psychiatrist.

22 Q. Right. But did this sales representative tell
23 you that Janssen in fact did have an indication for use
24 in kids?

25 A. No, he did not specifically say that.

1 Q. Did he suggest it?

2 A. I recall information from the rep regarding the
3 use of Risperdal, stating that it was safer than our
4 current neuroleptic medications that we used at that
5 time, the main one being Haldol or Thorazine. And these
6 are considered neuroleptic drugs or older medications
7 for the use of psychotic disorders in children.

8 One of the main concerns we had was the
9 condition called EPS, extrapyramidal side effects,
10 which -- which did seem to occur in children at a higher
11 rate than maybe the adult population. Risperdal was
12 presented as a safer medication than what we were
13 currently using in regard to EPS.

14 Q. I mean, as a result of the sales representative
15 from Janssen who called on you in the mid 1990s, as a
16 result of him sharing the adult trials or whatever
17 information he was sharing with you, did that cause you
18 to prescribe more Risperdal to your patients?

19 A. Yes.

20 Q. And what -- what drug would you have prescribed
21 had you not prescribed Risperdal?

22 A. It depends on what the condition would be.
23 There's a lot of things that go into the decision about
24 prescribing a medication for a particular condition in a
25 child.

1 Q. Would you have prescribed Haldol?

2 A. Yes.

3 Q. Would you have prescribed Zyprexa?

4 A. Yes.

5 Q. So insofar as there were other atypicals on the
6 market, those would have been other drugs that you might
7 have prescribed had you not prescribed Risperdal?

8 A. As I recall during this time frame, the only
9 two atypicals on the market were Risperdal and Zyprexa.

10 Q. Would you have prescribed Thorazine?

11 A. Yes.

12 Q. Would you have prescribed perphenazine?

13 A. Yes.

14 Q. Dr. Robinson, before the break, we were talking
15 about some statements that you believed were made to you
16 by someone at Janssen in the mid 1990s that you thought
17 to be misleading.

18 A. Correct.

19 Q. Do you recall who that sales representative
20 was?

21 A. Yes.

22 Q. Jeff Dunham?

23 A. That's correct. That's who it was.

24 Q. What I'm trying to find out is: Do you recall
25 the specific content or what he specifically said that

1 you believe to be misleading as it relates to Risperdal?

2 A. As far as the specific conversation we had, no,
3 I don't necessarily recall every single word. What I do
4 remember is enthusiasm about the medication, certainly
5 it was safer than what we were currently using, and it
6 covered a range of symptoms in child or in adolescents
7 with mental illness.

8 Q. I'm sorry. Covered what?

9 A. A range of symptoms in children and
10 adolescents, not a particular diagnosis.

11 Q. ... the record is clear. During this time
12 period during which you say Jeff Dunham was telling that
13 it -- Risperdal covered a range of symptoms in child and
14 adolescent patients --

15 A. Correct.

16 Q. -- what did you understand to be the
17 FDA-approved indication for Risperdal?

18 A. Schizophrenia in adults, psychosis disorders --
19 psychotic disorders in adults.

20 Q. And you said among the things that you recall
21 Mr. Dunham saying to you was that Risperdal was safer
22 than the other drugs that you were currently using?

23 A. In particular to a side effect that was very
24 bothersome in children.

25 Q. Okay. All right. So it was safer than drugs

1 that you were currently using as it pertains to a
2 specific side effect that you believe to be particularly
3 problematic in children?

4 A. That's correct.

5 Q. And what side effect is that?

6 A. Extrapyramidal side effects.

7 Q. Sometimes --

8 A. That's EPS, which leads to tardive dyskinesia,
9 or TD.

10 Q. Anything else?

11 A. Weight gain.

12 Q. And what did Mr. Dunham tell you about weight
13 gain as it relates to Risperdal?

14 A. That it could occur, but not a significant
15 problem in most children.

16 Q. What do you mean "significant"?

17 A. A 20 or 30-pound weight gain after its onset --
18 after the onset of the use of the drug.

19 Q. Okay. So --

20 A. A 20 or 30-pound weight gain in a month or two.

21 Q. Okay. So he did not tell you during this time
22 period sometime in the mid 1990s that Risperdal would
23 cause patients to gain 20 to 30 pounds --

24 A. Correct.

25 Q. -- following onset or use of the drug?

1 A. Correct.

2 Q. Within -- within how long after use of the drug
3 did the 20 or 30 pounds set in?

4 A. Within a month.

5 Q. And specifically, what you recall him telling
6 you or the information that he shared with you is that
7 Risperdal had better -- or was better with respect to
8 the side effects of EPS?

9 A. Yes.

10 Q. Relative to what?

11 A. Haldol, Thorazine, in particular.

12 Q. And what I'm trying to find out is what did
13 Dr. -- what did Mr. Dunham tell you about weight gain in
14 the use of Risperdal in kids, if anything?

15 A. He didn't tell me about the fact that it could
16 be this high. I guess if you're looking at a
17 pharmaceutical rep to give you information about a new
18 product, I want to know what have you -- what have you
19 studied, what do you know about this particular side
20 effect in child and adolescents? If you're calling on
21 me with a new medication to be prescribed for children
22 and adolescents, what do you have to share with me about
23 what I'm seeing clinically? Who -- what am I seeing
24 clinically in my own experience? Address that for me.
25 Let me talk to your medical liaison -- scientific

1 liaison people about this particular issue, because I am
2 concerned.

3 Q. And based on your use of the drug Risperdal in
4 treating child and adolescent patients, you found it to
5 cause weight gain in patients?

6 A. Yes.

7 Q. In all of your patients?

8 A. Majority. 80 percent or more.

9 Q. And prior to the 1992 to 1996 time period that
10 we've been talking about, you had experience prescribing
11 Haldol?

12 A. Yes.

13 Q. Thorazine?

14 A. Yes.

15 Q. Perphenazine?

16 A. Yes.

17 Q. Well, let me ask it this way: When Risperdal
18 became available -- and during which time Haldol,
19 Thorazine and perphenazine continued to be available,
20 correct?

21 A. Correct.

22 Q. Did you switch all of your patients who were
23 receiving Haldol to Risperdal?

24 A. At least half were switched.

25 Q. What about your patients who were on Thorazine?

1 A. Same, were switched.

2 Q. Four to six months after you started using
3 Risperdal --

4 A. Right.

5 Q. -- you determined that some of the information
6 that Mr. Dunham shared with you, at least you thought to
7 be false and misleading?

8 A. Correct.

9 Q. Can you remind me what it is that you recall
10 Mr. Dunham communicating to you about EPS as it relates
11 to Risperdal?

12 A. That there was a lower incidence of EPS with
13 Risperdal over neuroleptics, neuroleptics such as
14 Thorazine and Haldol.

15 Q. And neuroleptics, is that the same thing as the
16 conventional antipsychotics that were --

17 A. Right. Correct.

18 Q. -- available at the time?

19 A. Uh-huh. Correct.

20 Q. And you believe that statement to be
21 misleading?

22 A. Do I believe it now or did I believe it then?

23 Q. Well, let's start with then.

24 A. No. I believed what he said. I mean, if he
25 said it had a lower incidence, since he was the one who

1 knew about this new drug and I was just being introduced
2 to it, I believed him.

3 Q. Okay. And sitting here today in 2010, do you
4 believe that to be a misleading statement?

5 A. Yes.

6 Q. Why?

7 A. Because it's based on the dosage in children.
8 Basing on the dosage in children, you will definitely
9 get EPS.

10 Q. Do you think Risperdal is better than Haldol
11 generally as it relates to EPS?

12 A. No.

13 Q. You talked some about Mr. Dunham visiting you
14 in the '90s, and I want to show you what has previously
15 been marked in this case as Exhibit 1875 in Mr. Dunham's
16 deposition. And I want to represent to you that
17 Mr. Dunham indicated these were call notes kept in the
18 course of his work for Janssen. First, I want to ask
19 you to look at the first call note and the date on that
20 call note and then the very last date on the call note
21 on the back page.

22 A. Okay. The first date is 8/26/1994.

23 Q. Okay. And then if you'd look at the one on the
24 last page.

25 A. Is it November 18th, '02?

1 Q. That's -- that's what it looks like to me. If
2 this document -- if, in counting, it has either 96 or 97
3 call notes reflecting different dates when Mr. Dunham
4 visited you during this time period, do you have any
5 reason to dispute that's the amount of times Mr. Dunham
6 saw you?

7 A. No.

8 Q. Okay. When Mr. Dunham talked to you, what drug
9 was he talking with you about during these visits?

10 A. Risperdal.

11 Q. During the time period 1994 through 2002, did
12 you see any patients other than children and
13 adolescents?

14 A. No.

15 Q. Did you -- during the course of your many
16 visits with Mr. Dunham, did you make clear to him who
17 your patient population was?

18 A. Yes.

19 Q. When Mr. Dunham or any other Janssen
20 salesperson would come visit you, were you left samples
21 of Risperdal?

22 A. Yes.

23 Q. And can you describe generally what a
24 presentation of EPS looks like?

25 A. In children, primarily it's in the upper part

1 of their body in which they have involuntary motor
2 movements.

3 Q. Okay. Per EPS or TD, are those reversible
4 conditions?

5 A. EPS can be. Tardive dyskinesia is more
6 difficult.

7 Q. Okay. Given the fact that your patients are
8 children and adolescents, is EPS a concern for you?

9 A. Yes. It's a big concern.

10 Q. Can you give us your -- can you tell us what
11 diabetes is?

12 A. Well, there's two types. There's Type 1 and
13 there's Type 2. One is insulin dependent, like juvenile
14 onset; and the other one is more of an adult onset that
15 has to do with obesity.

16 Q. Is diabetes a permanent condition?

17 A. Yes.

18 Q. Okay. Is diabetes a concern when you treat the
19 patients within your practice?

20 A. Yes.

21 Q. I want to ask you: Have you -- over the course
22 of your career as a physician and a child and adolescent
23 psychiatrist, have you received Dear Healthcare Provider
24 letters from pharmaceutical companies?

25 A. Yes.

1 Q. And I'm going to hand you what's previously
2 been marked in the deposition of Ramy Mahmoud
3 Exhibit 686, and I want to ask you if you've seen that
4 document before.

5 A. Yes, I've seen this.

6 Q. Okay. Were you sent this Dear Healthcare
7 Provider letter addressed by Dr. Mahmoud?

8 A. Yes.

9 Q. Does this information provide you information
10 regarding diabetes?

11 A. Yes, it's in here.

12 Q. Okay. Do you -- when you receive Dear
13 Healthcare Provider letters, do you read them?

14 A. Yes.

15 Q. Do you rely upon them?

16 A. Yes.

17 Q. Earlier you were asked a couple of questions
18 about usage of the TMAP algorithm in clinical practice.

19 A. Yes.

20 Q. Was there a time when you utilized the TMAP
21 algorithm or had access to it?

22 A. Yes.

23 Q. When did that occur?

24 A. Shortly after coming to Texas Tech. So I would
25 say starting in 2004.

1 Q. Did the TMAP guidelines in any way -- did they
2 influence, in your view, prescribing behavior here
3 during your practice at Texas Tech?

4 A. Yes.

5 Q. In the event you deviated from the -- the TIMA
6 or TMAP decision trees, was there a requirement that you
7 document any sort of deviation?

8 A. Yes.

9 Q. Okay. I want you to turn, if you would,
10 please, to the diabetes letter dated -- or that's
11 Exhibit 686, if you would. And I want you to turn
12 specifically to Paragraph 4 which starts with
13 "Hyperglycemia-related adverse events have infrequently
14 been reported in patients receiving Risperdal."

15 Did I read that sentence correctly?

16 A. Yes.

17 Q. Did you read this in 2003 --

18 A. Yes.

19 Q. -- when you received the letter?

20 A. Uh-huh.

21 Q. Did you also read the next sentence that says
22 "Although confirmatory research is still needed, a body
23 of evidence from published peer-reviewed epidemiology
24 research suggests that Risperdal is not associated with
25 an increased risk of diabetes when compared to untreated

1 patients or patients treated with conventional
2 antipsychotics"?

3 Did you also review that sentence when you
4 received it?

5 A. Yes.

6 Q. Were you aware that the FDA sent a warning
7 letter to Janssen Pharmaceuticals actually in April of
8 2004?

9 A. No.

10 Q. I want to ask you to turn, if you would,
11 please, to Busti Exhibit 1839, and specifically Page 4
12 of that exhibit. I'm going to ask you to look above at
13 Dr. Stanis -- it says "Stanislaw," but I'll represent to
14 you that it's Dr. Steve Stanislav.

15 A. Okay.

16 Q. And this is testimony that he provided to the
17 P&T Committee; is that correct?

18 A. Yes.

19 Q. At the bottom of the first paragraph, it says,
20 "And we've demonstrated in a long-term study up to two
21 years, which was published in the *New England Journal of*
22 *Medicine* when patients are randomized to either
23 Risperdal or comparator, active comparator, relapse
24 actually is reduced and the timed relapse is extended."

25 Did I read that sentence correctly?

1 A. Yes.

2 Q. And in -- did Mr. Stanislav, in discussing or
3 referencing this *New England Journal of Medicine* study,
4 disclose Janssen Pharmaceuticals' funding of that study,
5 if any?

6 A. Not that I remember.

7 Q. In his testimony that's transcribed here, does
8 Mr. Stanislav disclose any role by Janssen
9 Pharmaceutical in helping either fund or conduct the
10 study that's referenced in the *New England Journal of*
11 *Medicine*?

12 A. No.

13 Q. I want to ask you to turn to the bottom
14 paragraph. Here it says, "Risperdal is first line in
15 terms of antipsychotics in national guidelines and
16 national algorithms. If you look at the EPA guidelines,
17 if you look at the TMAP guidelines in Texas" -- and I
18 want to stop there and ask you, does Mr. Stanislav
19 anywhere in his testimony disclose Janssen
20 Pharmaceuticals' funding of the TMAP algorithm?

21 A. No.

22 Q. Why is it -- for a physician, why is it a
23 problem if a pharmaceutical company who knows the risks
24 associated with a drug either misrepresents the truth
25 about that or doesn't tell the whole truth about it in

1 communicating with the medical community?

2 A. When you look at adverse events with any
3 medication, and in particular with Risperdal --
4 remember, these weren't related to children and
5 adolescents. These are adult studies. So we had no
6 idea how this would play out in children. And we found
7 out through basically trial and error that some of these
8 adverse events were alarming. I felt that I was putting
9 patients at risk and that it was basically up to my
10 clinical expertise to figure out what was wrong or how
11 to undo it or how to fix it, if you will, for the
12 benefit of the patients.

13 Q. And so with respect to weight gain, you found
14 out that what Mr. Dunham had told you wasn't true how?

15 A. Because the majority of the children, even at
16 low doses, gained significantly within a month.

17 Q. And with respect to EPS side effects, you found
18 out that what Mr. Dunham told you wasn't so in the same
19 way, by observing?

20 A. I found that out by the times when maybe I used
21 a little bit higher dose, not much -- a little bit
22 higher dose, and EPS would develop just like I saw with
23 Haldol or Thorazine and had to treat -- treat it.

24 Q. And how high of doses are we talking about
25 here?

1 A. Oh, two to three milligrams per day. Two to
2 three milligrams per day.

3 Q. With respect to hyperprolactinemia, what is
4 that?

5 A. That means there's an increase in prolactin
6 levels which can result in a condition called
7 galacturia, which means there's actually leakage of
8 breast milk in boys and girls.

9 Q. Boys and girls?

10 A. Boys -- males can have it as well, but
11 typically adolescent females.

12 Q. All right.

13 A. And also affect -- can affect their menstrual
14 cycle.

15 Q. And is that a side effect that you've seen with
16 patients taking Risperdal?

17 A. Yes.

18 Q. Did Mr. Dunham or anybody else from Janssen
19 ever tell you anything about that --

20 A. No.

21 Q. -- side effect?

22 A. Not -- no, he did not.

23 Q. Have you ever heard the expression "fair
24 balance" as it relates to what drug company
25 representatives are supposed to present to physicians

1 when they meet with them about a drug? Does that term
2 mean anything to you, "fair balance"?

3 A. Yes.

4 Q. When Mr. Dunham and other sales representatives
5 from Janssen have met with you about Risperdal, did they
6 devote as much time and energy and attention and
7 enthusiasm in discussing the adverse effects the drug
8 could cause as they did their touting its effectiveness?

9 A. No.

10 *(Video stopped)*

11 MR. MELSHEIMER: That concludes
12 Dr. Robinson's testimony.

13 MR. McCONNICO: Your Honor, the defendants
14 have a tender.

15 *(Video played as follows:)*

16 **CROSS-EXAMINATION**

17 Q. When were you first -- you have a board
18 certification, you've told this jury, correct?

19 A. Correct.

20 Q. When were you first board certified and in
21 what?

22 A. Adult psychiatry.

23 Q. Okay. Well, what -- what I'm trying to figure
24 out is: What did you find to be misleading about --
25 putting aside why -- why a Janssen sales rep would have

1 called on you if you were only treating kids, as far as
2 the actual information that he or she gave you about
3 Risperdal --

4 A. Uh-huh.

5 Q. -- what did you find about that information to
6 be false or was misleading?

7 A. There was no childhood indication for the use
8 of Risperdal in child -- child psychiatric conditions,
9 and that's what I was, a child and adolescent
10 psychiatrist.

11 Q. Right. But did this sales representative tell
12 you that Janssen in fact did have an indication for use
13 in kids?

14 A. No, he did not specifically say that.

15 Q. When prescribing medications to patients in the
16 mid 1990s, child and adolescent patients, insofar as
17 those drugs were not yet FDA approved for use in
18 children and adolescents, that's something you knew?

19 A. Yes.

20 Q. Okay. I mean, as -- as a licensed physician,
21 you generally stay abreast as to what are the
22 FDA-approved indicated uses for particular medications
23 as set forth in the drug's or the medication's package
24 insert?

25 A. Yes.

1 Q. And just so everybody's clear, what -- what is
2 a package insert or a label for a drug?

3 A. A package insert is a product of the
4 pharmaceutical companies that has to do with everything
5 and anything concerning a drug as far as, for example,
6 contraindications, adverse reactions, dosing range,
7 things of that nature.

8 Q. And while that is a product of the
9 pharmaceutical companies, that is something that is FDA
10 approved, isn't it?

11 A. Yes.

12 Q. In fact, the FDA requires pharmaceutical
13 companies to include that package insert?

14 A. That's right.

15 Q. And when your patients would gain 10 to 20
16 pounds within the first month of the use of Risperdal,
17 would you stop prescribing it?

18 A. It -- it depended on many factors if I would
19 stop it or not.

20 Q. Okay. So you didn't stop it in all instances?

21 A. No.

22 Q. Why not?

23 A. I lowered the dose. I added something else to
24 it.

25 Q. Why not -- why not stop prescribing Risperdal

1 and go back to using Haldol or Thorazine?

2 A. Sometimes I did.

3 Q. And sometimes you did not?

4 A. Sometimes I did not.

5 Q. Why not?

6 A. Because it was effective in the conditions I
7 was using it for on those children.

8 Q. You thought it was working?

9 A. Yes.

10 Q. But you made a determination as a -- as a
11 clinician as to which patients you would switch or start
12 a treatment on Risperdal who had been previously
13 receiving Haldol, Thorazine or perphenazine, correct?

14 A. That's correct.

15 Q. And how did you determine which patients you
16 would start on Risperdal and which ones you would leave
17 on the conventionals that they were currently receiving?

18 A. The ones that were on the conventionals and the
19 drug was effective, the patient was compliant and the
20 side effect profile was tolerable and safe, would stay.
21 The ones that were not compliant, the ones that had
22 difficulty with adverse events, I switched.

23 Q. To Risperdal?

24 A. To -- uh-huh, to Risperdal.

25 Q. Let me make sure I understand what you're

1 saying. If a patient was on Haldol and was doing well
2 and you were monitoring for adverse events and side
3 effects, you didn't just switch them over to Risperdal
4 just because it was the new drug on the market?

5 A. No.

6 Q. Kind of if it isn't broke, don't fix it?

7 A. That's correct.

8 Q. However, if a patient -- if a patient's needs
9 were not being met, at least in your opinion as their
10 treating physician, by the current treatment with the
11 conventional, you would explore other treatment options?

12 A. Yes.

13 Q. Which at that time included Risperdal --

14 A. Yes.

15 Q. -- as well and later? That included Zyprexa or
16 olanzapine?

17 A. Yes.

18 Q. Do you think Risperdal is right for all
19 patients?

20 A. No.

21 Q. Do you think Haldol is right for all patients?

22 A. No.

23 Q. Do you think any single antipsychotic
24 medication is right for all patients?

25 A. No.

1 Q. And in new patients, brand-new patients who
2 come through the door to see you for the first time and
3 you're left with the choice of selecting a medication to
4 start them on, has it been your practice to never start
5 them on Risperdal?

6 A. No.

7 Q. So you -- you, in fact, started brand-new
8 patients on Risperdal?

9 A. Yes.

10 Q. Did you believe that to be a good drug choice
11 for those patients?

12 A. Yes.

13 Q. And in follow-up visits -- well, let me ask you
14 this: When you start a new patient on an antipsychotic
15 medication, do you give them enough refills to get them
16 through the year before you see them again, or do you
17 expect to see them again in short order?

18 A. They get enough for a month.

19 Q. Because when you're dealing with patients
20 suffering from mental illness, whether it be
21 schizophrenia, bipolar disorder or any other abnormality
22 out there, it's important as a doctor to see them
23 frequently?

24 A. Yes.

25 Q. And the importance of that is -- is what?

1 A. Safety and efficacy.

2 Q. So if they're not responding well, you can
3 change therapies, right?

4 A. Yes.

5 Q. Sure, but I mean, one of the things -- one of
6 the reasons why it's important to see these patients
7 within a month fairly regularly is to monitor and keep
8 track of side effects?

9 A. True.

10 Q. Adverse events?

11 A. Yes.

12 Q. Make sure the drug is working?

13 A. Yes.

14 Q. And if any of those things send off a red flag
15 to you as their treating physician, you'd do something
16 about it, wouldn't you?

17 A. Yes.

18 Q. And if that meant stopping the current therapy,
19 whether it be Risperdal or any other drug, you'd do
20 that, wouldn't you?

21 A. Yes.

22 Q. You'd try another therapy, wouldn't you?

23 A. Yes.

24 Q. Maybe another atypical antipsychotic, maybe a
25 conventional antipsychotic, right?

1 A. Yes, or maybe no medication.

2 Q. Or maybe no medication at all?

3 A. Correct.

4 Q. But that's something that would be left to your
5 discretion, right?

6 A. Right.

7 Q. And it would be dependent upon the individual
8 patient and whatever symptomology that patient is
9 presenting to you?

10 A. Yes.

11 Q. Because if a patient comes in and tells you
12 "Dr. Robinson, I don't like this drug; it's making me
13 feel bad," you'd take that into account in whether to
14 renew or refill a prescription for whatever drug that
15 patient is on?

16 A. Yes.

17 Q. And that's not unique to Risperdal?

18 A. No.

19 Q. That's not unique to Zyprexa?

20 A. No.

21 Q. That's not unique to Haldol?

22 A. No.

23 Q. Or Thorazine or perphenazine?

24 A. No.

25 Q. It's not even unique to antipsychotic

1 medications, is it?

2 A. No.

3 Q. That's just good medicine?

4 A. Yes.

5 Q. You work in child and adolescent psychiatry?

6 A. Yes.

7 Q. And has it been your practice from time to time
8 to prescribe medications to patients for whom the drug
9 is not FDA approved?

10 A. Yes.

11 Q. And is that an off-label use?

12 A. Yes.

13 Q. And in your practice, is that something that
14 you do fairly often or is that uncommon, the off-label
15 use of a medication?

16 A. Now, in 2010 --

17 Q. Okay.

18 A. -- it's more common for me to use FDA
19 indications because we have them for child and
20 adolescent. Ten years ago, more off-label use --

21 Q. Okay. And --

22 A. -- because indications weren't there.

23 Q. Right. And in some cases, you haven't
24 necessarily changed the -- the selection of drugs that
25 you use; it's just that the drugs that you choose from

1 now have additional indications that include use in
2 child and adolescent patients?

3 A. Because they have indications for child and
4 adolescent, they will be oftentimes my first line drugs
5 that I will consider.

6 Q. And, in fact, today Risperdal has child and
7 adolescent indications, doesn't it?

8 A. Today, yes, it does.

9 Q. But as of, you know, when it first came out,
10 that wasn't the case?

11 A. No.

12 Q. Zyprexa, it didn't have a child and adolescent
13 indication?

14 A. No.

15 Q. Conventionals, they didn't either, did they?

16 A. Which drugs in particular are you talking
17 about?

18 Q. Well, first, Thorazine.

19 A. Oh, no.

20 Q. Perphenazine?

21 A. No.

22 Q. Haldol?

23 A. No.

24 Q. Okay. So the conventional antipsychotics, at
25 least those three, those -- those did not have an

1 FDA-approved indicated use in children and adolescents?

2 A. Correct.

3 Q. But you prescribed them anyway --

4 A. Yes.

5 Q. -- because you thought those were the right
6 drug choices for your patients?

7 A. In many cases they were like the only choices
8 we had. We were very limited.

9 Q. Have you ever prescribed an antipsychotic
10 conventional or atypical to a patient under the age of
11 12?

12 A. Yes.

13 Q. How about under the age of eight?

14 A. Yes.

15 Q. Under the age of six?

16 A. Yes.

17 Q. Why?

18 A. Because of severe symptomatology that may
19 require even a hospitalization or the behavior is
20 dangerous, the child is exhibiting dangerous behavior to
21 themselves or to others.

22 Q. And during this time period, I mean, these
23 medications were not FDA approved for use in patients
24 that young, correct?

25 A. What time frame?

1 Q. Any time before 2006.

2 A. No. No, there wouldn't have been indications
3 approved.

4 Q. Right.

5 A. Right.

6 Q. But nevertheless, you -- you would from time to
7 time prescribe antipsychotic medications to patients as
8 young as six?

9 A. Yes.

10 Q. And would you monitor the patient?

11 A. Yes.

12 Q. Closely?

13 A. Yes.

14 Q. And if the patient was not reacting well to
15 the -- to the therapy, would you do anything to change
16 it?

17 A. Yes.

18 Q. And did you in fact from time to time, from
19 patient to patient, change their therapy?

20 A. Yes.

21 Q. Today do you prescribe Risperdal to any
22 patients you treat?

23 A. Yes.

24 Q. Have you used TMAP in any of your clinical
25 work?

1 A. I was aware of TMAP guidelines after
2 Dr. Stanley came to the Health Science Center and would
3 work with the residents who were seeing our adult
4 outpatients. So I was aware of it. Did I use it
5 exclusively? Not necessarily.

6 Q. Are the atypicals on the preferred drug list
7 today?

8 A. Yes.

9 Q. Is Risperdal?

10 A. Yes.

11 Q. As of February of 2010, Risperdal is on the
12 State's preferred drug list?

13 A. Yes.

14 Q. Do you know if there's generic versions of
15 Risperdal available?

16 A. Yes.

17 Q. Do you know how many?

18 A. How many different generics?

19 Q. Uh-huh.

20 A. No.

21 Q. Do you know if they're on the State's preferred
22 drug list?

23 A. Yes.

24 Q. But in any event, if you-all wanted to, the DUR
25 board, you-all could -- could put in a -- a restriction

1 so that any time a doctor fills a prescription for
2 Risperdal in a patient who's a child or adolescent for
3 which there's not yet an indication, you-all could put
4 that restriction in place so that that claim doesn't get
5 reimbursed?

6 A. Correct.

7 Q. He asked you a question to the effect of
8 knowing now -- knowing today what you know now, would
9 you have put in a place restriction on -- on Risperdal
10 on the P&T Committee.

11 A. Uh-huh.

12 Q. Do you remember that?

13 A. Correct.

14 Q. And you said yes?

15 A. Yes.

16 Q. Y'all haven't done that, have you?

17 A. No.

18 Q. Dr. Robinson, isn't it fair to say sitting here
19 today in 2010, looking back at this letter in 2003, you
20 can't tell this jury with any reasonable certitude in
21 what way, if any, you changed your prescribing behaviors
22 as a result of this letter, right?

23 A. Right.

24 Q. Dr. Robinson, you mentioned in response to
25 Mr. Jack's questions that Mr. Dunham didn't tell you how

1 Risperdal's use would play out in children. Do you
2 remember that?

3 A. Yes.

4 Q. Did you expect him to?

5 A. Well, if he was in my office and I was a child
6 and adolescent psychiatrist, yes.

7 Q. Did you ask him how -- how is Risperdal going
8 to play out in treating child and adolescent patients?

9 A. Yes.

10 Q. Did he -- did he not answer your questions?

11 A. He didn't know.

12 Q. He didn't know?

13 A. No.

14 Q. Did he tell you that he didn't know?

15 A. Yes.

16 Q. Did he suggest that you could call somebody at
17 medical science, a medical science liaison and ask them?

18 A. Yes.

19 Q. Did you do that?

20 A. I don't remember.

21 Q. My question is: Sitting here today, is it your
22 belief that Risperdal ought not to be prescribed to
23 patients between the ages of six and 18?

24 A. No. It should be prescribed.

25 Q. Based upon what the doctor thinks?

1 A. Yes.

2 (Video stopped)

3 MR. McCONNICO: Your Honor, that is the
4 end of the defense tender.

5 MR. MELSHEIMER: Your Honor, may it please
6 the Court. At this time we would call -- it's a short
7 deposition of Sharon Dott.

8 THE COURT: When you say short --

9 MR. MELSHEIMER: Thirteen minutes.

10 THE COURT: Okay.

11 (Video played as follows:)

12 **SHARON DOTT, M.D.**

13 having been first duly sworn, testified as follows by
14 videotaped deposition:

15 **DIRECT EXAMINATION**

16 Q. Dr. Dott, could you please state your full name
17 for the record?

18 A. My name is Sharon Gail Dott.

19 Q. And then upon graduation --

20 A. I --

21 Q. -- you attended which medical school?

22 A. I attended the University of Texas Medical
23 Branch in Galveston.

24 Q. And after you graduated from medical school,
25 where did you do your residency?

1 A. I did my internship at the University of Texas
2 Medical Branch and my residency also at UTMB.

3 Q. And then associate professor in 1995; is that
4 correct?

5 A. That's correct.

6 Q. While you held these professor positions, what
7 were your duties and responsibilities?

8 A. For a number of years I was the medical
9 director at the acute inpatient units. In addition to
10 that, I was medical director of the Gulf Coast Center,
11 which is the MHMR authority for Galveston and Brazoria
12 County.

13 Q. Tell us what involvement you still have with
14 the UTMB.

15 A. I am retired faculty --

16 Q. Uh-huh.

17 A. -- in the department of psychiatry at a
18 clinical associate professorship. I am not salaried.

19 Q. Okay.

20 A. I am asked to teach seminars on occasion or
21 supervise residents.

22 Q. And in addition to the patient being able to
23 pay for the medication, what other payor sources did you
24 encounter?

25 A. Well, I can X off private insurance because we

1 did not have patients with private insurance. Medicare
2 did not provide medication. So that leaves patients'
3 resources and Medicaid.

4 Q. Do you know if pharmaceutical companies
5 communicated directly with the executive formulary
6 committee members?

7 A. Well, I was an executive committee member. I
8 had pharmaceutical reps communicate directly to me. So
9 I think the answer to the question is yes.

10 Q. Just generally, do you recall any other
11 instances of speaking with Janssen sales representatives
12 relating to Risperdal?

13 A. Oh, I've spoken to Janssen reps on many
14 occasions in the 17 years I've been here.

15 Q. And you as a psychiatrist taught -- I'm sorry,
16 treated patients suffering from mental illness; is that
17 correct?

18 A. Correct.

19 Q. Have you ever prescribed an antipsychotic
20 medication to a patient?

21 A. Yes.

22 Q. Have you prescribed a conventional or a
23 traditional antipsychotic medication?

24 A. I used both.

25 Q. Do you have any specific example of some

1 Janssen advertising that you think may have in some way
2 victimized a member of NAMI?

3 A. Sadly, when family members ask about new
4 medications with advertisements of being the best or a
5 better medicine than anything before and essentially
6 side effect free, which clinicians know is not the case
7 and does not exist, family members are given false hope
8 only to have what little strength they have kind of
9 blown away by the lack of response because every
10 medication is not for every person and they come with
11 that expectation based on what they interpret, and I say
12 they interpret from the advertisements.

13 Q. Is there a specific one that comes to mind, a
14 specific Janssen advertisement that may have resulted in
15 this sort of response?

16 A. In some of the advertising, Risperdal was
17 advised as effective for positive and negative symptoms
18 with little to no side effects.

19 Q. Can you identify any decision you made relating
20 to Risperdal that was a result of something my client
21 said or did?

22 A. Yes. The pharmaceutical representative from
23 Janssen informed me that Risperdal was a potent drug
24 that treated both negative and positive symptoms of
25 schizophrenia, which I didn't find in clinical practice

1 to treat the negative symptoms over time.

2 And more disconcerting was the promise
3 that it had lower EPS, extrapyramidal symptoms side
4 effects, which prompted residents under my supervision
5 to listen to and be fairly aggressive with treatment
6 which, for lack of a better term, blew up in their face
7 when patients encountered severe EPS.

8 Q. Okay. And --

9 A. And may I add one last thing?

10 Q. Sure.

11 A. That is the most disconcerting, the -- promise
12 is not the particular word, but the stance that Janssen
13 took that Risperdal was weight neutral was of particular
14 disconcert -- of particular concern when patients gained
15 weight. So there are three examples that were very
16 negative in my opinion.

17 Q. The second instance that you mentioned was a
18 representation that Risperdal had lower EPS?

19 A. Yes.

20 Q. First of all, you didn't clarify. Lower than
21 what?

22 A. Lower than what was available.

23 Q. Typical antipsychotics or other atypicals or
24 both?

25 A. Typical.

1 Q. Okay. Do you remember who made the
2 representation to you that Risperdal had lower EPS than
3 typical antipsychotics?

4 A. Dan Skarke.

5 Q. And as a result of Dan Skarke's representation
6 to you, did it cause you to prescribe more Risperdal?

7 A. Initially, yes, until I encountered that what
8 he was representing was not accurate.

9 Q. In your practice, did you have patients who
10 gained weight?

11 A. Yes, I did.

12 Q. And once the patients began gaining weight,
13 what did you do?

14 A. Without destabilizing them, you try to remove
15 the offending agent, so lowering the dose, trying to
16 switch medicines.

17 Q. So you made some adjustments to their
18 treatment?

19 A. Yes.

20 Q. And how long would it take you as a treating
21 physician to realize that a patient was gaining weight
22 on an agent?

23 A. Sometimes just weeks. That was alarming.

24 Q. And again, these -- these were -- the majority
25 of these patients were inpatient?

1 A. No. These -- the majority -- these that I'm
2 speaking of are outpatients.

3 Q. The -- the weight gain patients --

4 A. Yes.

5 Q. -- were outpatients. So you would see them
6 less frequently?

7 A. Not necessarily. They may have been in our day
8 hospital program where they were seen --

9 Q. Okay.

10 A. -- every day.

11 Q. With those three, how long do you think could
12 have elapsed between you prescribing a medication to a
13 patient and then you noticing a weight gain?

14 A. Oh, we took weights every visit, every doctor's
15 visit.

16 Q. So just the next -- the next visit you might
17 notice --

18 A. Yes.

19 Q. -- that there was some weight gain. And if
20 there were a significant amount of weight gain, you
21 would alter the treatment program, either with a reduce
22 of dosing or a different agent?

23 A. Sometimes a patient wouldn't tolerate that and
24 they would decompensate, so --

25 Q. Can you tell me what you mean by they wouldn't

1 tolerate that and they would decompensate?

2 A. Sometimes changing patient's medication was not
3 in their best interest because they were so fragile --

4 Q. Okay.

5 A. -- and any alteration in their medication would
6 destabilize them to the point that they would relapse.

7 Q. Can you think of a specific instance where you
8 had a patient who was exhibiting what you would consider
9 to be an unacceptable amount of weight gain on Risperdal
10 that you did not change their treatment?

11 A. No. That I did not change their treatment, no.
12 They had considerable weight gain, and psychotic
13 patients do not make good diabetic patients, so --

14 Q. I understand.

15 A. -- they are just dreadfully difficult in that
16 situation. So that was one situation where we really
17 struggled to be very proactive.

18 Q. Other than these three examples that we've just
19 gone through, is there anything else that someone from
20 Janssen told you relating to Risperdal that you later
21 learned was false?

22 A. I'm sure there was, but at this time that's
23 what I can recall.

24 Q. No more specific examples?

25 A. You want more?

1 Q. If you have more, yes.

2 A. Let it suffice at that point.

3 Q. Other than the examples that we've previously
4 discussed, do you recall any information that they gave
5 you that you thought was misleading?

6 A. Well, it only takes a little bit of information
7 to then wonder about the rest, so it became a dubious
8 situation.

9 Q. Do you mean that you thought maybe there was
10 information you did not receive?

11 A. Yes.

12 Q. Was there any -- did you ever ask any of these
13 sales reps about the omitted -- or the information you
14 perceived to be omitted?

15 A. Many of us were concerned about the effect on
16 prolactin and we received none of that information.

17 Q. Did you ask the Janssen sales reps about it?

18 A. Yes.

19 Q. And what was their response?

20 A. They didn't have any response.

21 Q. And in this instance, did you ask the senior
22 rep about prolactin?

23 A. I had asked him, yes.

24 Q. And what was his response to you?

25 A. It has no effect.

1 Q. Did you question his response?

2 A. Same as with weight gain. Weight neutral was
3 not a good answer to me when my patients were gaining
4 weight.

5 Q. Other than the representations that we've
6 discussed today, do you have any knowledge of anything
7 that my clients may have done that you consider to be
8 untruthful?

9 A. Representing a medication to a population of
10 patients that are severely impaired is, in my opinion,
11 bad enough. And to withhold information from the
12 prescriber about side effects from medication really
13 twists the knife in the families that have to take care
14 of these patients. I think that speaks for itself.

15 Q. When you make these two points about
16 representing lack of side effects and withholding
17 information about them, are you referring to the
18 representations made to you by the sales
19 representatives?

20 A. Yes.

21 Q. When Janssen sales representatives would visit
22 you, did the Janssen sales reps disclose to you
23 information that was negative about Risperdal?

24 A. No, they did not.

25 Q. Did they disclose to you the results of drug

1 studies that were negative about Risperdal?

2 A. No, they did not.

3 Q. Did they disclose to you results of drug
4 studies showing problems with the drug Risperdal?

5 A. I asked, but they never did.

6 Q. Did they disclose to you the results of drug
7 studies showing -- showing problems with side effects
8 with Risperdal?

9 A. No, they did not.

10 Q. When the Janssen sales representatives visited
11 you, did they talk to you about treatment algorithms?

12 A. They did talk some about treatment algorithms.

13 Q. Do you remember which treatment algorithm they
14 talked with you about?

15 A. Specifically schizophrenia.

16 Q. Did they show you information about TMAP?

17 A. An early form of TMAP was shown to me.

18 *(Video stopped)*

19 MR. MELSHEIMER: That concludes the
20 plaintiffs' offer.

21 MR. McCONNICO: Your Honor, the defendants
22 have a tender.

23 *(Video played as follows:)*

24 **CROSS-EXAMINATION**

25 Q. You just mentioned that you performed these

1 services prior to retirement. Does that mean you are
2 retired today?

3 A. I have been retired 11 years.

4 Q. Dr. Dott, you -- you've participated as the
5 lead investigator in several -- several studies funded
6 by pharmaceutical companies throughout your career,
7 haven't you?

8 A. Yes.

9 Q. And did you believe you were doing anything
10 inappropriate by participating in these studies?

11 A. No.

12 Q. Just generally, do you recall any other
13 instances of speaking with Janssen sales representatives
14 relating to Risperdal?

15 A. Oh, I've spoken to Janssen reps on many
16 occasions in the 17 years I've been here.

17 Q. After speaking with any of them, do you -- did
18 you change your prescribing of Risperdal to your
19 patients?

20 A. Not that I recall.

21 Q. And just to be clear, you did not adopt his
22 dosing strategy?

23 A. Just to be clear, I'd like to reiterate his
24 dosing recommendations were nonclinical and I did not
25 follow them.

1 Q. Do you typically rely on people who aren't
2 clinicians to give you information regarding drugs that
3 you may prescribe?

4 A. Generally not. I do look to the pharmaceutical
5 reps as knowing their drugs and being knowledgeable
6 about their drugs to some degree.

7 Q. Okay. And ultimately, do you -- if you were to
8 review a published study, would you rely on a
9 pharmaceutical company rep to explain it to you or would
10 you use your own understanding?

11 A. I would use my own judgment.

12 Q. And when you were treating your patients, which
13 set of information did you use, the information you
14 received from the pharmaceutical company or the outcome
15 of your clinical experience?

16 A. As a physician, I have to abide by do no harm,
17 and that is precisely that. So it overrode the
18 pharmaceutical -- pharmaceutical information provided to
19 me.

20 *(Video stopped)*

21 MR. McCONNICO: That is the end of the
22 defendants' tender.

23 THE COURT: Thank you. Ladies and
24 gentlemen, let's take our ten-minute afternoon break.

25 *(Recess taken)*

1 *(Jury present)*

2 THE COURT: Be seated, please. Yes, sir.

3 MR. MELSHEIMER: May it please the Court.

4 Your Honor, at this time -- I'm going to return to my
5 demonstrative chart. And the plaintiffs call Dr. Scott
6 Reines, a witness associated with Janssen.

7 *(Video played as follows:)*

8 **SCOTT REINES, M.D.**

9 having been first duly sworn, testified as follows:

10 **DIRECT EXAMINATION**

11 Q. Can you please state your full name, please,
12 sir?

13 A. It's Dr. Scott Reines.

14 Q. Can you briefly tell the jury what your
15 educational background is?

16 A. Yes. I graduated Cornell University as an
17 under -- undergraduate. I received a Bachelor of Arts
18 in chemistry. I have a Ph.D. from Columbia University
19 in chemistry, molecular biology. Sort of a combined
20 sort of study thesis. I have my medical degree from
21 Albert Einstein College in New York and my psychiatric
22 residency training from Montefiore Hospital, which is
23 part of Albert Einstein.

24 Q. And then you joined Johnson & Johnson in July
25 of 2003 and stayed with Johnson & Johnson Pharmaceutical

1 Research & Development until September of 2008; is that
2 correct?

3 A. Yes.

4 Q. Once you became involved with the CNS
5 component, explain what your responsibilities were once
6 CNS came under your umbrella.

7 A. I was responsible for the conduct of the
8 clinical trials for interactions with regulatory
9 agencies for personnel issues. I was responsible for
10 regulatory submissions.

11 Q. Can you tell the jury what you mean by
12 regulatory submissions?

13 A. Yes. When the company collects data and --
14 and -- and the data are important either because they
15 involve safety issues or because the company is seeking
16 a new indication, more summarizing what it's been doing
17 with a certain drug. Those data are put together.
18 They're written up, and they're submitted to the FDA, if
19 we're talking about the U.S. And those -- that's what I
20 mean by regulatory submissions.

21 Q. All right. And am I correct in understanding
22 that the regulatory submissions you might have dealt
23 with at any given time might have been either just
24 voluntarily submitted and/or requested by the FDA
25 depending on the circumstance?

1 A. Yes.

2 Q. And when it came to Risperdal, you were
3 performing those responsibilities for a drug that was
4 marketed by a Janssen entity, correct?

5 A. Correct.

6 Q. Do you have general familiarity with the rules
7 about off-label promotion of a drug?

8 A. Yes.

9 Q. And so you've heard the phrase "off label" or
10 "off-label marketing"? You've heard that before?

11 A. Yes.

12 Q. Can you explain to the jury in your
13 understanding and experience what that means?

14 A. In my understanding, off-label promotion would
15 be communications or dissemination of information that
16 is outside of the product label or inconsistent with the
17 product label.

18 Q. You are aware of the November 2003 Dear Doctor
19 letter that Dr. Mahmoud sent out regarding the class
20 label issue?

21 A. I'm aware of a letter that was sent, yes.

22 Q. Okay. Were you involved in drafting that
23 letter before it went out or reviewing it?

24 A. No, I was not aware of that letter until after
25 it had been sent.

1 Q. And what was your reaction when you saw the
2 November 2003 Dear Doctor letter from Dr. Mahmoud
3 concerning the class label issue?

4 A. I was upset.

5 Q. Why were you upset?

6 A. Because in my opinion, the letter was something
7 that was -- was inconsistent with the regulatory -- it
8 was inconsistent with the regulations that -- that
9 governed the types of communications that were
10 permissible.

11 Q. And that upset you why?

12 A. Because there are regulatory consequences that
13 follow that type of communication, assuming that the FDA
14 were to agree, and I thought they would, that that
15 communication was inconsistent with their regulations.

16 Q. Okay. And when you say there are regulatory
17 consequences that follow, what do you mean by that?

18 A. Well, as -- as actually played out in this
19 case, there was a letter that was issued by the DDMAC
20 division of the FDA some months later that was critical
21 of the company for having issued that communication.

22 Q. Did you think that the letter violated FDA
23 rules and regulations?

24 A. I thought that the statements in the paragraph
25 we discussed were inconsistent with the product label

1 that was being disseminated and that therefore there was
2 a potential regulatory consequence.

3 Q. Would you have approved the Dear Doctor letter
4 to go out had you reviewed it before it went out?

5 A. No.

6 Q. Exhibit 2292 appears to be an e-mail chain
7 starting with the September 16th e-mail and ending with
8 the September 7th, 2003 e-mail, which, again, is about a
9 week or so after the FDA request for a class label
10 change, correct?

11 A. Yes.

12 Q. And do you see where he says "From our
13 perspective, we looked at some rough financial scenarios
14 to put into perspective," and then he lists three
15 scenarios?

16 A. I see that.

17 Q. And the title of this e-mail, when it's talking
18 about financial scenarios, it's talking about the
19 Risperdal bipolar mania and diabetes labeling in the
20 U.S., correct?

21 A. Yes.

22 Q. And the first scenario that Mr. Pruden lists is
23 to accept the current label and launch bipolar, and he
24 puts next to that that it has approximately a 55 to
25 100-million-dollar downside based on final assumptions.

1 Did I read that correctly?

2 A. Yes.

3 Q. The second scenario that Mr. Pruden lists is to
4 submit further data to agency to strive for revised
5 wording, but agency fails to accept post review. Cost
6 of delaying bipolar approval until January is
7 approximately five to seven-million-dollar downside.

8 Did I read that correctly?

9 A. Yes.

10 Q. The third scenario that Mr. Pruden lists in
11 Exhibit 2292 as follow-up from that teleconference with
12 the FDA is to submit further data to the agency, meeting
13 in December for review, FDA accepts revisions. And he
14 states in parenthesis, i.e., low risk for Risperdal. We
15 get precaution versus warning for others. Other
16 competitors get class label. And then he lists in bold
17 an upside approximately 100 million in incremental
18 sales.

19 Did I read that correctly?

20 A. All of the numbers are in bold.

21 Q. Do you see anything -- any discussion
22 whatsoever in this e-mail that's Exhibit 2292 of how
23 this class label issue concerning diabetes impacts use
24 of Risperdal in vulnerable populations such as children
25 and adolescents?

1 A. No.

2 Q. Do you see anything in Exhibit 2292 when you're
3 discuss -- when Mr. Pruden is discussing financial
4 impact to the company of various scenarios associated
5 with the label change that discusses how the diabetes
6 warning impacts patient welfare?

7 A. This is a financial -- as I read this, it -- it
8 has financial estimates only.

9 Q. Do you think it's appropriate to have this kind
10 of a financial impact discussion without also evaluating
11 the safety issue involved and how that might impact
12 public welfare?

13 A. I don't have an opinion.

14 Q. You can't tell the jury one way or the other
15 whether you have an opinion on that?

16 A. Correct.

17 Q. Okay. In Exhibit 1884, there appears to be a
18 number of people copied on this, but it states that it's
19 a voicemail message on safety data Risperdal, and it's
20 dated September 29th, 2003, correct?

21 A. Yes.

22 Q. And then it has a voicemail message
23 confirmation for Friday, September 26th, 2003?

24 A. Yes.

25 Q. And that's within two or three weeks of

1 receiving the requested label change from the FDA,
2 correct?

3 A. Yes.

4 Q. Mr. Walsman goes on to state, "The data does
5 not show an association between Risperdal and an
6 increased risk of diabetes."

7 Is this statement that Mr. Walsman sent to
8 the entire CNS sales force consistent with the language
9 of the warning the FDA suggested just a couple of weeks
10 earlier?

11 A. The FDA warning does -- does not address the
12 question of what the company's data showed.

13 Q. And nowhere in that suggested warning does it
14 state that the data does not show an association between
15 Risperdal and an increased risk of diabetes, correct?

16 A. Correct.

17 Q. Okay.

18 A. The FDA does not make that statement.

19 Q. Okay. That's not a statement that would have
20 been permitted under that particular label suggestion,
21 right?

22 A. It was not included in that label.

23 Q. And the FDA label did -- did not say, though,
24 that there was a greater association of diabetes with
25 some products versus others such as Risperdal?

1 A. The FDA label did not say that, correct.

2 Q. Okay. Later in this paragraph, Mr. Walsman
3 states in his message to you and the entire CNS sales
4 force, quote, "In the meantime" -- do you see where I'm
5 at? Still on the first page, kind of --

6 A. Yes.

7 Q. -- second -- okay. "In the meantime, you
8 should follow our company position and sales direction
9 and continue to emphasize that Risperdal has a low risk
10 of diabetes and DKA compared to other drugs in the class
11 utilizing our diabetes reprint carrier combined with our
12 new sales brochure." Did I read that correctly?

13 A. Yes.

14 Q. Have you seen the acronym DKA used before?

15 A. Yes.

16 Q. And what does that typically stand for in your
17 experience?

18 A. Diabetic ketoacidosis.

19 Q. Okay. Can you identify and read for the jury
20 the paragraph of Exhibit 686 that upset you when you saw
21 the Dear Doctor letter?

22 A. "Hyperglycemia" -- and this is the second --
23 well, actually, one, two -- it's the third or fourth
24 paragraph of the letter. "Hyperglycemia-related adverse
25 events have infrequently been reported in patients

1 receiving Risperdal. Although confirmatory research is
2 still needed, a body of evidence from published
3 peer-reviewed epidemiology research," and there's
4 footnotes one through eight, "suggests that Risperdal is
5 not associated with an increased risk of diabetes when
6 compared to untreated patients or patients treated with
7 conventional antipsychotics. Evidence also suggests
8 that Risperdal is associated with a lower risk of
9 diabetes than some other studied atypical
10 antipsychotics."

11 Q. And how about the next sentence that says
12 "Although confirmatory research is still needed, a body
13 of evidence from published peer-reviewed epidemiology
14 research suggests that Risperdal is not associated with
15 an increased risk of diabetes when compared to untreated
16 patients or patients treated with conventional
17 antipsychotics."

18 Did that statement in Dr. Mahmoud's Dear
19 Doctor letter concern you at the time that you read the
20 letter?

21 A. Yes.

22 Q. Why?

23 A. Because that statement is not consistent with
24 what the FDA had imposed in the class label.

25 Q. And turning back to the first page of the Dear

1 Doctor letter, the last sentence, "Evidence also
2 suggests that Risperdal is associated with a lower risk
3 of diabetes than some other studied atypical
4 antipsychotics."

5 My first question is: Is the statement
6 that Risperdal is associated with a lower risk of
7 diabetes than some other studied atypical antipsychotics
8 a statement that was contained in the class warning for
9 diabetes that was ultimately put in the Risperdal label?

10 A. That is not in the class labeling.

11 Q. So then can we agree that this letter is
12 conveying at least some information that is not in the
13 FDA-approved label for Risperdal?

14 A. Yes.

15 Q. All right. What is Exhibit 2302?

16 A. This is a response from J&J to Dr. Katz.

17 Q. Dr. Katz with the FDA, correct?

18 A. Yes.

19 Q. Okay.

20 A. And it says, among other things that that the
21 Dear Doctor letter has -- that he's requesting has been
22 voluntarily mailed.

23 Q. Okay. And it explains that Janssen had already
24 voluntarily mailed a medical communication concerning
25 the new hyperglycemia and diabetes mellitus labeling to

1 more than 600,000 physician and healthcare providers.

2 A. Yes.

3 Q. Did I read that correctly?

4 A. Yes.

5 Q. Okay. It apparently encloses a copy of a
6 letter, although that's not attached to this exhibit,
7 and it also states that Janssen has individually
8 informed over 70,000 physicians of this label change for
9 Risperdal.

10 Did I read that correctly?

11 A. Yes.

12 Q. Okay.

13 A. Well, that -- I think you read most of that
14 sentence.

15 Q. Yes. And then it goes on to explain a complete
16 copy of the package insert including the new warning was
17 provided as part of both communications to physicians?

18 A. Yes.

19 Q. Okay. Did you have any input or review or
20 approval or anything of this letter that went to
21 Mr. Katz?

22 A. No.

23 Q. Okay.

24 A. I wasn't aware of it.

25 Q. What is Exhibit 2304?

1 A. It's an e-mail string including Jack Grebb and
2 me and a number of other people.

3 Q. You take the e-mail and it eventually gets
4 forwarded to you and you send a separate e-mail to Fred
5 Grossman and Jack Grebb and Garry Neil that says, "Fred,
6 Jack, what was the internal clearance procedure for
7 Ramy's letter? Did PRD have any signoff?"

8 Did I read that correctly?

9 A. Yes. I believe this is the first time that I
10 saw the November 10th letter.

11 Q. So what was the response you received to your
12 questions?

13 A. So do you want me to read Jack Grebb's note
14 back to me.

15 Q. Sure.

16 A. "Scott, The letter would have been approved by
17 the CDT leader and the CDT regulatory leader, Jack."

18 Q. And then what do you respond to Jack?

19 A. "Jack - Do you think that's sufficient? I'm
20 troubled by the liberties they've taken. To me it seems
21 like off-label promotion of differences among the
22 atypical agents."

23 Q. Do you have any regrets for expressing your
24 opinions on this letter?

25 A. I don't have any regrets about my attempt at

1 the time and after that to be sure that the company to
2 the best of its ability was compliant with the
3 regulations.

4 Q. And what is Exhibit 2306?

5 A. It's e-mail correspondence between Fred
6 Grossman and me.

7 Q. And it's dated January 8th, 2004, correct?

8 A. Yes.

9 Q. On the second paragraph he states to you, "Ris
10 diabetes - I recognize why JPI wants to push improving
11 the diabetes label for Ris, but it may not be
12 advantageous to us with respect to our relationship with
13 the FDA in the long run. If a meeting with the FDA does
14 take place, it should be with the intention to share
15 additional data and analysis that the FDA hasn't seen.
16 I believe that the FDA will not reverse their class
17 labeling without very compelling data (which we do not
18 have)."

19 Did I read all that correctly?

20 A. Yes.

21 Q. You respond to his e-mail: Thanks for the
22 update, Fred. Ris diabetes is another example of
23 agreeing with the FDA and then trying to back out which
24 is going to hurt us.

25 Did I read that correctly?

1 A. Yes.

2 Q. Okay. What did you mean when you said that it
3 was another example of agreeing with the FDA and then
4 trying to back out which is going to hurt us?

5 A. Well, I don't -- I don't recall what I meant by
6 another example, if there were any other examples. I
7 think looking at that now, that's kind of an unfortunate
8 characterization written at 11:01 p.m.

9 Q. And one -- you're saying that RIS diabetes is
10 an example of agreeing with the FDA and then trying to
11 back out. What specifically are you referencing?

12 A. Well, from the context of this e-mail, I -- I
13 must be referencing the class label.

14 Q. Do you recognize Exhibit 687?

15 A. Yes.

16 Q. Okay. What is it?

17 A. It's a warning letter from the DDMAC division
18 of the FDA --

19 Q. Okay.

20 A. -- to J&J --

21 Q. Okay.

22 A. -- concerning Risperdal.

23 Q. And did you agree that it conveyed a different
24 impression than what the class label had stated?

25 A. It was inconsistent with the label.

1 Q. Do you agree that the claims that Risperdal is
2 safer than other atypical antipsychotics would be a
3 claim that is not consistent with the Risperdal label at
4 that time?

5 A. Yes.

6 Q. And it goes on to state, "Instead, as discussed
7 below, the letter minimizes risks associated with
8 Risperdal and claims that Risperdal is safer than other
9 atypical antipsychotics when this has not been
10 demonstrated by substantial evidence or substantial
11 clinical experience."

12 Did I read that correctly?

13 A. Yes.

14 Q. Okay. Do you agree with any part of that
15 conclusion from the FDA?

16 A. I agree that the letter claims that Risperdal
17 is safer than other atypical antipsychotics, at least in
18 terms of the context that we're talking about of
19 diabetes hyperglycemia.

20 Q. And certainly the FDA's position was that the
21 statements in Dr. Mahmoud's Dear Doctor letter were
22 false or misleading, correct?

23 A. That was the FDA's position.

24 Q. Do you recognize Exhibit 2308?

25 A. Yes.

1 Q. What is it?

2 A. It's e-mail correspondence including a number
3 of people but also myself and Joanne Waldstreicher.

4 Q. Okay. And the e-mail correspondence is in the
5 April 28th, 2004 time frame, roughly a week or so after
6 the warning letter from the FDA, correct?

7 A. Correct.

8 Q. Okay. You go on to state, "Also, I think it's
9 ironic that Christine is so purist about the database,
10 after JPI wrote such a flagrant letter about Risperdal
11 that the whole management team almost got canned. I'm
12 sure you've seen the DDMAC warning letter."

13 Did I read all that correctly?

14 A. Yes.

15 Q. Okay. And when you -- you've been using the
16 term JPI in your e-mails. Can you explain to the jury
17 what you are referencing when you say JPI?

18 A. It's the same as Janssen. It's Janssen
19 Pharmaceutica Inc.

20 Q. And it was your opinion at this time when you
21 wrote to Ms. Waldstreicher that the Dear Doctor letter
22 that Dr. Mahmoud sent out was a flagrant letter about
23 Risperdal, correct?

24 A. Yes.

25 Q. And did you characterize it as a flagrant

1 letter because of the reasons we've already discussed
2 today?

3 A. Because of the regulatory compliance issue,
4 yes.

5 Q. When you're addressing the warning letter in
6 the second paragraph, tell the jury what you stated
7 about it.

8 A. Do you want me to read the second paragraph?

9 Q. Yes, sir.

10 A. "The warning letter is ugly. As soon as I saw
11 the JPI letter last November, I called Garry and asked
12 how it could have gone out, but it was too late. They
13 never consulted the team or anyone in PRD except some
14 unnamed regulatory and legal people whom they say
15 reviewed it. But no competent person would have let it
16 go out. If you're interested, I can send it. It's
17 really a black mark for J&J. The *Wall Street Journal*
18 and other media slammed us yesterday. Regards."

19 Q. And was that how you felt in April 2004?

20 A. Yes.

21 (Video stopped)

22 MR. MELSHEIMER: That concludes the
23 plaintiffs' offer.

24 MR. McCONNICO: Your Honor, the defense
25 has an offer.

1 *(Video played as follows:)*

2 **CROSS-EXAMINATION**

3 Q. And was there anything at this time in the fall
4 of 2003 -- was there anything in this particular
5 paragraph that I just read under the warning section
6 suggested by the FDA that you disagreed with?

7 A. Yes.

8 Q. Okay. What did you disagree with at that time?

9 A. I disagreed with the -- the lumping of all of
10 the atypical antipsychotics studied and the -- the
11 statement that epidemiological studies suggest an
12 increased risk, and I'm paraphrasing, in patients
13 treated with the atypical antipsychotics, because our
14 own epidemiological data and all of the data we could
15 find from the literature did not substantiate that
16 statement.

17 Q. Did you have any understanding when you worked
18 for the company of how a label change such as the one
19 suggested by the FDA would -- whether it would advantage
20 or disadvantage Risperdal compared to other manufacturer
21 drugs?

22 A. You're asking me whether the class label that
23 the FDA was proposing would give Risperdal either a
24 competitive advantage or a disadvantage? The problem
25 with the class label was that in our opinion it was

1 incorrect. So a class label is designed to blur
2 distinctions across the drugs that are covered by the
3 class label. And in our opinion, there were
4 distinctions among the drugs. And the distinction in
5 particular was that Risperdal was different from
6 olanzapine in terms of these types of risks.

7 Q. And then it misleading -- it also states that
8 the Dear Doctor letter misleadingly claims that
9 Risperdal is safer than other atypical antipsychotics.
10 Did I read that correctly?

11 A. Yes.

12 Q. Okay. Did you agree with that conclusion?

13 A. No.

14 Q. And why didn't you agree with that conclusion?

15 A. Because I understand in their letter they're
16 using the term misleadingly to mean that there's a
17 statement made that's inconsistent with the product
18 label. That's their definition of misleading. But my
19 definition of misleading has more to do with the
20 accuracy of the data. And after my review of the data,
21 my opinion was that the information conveyed was not
22 misleading.

23 Q. Okay. And where do you get the understanding
24 that when they say misleading, they're specifically
25 using that term in reference to the label?

1 A. Well, from the experience I've had in the
2 pharmaceutical industry, including participation on
3 medical/legal boards, crafting labels, negotiating
4 labels, my impression is that the terms false or
5 misleading are regulatory terms that they use for
6 communications that they consider to be inconsistent
7 with the label.

8 Q. Do you have Exhibit 686 in front of you?
9 That's the November 10th, 2003 Dear Healthcare Provider
10 letter?

11 A. Yes.

12 Q. And can you tell us when -- when did you first
13 see this letter?

14 A. Approximately November 26th.

15 Q. 2003?

16 A. Correct.

17 Q. All right. So about two weeks after it had
18 gone out?

19 A. Yes.

20 Q. Okay. And at that time, did you have an
21 opportunity to assess the scientific validity of the
22 statements contained within the letter, specifically the
23 paragraph that starts with hyperglycemia-related adverse
24 events?

25 A. Yes, I did.

1 Q. And what did you do?

2 A. I reviewed the references cited in this letter,
3 as well as other information that the company had,
4 including literature and the company's database.

5 Q. Okay. And upon that -- that review, did you
6 reach any conclusions?

7 A. Yes, I did.

8 Q. And what were they?

9 A. I concluded that based on that review, that the
10 statements in the letter were accurate and -- and
11 represented the -- the data that we had.

12 Q. And -- when did -- when did you reach those
13 conclusions?

14 A. It was sometime in December, I'd say, late
15 2003.

16 Q. And we've seen some e-mail communications where
17 you were critical of Exhibit 686, correct?

18 A. Correct.

19 Q. And with those criticisms did you try to
20 retract the November 10, 2003 letter?

21 A. You mean did I -- did I work within the company
22 to somehow change or retract the letter that had gone
23 out?

24 Q. Yes, sir.

25 A. No.

1 Q. Why not?

2 A. Because after I reviewed the data, I was
3 completely satisfied that the data that had been
4 communicated were accurate, and therefore, there was not
5 a patient safety issue at stake. Given, though, as
6 we've discussed during this day many times, that there
7 was an issue from a regulatory compliance perspective,
8 but no issue from a patient safety perspective in my
9 opinion.

10 Q. Do you know if the FDA was provided a copy of
11 the November 10th, 2003 Dear Healthcare Provider letter
12 at or about the time that it went out?

13 A. Yes. The documents we have reviewed show that
14 there was a letter. The letter was provided to the FDA
15 shortly after it went out.

16 Q. Do you have a copy of Exhibit 2302 in front of
17 you?

18 A. Yes.

19 Q. And that's a letter sent from Susan Merchant,
20 Manager of Regulatory Affairs at Johnson & Johnson to
21 Dr. Katz with the Division of Neuropharmacological Drug
22 Products at FDA, correct?

23 A. Yes.

24 Q. And do you see there on the front page, the
25 bottom paragraph?

1 A. Yes.

2 Q. And let me read that. There she states to
3 Dr. Katz, quote, "We request that you review the
4 proactive efforts already undertaken by Janssen to
5 inform and educate the medical community, consider the
6 overall level of information already provided to the
7 public and physicians concerning the issue and concur
8 that no additional communication on this topic is
9 necessary."

10 Do you see that?

11 A. Yes.

12 Q. Do you have an understanding as to what's being
13 referred to there?

14 A. My understanding is that she's referring to the
15 November 10th letter.

16 Q. And when was the first time that you or others
17 at Janssen heard of any criticism from the FDA regarding
18 that letter?

19 A. The first time was the April warning letter
20 from the DDMAC division.

21 Q. And how many months later was that?

22 A. Five.

23 Q. Do you know if Exhibit 686 was sent out as --
24 as just this two-page letter?

25 A. It also included the new class labeling

1 warning.

2 Q. That was an enclosure with this letter?

3 A. Yes.

4 Q. Okay. And also turn your attention back to
5 Exhibit 697 in your e-mail to Mr. Frost and Al. I'm
6 sorry, is that Al --

7 A. Derivan.

8 Q. Derivan. In -- in your e-mail, your July 25th,
9 2004 e-mail, you write: Al - this stems from a "Dear
10 Doctor" type letter that Janssen sent to physicians
11 after we included a class warning about diabetes in the
12 label. DDMAC objected to the letter and required the
13 company -- that the company send a corrective document,
14 which is the source of the, quote, misleading, closed
15 quote, statement, referring to the original
16 communication.

17 In your e-mail, you've put misleading in
18 quotation marks?

19 A. Yes.

20 Q. Why?

21 A. That was to indicate that this was a regulatory
22 definition. And as I testified earlier, that I did not
23 think that the information was misleading.

24 Q. The last sentence in that paragraph reads,
25 quote, the first letter was by no means optimal, but it

1 did contain the new warning. What did you mean there?

2 A. That refers to the November 10th letter. And I
3 meant that from a regulatory perspective, it was not
4 optimal because of the issues we've discussed today, but
5 I did want to point out to Al Derivan that that
6 warning -- the most current class labeling warning had
7 been included in that letter.

8 Q. You mentioned earlier that Risperdal CONSTA was
9 a very important product. Do you remember that?

10 A. Yes.

11 Q. What did you mean?

12 A. Risperdal CONSTA was the first atypical
13 antipsychotic drug available by injection, and the --
14 the population treated is schizophrenia, which is a very
15 vulnerable population and a population that does not
16 typically comply well with medication. The opportunity
17 for a physician to provide an injection of Risperdal
18 CONSTA meant that the patients could be treated without
19 the uncertainty of whether they were taking their
20 medication or not.

21 *(Video stopped)*

22 MR. MELSHEIMER: Your Honor, at this time
23 we call Dr. Joseph Glenmullen.

24 THE COURT: Doctor, may I get you to raise
25 your right hand for me, please.

1 THE WITNESS: Yes, sir.

2 *(The witness was sworn)*

3 THE COURT: I appreciate it. Thank you.

4 There is a front door.

5 MR. MELSHEIMER: May it please the Court,

6 Your Honor.

7 **JOSEPH GLENMULLEN, M.D.**

8 having been first duly sworn, testified as follows:

9 **DIRECT EXAMINATION**

10 BY MR. MELSHEIMER:

11 Q. Doctor, tell the jury who you are.

12 A. I am Dr. Joseph Glenmullen.

13 Q. Where do you live, sir?

14 A. Cambridge, Massachusetts.

15 Q. How long have you lived in Cambridge?

16 A. Oh, about 30 years.

17 Q. Do you have children?

18 A. I do.

19 Q. How many?

20 A. Three grown children, daughter and two sons.

21 Q. What do you do for a living, Doctor?

22 A. I'm a psychiatrist.

23 Q. All right. And what is your practice as a
24 psychiatrist?

25 A. I do a number of things. I see patients in a

1 private practice. I research and write books on
2 psychiatric issues. And I teach at Harvard Medical
3 School.

4 Q. Tell the jury about your practice as a
5 psychiatrist.

6 A. I see all kinds of patients. I trained in the
7 public sector. And I've always treated severely
8 mentally ill patients and also very high-functioning
9 patients, too.

10 Q. How many patients -- private patients do you
11 see currently?

12 A. Currently I'm seeing about 10 to 20 patients.

13 Q. How long have you been doing that?

14 A. Oh, about 30 years now.

15 Q. All right. You also mentioned that you're an
16 author and a researcher in psychiatric issues.

17 A. Right.

18 Q. Have you written any books?

19 A. Four.

20 Q. What are they?

21 A. Well, two of the books were on antidepressants
22 and their side effects. Another book was on
23 psychotherapy. And the most recent one was on death and
24 dying issues.

25 Q. Was one of the books you wrote called *Prozac*

1 *Backlash?*

2 A. It is.

3 Q. What was *Prozac Backlash* about?

4 A. It was a book about Prozac-type
5 antidepressants. So that would include Zoloft, Paxil,
6 Celexa, the whole class. And half the book was about
7 the side effects that I didn't think doctors and
8 patients were being told enough about at the time. And
9 the other half was how to make a reasoned decision as a
10 prescriber or a patient when it would be appropriate to
11 use them.

12 Q. Did that book receive any honors or awards,
13 Doctor?

14 A. Yes. I got the annual Achievement Award from
15 the American College for Advancement of Medicine for
16 that book.

17 Q. Now, you mentioned that you work as a clinical
18 instructor at Harvard Medical School.

19 A. That's correct.

20 Q. What does that mean?

21 A. So I have been teaching at Harvard Medical
22 School since I finished my residency, and I typically
23 teach psychiatric residents late in their training and
24 supervise their case loads, advise them about treating
25 their patients.

1 Q. How many psychiatric residents do you supervise
2 every year?

3 A. Typically, it's two or three, and I'll meet
4 with each of them weekly, individually.

5 Q. How many patients are they seeing?

6 A. They're seeing hundreds of patients.

7 Q. Are some of the psychiatric residents you're
8 overseeing treating patients with schizophrenia or other
9 severe mental illnesses?

10 A. Yes, sir. The -- I teach at Cambridge City
11 Hospital, which again is a public hospital, so lots of
12 people with no insurance or Medicaid, street people,
13 a lot of patients with very serious mental illness.

14 Q. I want to talk to you a little bit about your
15 educational background, all right?

16 A. Sure.

17 Q. Did you go to college?

18 A. I did, sir.

19 Q. Did you graduate?

20 A. Yes, sir.

21 Q. Where did you graduate from?

22 A. Brown University.

23 Q. Did you go back to school -- when did you
24 graduate?

25 A. 1972.

1 Q. Did you go back to school in 1978?

2 A. I did.

3 Q. Why?

4 A. I took a number of years off, and then I
5 decided I wanted to try to go to medical school. So in
6 1978, I went back and did the pre-med requirements
7 hoping to get into medical school.

8 Q. You got into a pretty good one?

9 A. I went to Harvard Med.

10 Q. All right. And when did you graduate from
11 Harvard Medical School?

12 A. 1984.

13 Q. What type of courses -- tell the jury, what
14 kind of courses did you take in medical school?

15 A. Well, in medical school, they really want you
16 to sample all of medicine, so really everything,
17 anatomy, physiology, biochemistry, general medicine,
18 surgery, pediatrics, psychiatry, something of
19 everything, so you can make the decision what you would
20 like to do.

21 Q. After you graduated, did you decide to
22 specialize in a particular area of medicine?

23 A. That's when I decided to specialize in
24 psychiatry.

25 Q. All right. In order to specialize in

1 psychiatry, did you have to take some specialized
2 training?

3 A. I did.

4 Q. Tell the jury about that.

5 A. So for that, you have to do a one-year
6 internship, followed by three years of specializing in
7 psychiatry.

8 Q. Where did you do your internship and residency?

9 A. Those I did at one of the Harvard teaching
10 hospitals, Cambridge City Hospital, the same one I've
11 been teaching at ever since.

12 Q. What kind of internship did you complete?

13 A. So I did a general medical internship, which
14 meant I spent time in the emergency room, intensive
15 care, medical wards. I did a month of pediatrics,
16 again, kind of the spectrum of medicine.

17 Q. After you completed your internship, how long
18 was your residency?

19 A. It was three additional years. The first one
20 is inpatient work. The second one is outpatient work.
21 And the last year I was the chief resident in the
22 outpatient department.

23 Q. So during your residency, did you see patients
24 with serious mental illnesses?

25 A. Oh, very much so. Again, because this was a

1 public hospital, the city hospital, a lot of
2 schizophrenics, a lot of bipolar disorder, a lot of
3 severe depression, many patients with no insurance, many
4 patients with Medicaid.

5 Q. Now, we've heard some testimony about this
6 before, Doctor, but what does it mean when you say a
7 public hospital, so therefore you were likely to see a
8 lot of patients with severe mental illnesses? What do
9 you mean by that?

10 A. Well, that's in contrast to private hospitals
11 where most of the patients would have insurance. This
12 is a city hospital specific -- with a specific mission
13 to treat poor patients, indigent patients, people with
14 Medicaid or no insurance at all.

15 Q. When did your formal education conclude, sir?

16 A. 1988.

17 Q. What did you do after you completed your formal
18 training in 1988?

19 A. So I did a number of things. I started my
20 private practice. I took the teaching position at
21 Harvard Medical School. And I was also offered a job at
22 the Harvard Student Health Services where I saw
23 students, staff and faculty.

24 Q. Are you still doing all those three things
25 except the student health services?

1 A. Yeah. I retired from the student health
2 services a little over three years ago.

3 Q. You don't look enough to be retired?

4 A. Thank you, sir.

5 Q. All right. Now, from the time you started
6 practicing as a psychiatrist until very recently, how
7 many patients would you say you saw a month?

8 A. Probably about 200 appointments a month with my
9 patients.

10 Q. Is that a combination of private patients and
11 students?

12 A. Exactly.

13 Q. Okay. Now, as a psychiatrist, have you had an
14 occasion to prescribe antipsychotic drugs?

15 A. Oh, absolutely.

16 Q. How long have you been doing that?

17 A. Pretty much the whole 30 years.

18 Q. Which ones?

19 A. All of them, both the older less expensive
20 drugs that I'm sure the jury has heard a lot about and
21 the newer more expensive ones.

22 Q. Have you, Doctor, ever participated in any
23 medical studies?

24 A. I have.

25 Q. What kind of studies?

1 A. The ones that I've done are called
2 epidemiological studies.

3 Q. What's that?

4 A. It's when you look back in time,
5 retrospectively, at a patient population and you're
6 looking at a particular issue. It might be a disease.
7 It might be a side effect of a drug. And you're looking
8 backwards in time in a particular defined population.

9 Q. Now, in addition to your private practice and
10 your teaching, have you ever been engaged in consulting
11 work on psychiatric issues?

12 A. I have.

13 Q. Describe how you first became involved with
14 that kind of consulting work.

15 A. So that book that I talked a little bit about,
16 *Prozac Backlash*, half of it about side effects, some of
17 those side effects then became the subject of lawsuits,
18 and I was asked to consult in those lawsuits.

19 Q. Have you been hired or retained as an expert in
20 other legal cases?

21 A. Yes, sir.

22 Q. And what was the subject matter of your expert
23 testimony and opinion offered in those cases?

24 A. I have expertise and typically testify on
25 either psychiatric medications or other kinds of

1 medications that have psychiatric side effects.

2 Q. Now, in those other cases, do you conduct
3 what's called a forensic analysis?

4 A. I do.

5 Q. What is that?

6 A. That involves typically looking through lots
7 and lots of pharmaceutical company documents, what the
8 pharmaceutical company's internal company reports said
9 about their studies, what they submitted to the FDA, the
10 FDA's reviews back to the company of those studies, all
11 of which is confidential but comes available in the
12 lawsuits, then the published versions of the studies,
13 what the company's public face about those studies was
14 to doctors and patients, internal company memos,
15 e-mails, business plans, marketing plans, sales
16 training, call notes. As the cases go on, as you know
17 from some of these videotapes, there's deposition
18 testimony, and I will read some of that.

19 Q. What about medical studies?

20 A. Oh, all -- not only the company studies, but
21 other medical studies on the same class of drugs or the
22 same side effects.

23 Q. Have you given sworn testimony in lawsuits as
24 an expert witness?

25 A. I have.

1 Q. Have you testified in both depositions and in
2 jury trials?

3 A. That's correct.

4 Q. Have you issued or provided in most of those
5 cases written reports of your analysis and conclusions?

6 A. Yes. Typically I have to write a report before
7 I get deposed.

8 Q. Dr. Glenmullen, did one of your reports in one
9 of your cases become the basis for a request for an
10 inquiry to the FDA by Senator Grassley of Iowa into the
11 practices of another large pharmaceutical company called
12 GlaxoSmithKline?

13 A. Correct. Two judges made that report public,
14 and then Senator Grassley's office got it and he
15 initiated an investigation by the FDA into that
16 pharmaceutical company's practices.

17 Q. In the experience you've had as an expert
18 consultant, has it always been in psychiatric issues?

19 A. Correct.

20 Q. Has it sometimes involved antipsychotic drugs
21 like the ones that we're talking about in this case?

22 A. It has.

23 Q. Have you been retained by the United States
24 Department of Justice, the justice department, to
25 consult on psychiatric issues?

1 A. Correct.

2 Q. How much of your time currently is spent doing
3 this kind of forensic analysis in legal cases?

4 A. In recent years, it's been over half my time.

5 Q. Can you tell the jury why that's changed over
6 the last couple of years?

7 A. What's happened is that cases like this one are
8 so large and require so much time to go through all of
9 what -- all these documents and all the science, that I
10 haven't had as much time left to see patients.

11 Q. Can you give the jury an idea of how much time
12 you've personally spent working on this case?

13 A. I have spent over 3,000 hours on this case in
14 four and a half years.

15 Q. Did you review sworn testimony?

16 A. About 114 depositions taken in this case.

17 Q. Did you review documents?

18 A. I reviewed documents in the database with over
19 ten million documents in it.

20 Q. Did you have some help doing that?

21 A. I did, sir.

22 Q. How many medical studies did you review?

23 A. Hundreds.

24 Q. Let's talk about an example of one of the
25 studies you reviewed and analyzed.

1 MR. MELSHEIMER: Can we pull up PX 94?

2 Q. (BY MR. MELSHEIMER) Dr. Glenmullen, is PX 94
3 one of the studies you reviewed as part of your analysis
4 in this case?

5 A. Correct. This is Study 35, one of Janssen's
6 studies of new patients in the early stages of
7 psychosis.

8 Q. Why did you review and analyze this particular
9 study which we'll call Study 35?

10 A. This was an example of where the internal
11 company report did not match the published version of
12 the study. The results were different.

13 Q. What do you mean by that?

14 A. Well, the internal study report made it clear
15 that when Risperdal was compared to Haldol on the
16 primary measure and most of the other measures, the two
17 drugs were comparable. And then by the time it appeared
18 in print, the published version said that Risperdal was
19 superior.

20 Q. Are we going to talk a little bit more about
21 that study later?

22 A. Correct.

23 Q. Now, did part of your work in this case to get
24 ready to come to court involve reviewing the expert
25 reports from the pharmaceutical company?

1 A. The defense reports, yes.

2 Q. Did the defendants provide just one report to
3 rebut your analysis or more than one?

4 A. More than one.

5 Q. How many defense expert reports did you review
6 from defense experts who responded to your conclusions?

7 A. I reviewed about a dozen defense reports.

8 Q. Now, during your review of those reports, was
9 it possible for you to determine just from the reports
10 how much time those folks spent doing their work?

11 A. No, not from their reports.

12 Q. Now, so the kind of review and analysis that
13 we've talked about, is that the kind of work that makes
14 up the bulk of the more than 3,000 hours you spent on
15 this case?

16 A. Correct.

17 Q. Okay. Now, it's been said at the very
18 beginning of trial -- it seems a while ago -- that all
19 you did was flip through or look through some documents.
20 Have you heard that?

21 A. I have.

22 Q. Does that sound right?

23 A. I don't think that's a fair characterization.

24 Q. Why is it unfair?

25 A. Well, these are dense medical studies and very

1 complicated. I really had to read hundreds of thousands
2 of pages word for word and in many instances check the
3 data, check the analyses with a lot more than just
4 flipping through.

5 Q. Did you bring your medical expertise, your
6 experience and training to bear when you reviewed those
7 studies?

8 A. Exactly.

9 Q. And your own experience as a practicing
10 psychiatrist?

11 A. Yes.

12 Q. Now, when were you first contacted about this
13 lawsuit?

14 A. In the fall of 2000 -- fall of 2007.

15 Q. Who contacted you?

16 A. The Texas State Attorney General's Office.

17 Q. What happened next?

18 A. They invited me to come down here to Austin.

19 Q. Did you?

20 A. I did.

21 Q. What did you talk about?

22 A. Well, they told me some about the case and I
23 told them some about my qualifications.

24 Q. What did the attorney general of Texas ask you
25 to do in this case as an expert?

1 A. They asked me to review this issue of off-label
2 marketing, whether or not Risperdal had been off-label
3 marketed. They asked me to review the effectiveness in
4 Ris -- of Risperdal, and in particular, whether or not
5 Janssen had made superiority claims that it was more
6 effective. They asked me to review the safety of
7 Risperdal, and again, particularly whether or not
8 Janssen had made claims that it was superior when it
9 came to safety. And the attorney general also asked me
10 to review the whole TMAP process, the way in which TMAP
11 came into existence and was adopted in Texas.

12 Q. Did they also ask you to evaluate whether the
13 TMAP algorithm resulted in -- the TMAP algorithm was
14 based on valid medical science as opposed to drug
15 company marketing?

16 A. That was the heart of it, yes.

17 Q. Did you do all those things?

18 A. I did.

19 Q. And you agreed to act as an expert?

20 A. I did.

21 Q. Now, did you tell them the kinds of documents
22 that you think you needed to see to perform your
23 analysis? I think we have a demonstrative to illustrate
24 that. Did you tell the Attorney General's Office the
25 kind of documents you thought you would need?

1 A. I did.

2 Q. And review for us, if you would, sir, what you
3 told them.

4 A. Well, there's a voluminous -- in this case of
5 this drug, there was like around 300 volumes of material
6 submitted by Janssen to the FDA. It's called a new drug
7 application. I told them I would need everything in the
8 new drug application, all the original studies, the
9 internal company reports on those studies, the FDA's
10 review of those reports, the FDA's correspondence with
11 the company about the studies, then the published
12 versions, internal company e-mails, memos, the
13 depositions as they were taken. I also wanted to look
14 at the business plans, the marketing plans, sales
15 training, call notes. That's what made up the database
16 of over ten million documents.

17 Q. Did you write a report, Doctor, that included
18 the results of your analysis and your conclusions?

19 A. I did.

20 Q. Why did you do that?

21 A. Well, two reasons. One, it's actually required
22 in cases like this. And two, I personally find that a
23 very useful exercise, because for me it's when I write
24 it down that I have to really cross all the T's and dot
25 all the I's and make sure that I have the science right.

1 Q. Is your report in this case short or long?

2 A. It's a long one.

3 Q. How long is it?

4 A. It's 400 pages.

5 THE COURT: 444.

6 THE WITNESS: Thank you, Your Honor.

7 Q. (BY MR. MELSHEIMER) You're under oath, Doctor.
8 Here's a softball. Does it have more than a thousand
9 footnotes?

10 A. 1300.

11 Q. So you've worked on this case for over four
12 years, almost five years. You've spent 3,000 hours --
13 over 3,000 hours. You wrote a 400-page report. I take
14 it you charge for your time, sir.

15 A. I do.

16 Q. All right. And what's your hourly rate for
17 this kind of forensic work?

18 A. \$550 an hour.

19 Q. Dr. Glenmullen, I want to talk about the issue
20 of diabetes.

21 A. Sure.

22 Q. All right. Is that one of the issues that you
23 looked at in your analysis?

24 A. Yes, sir.

25 Q. Okay. And is one of the issues about diabetes

1 that you considered was a review of the scientific
2 evidence and the evidence from Janssen's own files
3 surrounding the issue of Risperdal's risk for diabetes?

4 A. Yes.

5 Q. Okay. So, Doctor, we're not going to get
6 through all your testimony today, so we're going to
7 focus on diabetes, and hopefully we can get -- we can
8 get through that. Did Janssen make representations in
9 one form or another that Risperdal did not cause
10 diabetes?

11 A. That's correct.

12 Q. Is that true or false?

13 A. That's false.

14 Q. All right. So let's look at some examples of
15 what you've concluded are Janssen's false
16 representations. Is this one of them?

17 A. That's the November 10, 2003 Dear Doctor letter
18 which I think the jury has heard quite a lot about.

19 Q. Okay. And this is actually -- it's labeled
20 DX 441. I think we've got it as a plaintiffs' exhibit.

21 MR. MELSHEIMER: What is it, Mr. Roberts?

22 Q. (BY MR. MELSHEIMER) Does this contain false
23 representations about Risperdal and diabetes?

24 A. It does.

25 Q. Okay. And what are some other -- I want to

1 talk about that in just a moment. But what are some
2 other examples of other false statements that you found
3 that Janssen had made about Risperdal and diabetes?

4 A. Well, it wasn't just this letter. The company
5 business plans, marketing plans made it very clear that
6 the company was taking the position that Risperdal
7 caused very little or no diabetes. The sales training
8 reflected that. And then the call notes made it clear
9 that that was what was being communicated in the field
10 to doctors. And I think the jury heard earlier in the
11 week, or maybe it was -- well, from Mr. Friede that this
12 is one way to really look through the whole process,
13 what did the company intend to do, what did they plan --

14 Q. Let me stop you. So that's in their business
15 plans?

16 A. Correct.

17 Q. And what's the next one?

18 A. What did they actually implement. That would
19 be the training, the sales training. And then what
20 actually happens in the field, what do the call notes
21 that the sales reps wrote indicate.

22 Q. All right. So you looked at all those things?

23 A. I did.

24 Q. Did you find out any way to make those call
25 notes easier to read?

1 A. Not yet.

2 Q. Okay. Did you come to a conclusion about
3 whether the medical science supported Janssen's
4 representations that Risperdal was either no or low risk
5 for diabetes?

6 A. I concluded that the science did not support
7 that claim.

8 Q. Okay. Let's take a look at the November 10th,
9 2003 Dear Doctor letter that we've heard so much about,
10 and this is Plaintiffs' Exhibit 938. It's also
11 displayed here in our demonstrative in front of the
12 jury. So is this the letter that -- the so-called Dear
13 Doctor letter that you reviewed?

14 A. It is.

15 Q. So where in this letter -- let's just cut right
16 to it. Where in this letter does Janssen say that
17 Risperdal does not cause diabetes?

18 A. Well, you heard Dr. Reines say just a little
19 while ago that the key paragraph is the middle
20 paragraph, and the key sentence is the middle sentence
21 that Risperdal is not associated with an increased risk
22 of diabetes when compared to untreated patients or
23 patients treated with conventional antipsychotics.

24 Q. So I just want to focus on that for a minute.
25 So they're saying that -- when they say Risperdal is not

1 associated with an increased risk of diabetes when
2 compared to untreated patients, in other words, are they
3 saying that when you compare somebody that's never
4 gotten Risperdal at all?

5 A. Exactly.

6 Q. Okay. So that sounds like a pretty good
7 comparison. If you're not -- if you're not causing
8 diabetes compared to someone that doesn't even get your
9 drug, is that a pretty powerful statement?

10 A. That's essentially saying Risperdal doesn't
11 cause it.

12 Q. Okay. And then "or patients treated with
13 conventional antipsychotics."

14 A. Correct.

15 Q. All right. That would be like the Haldol.

16 A. Thorazine, perphenazine.

17 Q. Let me ask you a question. At the very end of
18 Dr. Reines' testimony he talked about the injectable
19 form of Risperdal called CONSTA.

20 A. Correct.

21 Q. Was there an injectable form of Haldol as well?

22 A. Injectable Haldol. There was an injectable
23 Prolixin. There were injectable forms of the older
24 drugs.

25 Q. Okay. So that really wasn't all that big of a

1 deal?

2 A. No, sir.

3 Q. Okay. So let's talk about -- this is the claim
4 that you're saying is not supported by the science?

5 A. Correct, that Risperdal is not associated with
6 an increased risk compared to untreated patients.

7 Q. Okay. But there's eight footnotes.

8 A. That's correct.

9 Q. One to eight.

10 A. Again, we heard -- we just heard Dr. Reines
11 refer to those eight footnotes.

12 Q. Now, what are those eight footnotes?

13 A. On the back of the letter, there are eight
14 references which Janssen was citing to support that
15 claim.

16 Q. All right. So these are the eight footnotes.
17 I've never actually seen a sentence that had eight
18 footnotes, but this -- it says one through eight, and
19 these are -- these are they?

20 A. Those are the studies.

21 Q. Okay. So did you check these references and
22 review them closely?

23 A. I did. I got all of those papers and read
24 them.

25 Q. Now, Dr. Reines said he checked them, too, but

1 let's figure out -- or let's hear what you found out.

2 First of all, do these eight references support
3 Janssen's claims that Risperdal is not associated with
4 diabetes?

5 A. No. Two of the eight do not.

6 Q. Okay. Let's talk about that. No. 1, Buse?

7 A. That's the Buse study, and No. 8, the Sernyak
8 study.

9 Q. Let's take a look at Buse, all right? That is
10 Plaintiffs' Exhibit 1920. Plaintiffs' Exhibit 1920 is a
11 retrospective cohort study of diabetes and antipsychotic
12 treatment in the United States, and the first author is
13 a man named Buse, correct?

14 A. Correct.

15 Q. What was this study trying to look at?

16 A. So this was one of those epidemiological
17 studies looking at a large insurance database
18 retrospectively and comparing the incidence of diabetes
19 in patients treated with different antipsychotics.

20 MR. MELSHEIMER: And if we could go to the
21 highlight, Mr. Barnes.

22 Q. (BY MR. MELSHEIMER) What is the bottom line of
23 the Buse study? Let's wait until we get it pulled up.

24 A. Well, you can see here that this study is
25 actually saying of the atypical newer more expensive

1 antipsychotics, only Risperdal was associated with a
2 significantly greater risk of diabetes than the
3 Haldol -- haloperidol is another name -- cohort.

4 Q. So this is Footnote 1?

5 A. This is Footnote 1.

6 Q. It's offered in support of the claim that
7 Risperdal is not associated with diabetes?

8 A. Correct.

9 Q. And it actually shows just the opposite?

10 A. That's right, sir.

11 Q. All right. Was there another study in the
12 eight footnotes -- let's go back to our eight
13 footnotes -- that did not support Janssen's claim that
14 Risperdal was not associated with diabetes?

15 A. Footnote No. 8, Sernyak.

16 Q. Okay. Let's take a look at the cover of the
17 Sernyak study. What was that?

18 A. This was, again, an epidemiological
19 retrospective study comparing antipsychotics for the
20 risk of diabetes.

21 Q. What did it conclude?

22 A. It concluded that in patients under 40 years of
23 age who are not normally at an elevated risk, all of the
24 antipsychotics, including Risperdal, increased the risk
25 of diabetes.

1 Q. Dr. Glenmullen, a doctor or healthcare provider
2 reading that letter referencing these studies, how would
3 they know that a quarter of the studies cited say just
4 the opposite?

5 A. They wouldn't know. You would assume that all
6 of the studies cited supported the statement that was
7 being made.

8 Q. Now, let's take a look at the warning letter.

9 MR. MELSHEIMER: Can you pull up the
10 warning letter, Mr. -- oh, there it is, Plaintiffs'
11 Exhibit 138.

12 Q. (BY MR. MELSHEIMER) And here's a big copy of
13 it. In fact, Doctor, is what you just told the jury
14 about, that two of these studies don't even -- support
15 the opposite of what the assertion was in the letter, is
16 that one of the criticisms that the FDA leveled at
17 Janssen in this warning letter?

18 A. That's correct. The FDA identified the same
19 two studies as not supporting Janssen's claim and
20 criticized them for that.

21 Q. Is that good medical science to cite a study
22 for a proposition that's just the opposite?

23 A. Bad medical science.

24 Q. How about citing two? Twice as bad?

25 A. Twice as bad.

1 Q. All right. Now, are there any -- now, those --
2 let's go back to the footnote, though, the studies. So
3 we've got two of them we've got to cross out, but let's
4 go back and look at the other six. So 1 and 8 are gone.
5 Of the remaining six, are any of those Janssen funded or
6 related studies?

7 A. Four of the six are.

8 Q. How do you know that?

9 A. Again, from checking the papers and internal
10 Janssen documents.

11 Q. Now, there's nothing wrong with a drug company
12 funding a study, right?

13 A. That's correct.

14 Q. And there's nothing wrong with people
15 associated with drug companies being involved with
16 studies, right?

17 A. Correct.

18 Q. And you're not here to criticize that or say
19 that's a bad practice?

20 A. No.

21 Q. But is there anything wrong with any of these
22 six -- or four Janssen funded or involved studies?

23 A. Well, from the internal Janssen documents, at
24 least one of these studies, No. 3, Fuller, the results
25 had been manipulated before the study was published.

1 Q. Okay. Is that the study No. 3, Fuller, also
2 known as -- another name there is Shermock?

3 A. Correct.

4 Q. Now, that's a pretty sharp claim, Doctor. How
5 do you know that Janssen manipulated the results of this
6 study before it was published?

7 A. From internal Janssen documents saying that
8 originally the study had shown there was no difference
9 between Risperdal and Zyprexa, and by the time it was
10 published the claim was that Zyprexa was worse.

11 Q. Well, let's take a look at it. Let's take a
12 look at Plaintiffs' Exhibit 232. Do you see that, sir?

13 A. Yes.

14 Q. Now, this is an e-mail from someone named Amy
15 Grogg who's on our organizational chart. Maybe you can
16 help me find here. Right there. Okay. She's a
17 director of Outcomes Research, actually is right -- on
18 our chart is right below Dr. Mahmoud, who was the author
19 of the letter that the FDA found was deceptive.

20 A. Correct.

21 Q. Okay. So let's take a look at this e-mail
22 dated October 15th, 2001 from Ms. Grogg. And this is
23 this VA diabetes study. Is that the study that became
24 the Fuller study?

25 A. Correct.

1 Q. And what does she say?

2 A. So she's saying here "Hot off the presses."
3 This is the original unmanipulated results. The general
4 gist is there is not a difference between Risperdal and
5 olanzapine, which is Zyprexa, in diabetes risk.

6 Q. Now, let's go to Plaintiffs' Exhibit 1960. And
7 is 1960 the published version of this Fuller study?

8 MR. MELSHEIMER: Just -- Mr. Barnes or
9 Mr. Roberts, if you could show -- just go back to the
10 very top of the article and see that this is in fact
11 Mr. Fuller or Dr. Fuller.

12 Q. (BY MR. MELSHEIMER) All right. So this is the
13 Fuller/Shermock study that was cited in the footnote,
14 right?

15 A. And you can see that Amy Grogg was actually a
16 co-author of the published version.

17 Q. Oh, she got on it, too?

18 A. She did.

19 Q. Okay. So what does this published version
20 conclude? And we've got that highlighted.

21 A. So the published version said Zyprexa therapy
22 was associated with a significantly higher risk of
23 development of diabetes compared with Risperdal.

24 Q. So let's go back to the e-mail. And in the
25 e-mail she says the gist is that there's no -- she says

1 not difference -- no difference between Risperdal and
2 olanzapine to diabetes risk.

3 A. Correct.

4 Q. All right. So how did they manipulate the data
5 to get the result for the published study that they
6 cited to the FDA?

7 A. What they did was they actually threw out some
8 of the data. They dropped female patients. They took
9 all the female patients out. They took all of the
10 Hispanic patients out. They took all of the Asian
11 patients out. They removed about 12 percent of the
12 percent from the study, which included about 13 percent
13 of the patients who had developed diabetes. And when
14 those patients were taken out, that changed the result
15 in favor of Risperdal.

16 Q. Let me focus on this for just a second, because
17 I think we're going to hear from Janssen -- indeed we
18 have heard that, well, you know, many years later, many
19 years later, it turned out that a lot of people agreed
20 that Zyprexa was a little worse with weight gain than
21 Risperdal. Are you aware of that?

22 A. I am aware of that.

23 Q. As a doctor and as a scientist, does that
24 justify throwing out the data that didn't support their
25 conclusion back in 2001?

1 A. No, it does not.

2 Q. Do you know of any accepted scientific
3 standards that would permit that kind of manipulation of
4 data?

5 A. No, I do not.

6 Q. Now, in addition to this Fuller study before it
7 was manipulated, had Janssen done any other studies
8 showing that Risperdal was associated with diabetes?

9 A. Actually, they had. I discovered that they had
10 done three additional studies.

11 Q. All right. Now, were those studies cited by
12 Dr. Mahmoud in this letter?

13 A. None of them were in the eight footnotes.

14 Q. Okay. Not even generally mentioned or referred
15 to in any way?

16 A. Not at all.

17 Q. Okay. Now, did Janssen tell the FDA --
18 separate from this letter, did Janssen tell the FDA
19 about these three studies?

20 A. No. In this time frame, the FDA had written to
21 all the companies in 2000 saying we're examining this
22 closely because it's so serious, send us everything you
23 have, and Janssen made a mission several months later
24 and did not tell them about any of these studies, two of
25 which had been completed by that time.

1 Q. What are the studies you're referring to that
2 Janssen concealed from the FDA?

3 A. They're called 113, ERI and 275.

4 Q. All right. What was Study 113?

5 MR. MELSHEIMER: Let's pull up
6 Plaintiffs' Exhibit 115, please, sir.

7 A. 113.

8 Q. (BY MR. MELSHEIMER) It's Exhibit 115.

9 A. Oh, sorry about that.

10 Q. The study is 113, correct? That's a little
11 confusing. So this -- tell us what Exhibit 115 is, sir.

12 A. So this is the first of these three studies.
13 This is actually an extremely high-quality study, much
14 higher than any of the eight in the footnotes.

15 Q. Why do you say that?

16 A. Because the eight in the footnotes were
17 epidemiological studies, looking backwards at a
18 population. That's considered a lower level of science
19 than when you specify prospectively, "I'm going to do a
20 study." And I think you heard something about it in the
21 last week about blinding the study so that neither the
22 patients nor the doctors doing the study can have any
23 bias about who's taking what. So this was one of those
24 high-quality blinded studies. It was a year. It was
25 large with a lot of patients. This was a superb study.

1 In the Fuller article, the company had said we're not
2 aware of any prospective studies like this, and they had
3 actually already done one.

4 Q. Well, what does this study purport to evaluate?

5 A. Comparing the risk of medically serious weight
6 gain for diabetes in patients taking Risperdal or
7 Zyprexa.

8 Q. So did Risperdal cause weight gain in this 113
9 study?

10 A. It did, medically serious weight gain.

11 Q. Let's take a look at Plaintiffs' Exhibit 71.
12 What is this, sir?

13 A. So these are the results for the -- what's
14 called medically serious weight gain, which means a
15 weight gain -- the FDA and scientists define that as
16 weight gain of more than 7 percent of your body weight.

17 Q. Okay. And does the study conclude that --
18 first, that there appears to be no difference in the
19 incidence of 7 percent weight gain in the two groups?

20 A. Correct.

21 Q. And then does it say both support the finding
22 of significant weight gain in the risperidone treated
23 patients, especially at week 52?

24 A. So about half the Risperdal patients had
25 medically serious weight gain in this study during a

1 year.

2 MR. MELSHEIMER: Let's take a look at the
3 next slide from this exhibit, Mr. Barnes.

4 Q. (BY MR. MELSHEIMER) Did Risperdal cause
5 diabetes in this study?

6 A. So this study used as a marker of diabetes
7 what's called hemoglobin A1c. That's the abbreviation
8 HbA1c. And you can see in the table that 2.8 percent of
9 the Risperdal patients got diabetes during the one year
10 of this study.

11 Q. A couple things I want to ask you about that.
12 So that's actually more than under olanzapine?

13 A. Zyprexa, correct.

14 Q. Now, 2.8 percent doesn't sound like very much
15 to the average person. Is it significant in a medical
16 study?

17 A. It is. Pharmaceutical companies themselves
18 actually define any side effect that occurs in more than
19 1 percent of patients as a frequent side effect. And
20 this side effect is very serious. It can be
21 life-threatening.

22 Q. So 1 percent is the threshold for frequent, and
23 this is nearly triple that?

24 A. That's correct.

25 Q. Okay. Now, when did Janssen have the results

1 of 113?

2 A. In 1999.

3 Q. This is before the FDA had asked for all this
4 information about diabetes?

5 A. That's correct, the previous year.

6 Q. Now, tell the jury how it is that the FDA
7 became aware that there was this issue with these newer
8 more expensive antipsychotics like Risperdal, Zyprexa
9 and other drugs, how they became aware that there was
10 this diabetes problem.

11 A. Well, you've heard multiple doctors testify
12 like Dr. Dott earlier, Dr. Robinson, you heard
13 Dr. Van Norman last week, that shortly after these drugs
14 came on the market and psychiatrists started prescribing
15 them for patients, it was just so obvious that they were
16 gaining huge amounts of weight. And there started to be
17 reports in the medical literature. The FDA started to
18 get reports into their adverse event database, meaning
19 side effect database. And so by the late 1990s, it was
20 a very big issue. This study was completed by Janssen
21 in 1999, and it's in 2000 that the FDA formally writes
22 to all the companies in the spring and says we would
23 like everything you have on this subject by August.

24 Q. Did Janssen provide Study 113 to the FDA at
25 any time during this time frame when the FDA was

1 investigating the serious risk between these newer
2 antipsychotics and diabetes?

3 A. The company did not.

4 Q. Did they actually -- in addition to not telling
5 the FDA about it, did they in fact tell -- well, did
6 they in fact represent that they had no long-term
7 comparison studies even available?

8 A. Correct. So this --

9 Q. Let me stop you there. This is -- just for the
10 record, this is DX 671. This is the submission from
11 Janssen to the FDA. And tell us -- with regard to this
12 diabetes issue, tell us where you're directing our
13 attention, Doctor.

14 A. So there was a sentence in the summary at the
15 front. This was a huge submission of about 18 to 20
16 volumes. And there's typically a summary, like 30 to 50
17 pages at the front. And in the summary, Janssen said
18 there were no long-term, double blind trials with either
19 placebo or Zyprexa, because again, they would have been
20 considered the gold standard, and the company was
21 representing that they didn't have any, even though they
22 had completed one the previous year.

23 Q. Well, but what we've heard in the trial,
24 Doctor, I think -- or not evidence, but argument, I
25 think, that this 113 was a broken study that should

1 never have been submitted to anyone.

2 A. I have heard that.

3 Q. I want to talk to you a little about that.

4 First of all, did -- did Janssen -- broken or no, did
5 Janssen actually end up publishing the results of this
6 study that they didn't give to the FDA?

7 A. As best I could determine, they've never
8 published it.

9 Q. Okay. Now, the notion that a study can have
10 problems with the patients getting the drug or similar
11 issues, is that a common or an uncommon problem in
12 medical studies?

13 A. It's actually quite common. When you do
14 studies at multiple sites with hundreds of patients,
15 there's very often problems with some of the data.

16 Q. So does the notion that some of the data has
17 problems -- does that render a study broken or unusable?

18 A. No, not at all.

19 Q. And in fact, does it happen pretty often in
20 studies that there's some glitch with the data that has
21 to be corrected for or dealt with?

22 MR. McCONNICO: Excuse me. Counsel
23 doesn't need to constantly lead the witness. That's the
24 objection.

25 MR. MELSHEIMER: I'll rephrase, Your

1 Honor.

2 Q. (BY MR. MELSHEIMER) Can you tell the jury if
3 there -- if there ever is an issue with studies being
4 run and published even with data problems?

5 A. Again, it's very common. What you typically do
6 is identify the small amount of data that's problematic
7 and you calculate the results with and without, and if
8 it makes no difference to the results, then you're quite
9 clear that it's not a broken study.

10 Q. Dr. Glenmullen, did you find evidence -- tell
11 us if you found evidence that that exact problem had
12 happened to Janssen in studies that they did submit to
13 the FDA to get Risperdal approved in the first place.

14 A. Yes, and that they had published.

15 Q. All right. Let's take a look at Plaintiffs'
16 Exhibit 118. What is Plaintiffs' Exhibit 118, Doctor?

17 A. So this is, again, one of Janssen's internal
18 reports on a study called 79.

19 Q. Was this one of the studies that Janssen
20 submitted to the FDA to get Risperdal approved?

21 A. This was a study that was specifically
22 submitted to the FDA for what was called a long-term
23 approval. The original approval were six- to eight-week
24 studies for approval for the drug. And then at a later
25 stage, they went for what's called a long-term

1 maintenance approval, and this was their key study.

2 Q. Did this study have a data issue in it?

3 A. It did.

4 Q. Can you direct the jury's attention to that,
5 please, sir?

6 A. So you can see here during the trial audit, it
7 was determined that the data from one site did not meet
8 the Janssen Pharmaceutica quality standard; therefore,
9 analyses were performed with all sites, 395 patients,
10 and without site No. 8, 365 patients. That's a
11 30-patient difference.

12 Q. So the 30-patient difference here did not
13 render this study broken?

14 A. No, sir.

15 Q. How many patients were at issue that got the
16 wrong medication in Study 113?

17 A. Nine patients.

18 Q. Did they publish this study in addition to
19 submitting it to the FDA, Plaintiffs' Exhibit 118?

20 A. The company did publish it.

21 Q. Did they ever represent that it was broken or
22 couldn't be used?

23 A. No. They became the centerpiece. This was
24 Csernansky, and it became the centerpiece of their
25 marketing.

1 Q. Now, you said there were three studies that the
2 FDA did not get from Janssen. One of them was this
3 Shermock. One was this 113. What's the last one?

4 A. No, the first one is 113.

5 Q. I'm sorry. 113. What's the second one?

6 A. It's called the ERI study.

7 Q. And what's that?

8 A. Epidemiological Research Institute was a
9 company that Janssen had contracted with to do one of
10 these retrospective epidemiological studies.

11 Q. And what did the ERI study look at?

12 A. It again compared the incidence of diabetes in
13 patients taking the antipsychotic drugs.

14 Q. What were the results of it?

15 A. The results of this study were that there was
16 no difference between Risperdal and Zyprexa.

17 Q. Now, when did Janssen have the results of this
18 ERI study?

19 A. They had the results of this study in late
20 July 2000, early August, just a little before the
21 submission to the FDA, which was on August 8th.

22 MR. MELSHEIMER: Let's take a look at
23 Plaintiffs' Exhibit 238, Mr. Barnes.

24 Q. (BY MR. MELSHEIMER) Is this an e-mail in which
25 the ERI report is forwarded or sent by Ms. Grogg who

1 we've talked about earlier?

2 A. Correct.

3 Q. And in the subject line, what does she say
4 about this study and the FDA?

5 A. She says do not include in FDA submission. And
6 this is August 1, just a week before the submission.

7 Q. Now, Doctor, had Janssen planned to submit this
8 ERI study to the FDA before the results turned out bad
9 for their argument?

10 MR. McCONNICO: Objection. This is
11 argumentative and continues to lead. He doesn't need to
12 lead the witness, doesn't need to make argument with
13 questions.

14 MR. MELSHEIMER: Let me rephrase, Your
15 Honor.

16 Q. (BY MR. MELSHEIMER) Did you find evidence that
17 Janssen had originally planned to submit this ERI study
18 to the FDA?

19 A. Internal company documents showed that in July
20 when they were waiting for the results, they did plan to
21 submit it.

22 MR. MELSHEIMER: PX 546, Mr. Barnes.

23 Q. (BY MR. MELSHEIMER) This is an e-mail again
24 from Ms. Grogg of Janssen dated July 19th, 2000. What
25 does this say about the ERI study?

1 A. That it will be available July 28th, 2000 in
2 order to be incorporated into the response to the FDA,
3 due August 10th.

4 Q. So just so we're clear, the first sentence
5 before that says "I have also enclosed table shells from
6 the second project from ERI, the vendor for the
7 project." Is that this epidemiological study you've
8 told us about?

9 A. Correct, the ERI, Epidemiological Research
10 Institute study.

11 Q. All right.

12 MR. MELSHEIMER: And then can we just go
13 back to 238, Mr. Barnes?

14 Q. (BY MR. MELSHEIMER) And this is the same study
15 that is now stated about a couple of weeks later "do not
16 include"?

17 A. Correct. It says just before the highlighting,
18 "ERI report and tables."

19 Q. Is either the 113 study or the ERI study
20 mentioned in the November 10th, 2003 healthcare provider
21 letter?

22 A. No, they are not.

23 Q. And you mentioned a third study --

24 A. Correct.

25 Q. -- Janssen had. What study was that?

1 A. This study was called 275.

2 MR. MELSHEIMER: Plaintiffs' Exhibit 100,
3 please, Mr. Barnes.

4 Q. (BY MR. MELSHEIMER) What is Plaintiffs'
5 Exhibit 100, Dr. Glenmullen?

6 A. This is another internal Janssen company report
7 on the study. And you can see the trial number -- trial
8 stands for study, RIS-USA-275.

9 Q. Describe what this study was --

10 A. So this was another one of these higher
11 standard studies, double blind, prospectively designed,
12 again, an extremely high-quality study. It was long
13 term, in this case six months. And it was a very
14 sophisticated sensitive study with multiple levels --
15 multiple measurements of blood glucose regulation, which
16 is what ultimately when it goes awry can cause diabetes.

17 Q. When did Janssen have the results of Study 275?

18 A. They had the earlier results in September 2003.

19 Q. What were the results of 275?

20 A. Once again, in this study, Risperdal and
21 Zyprexa were comparable.

22 Q. Did Janssen share the results of this study --
23 in this time frame when the FDA was investigating the
24 diabetes risk, did Janssen share this study with the FDA
25 in any way that you can tell?

1 A. Not as best as I could tell.

2 Q. Do they in any way cite them in the letter?

3 A. No, they do not.

4 Q. Now, I want to ask you about this issue,
5 Dr. Glenmullen, that diabetes was already in the label
6 of Risperdal. There was already warnings about diabetes
7 in the Risperdal label. Do you -- have you heard that
8 argument made?

9 A. I have.

10 Q. All right.

11 MR. MELSHEIMER: Can we pull up the
12 Plaintiffs' Exhibit 13, Page 5?

13 Q. (BY MR. MELSHEIMER) Now, tell the -- tell the
14 jury what we are showing in Plaintiffs' Exhibit 13.

15 A. So I think you've heard a lot about the label,
16 which is a technical term for the prescribing
17 guidelines. I think Mr. Jacks unfolded one in front of
18 you. It's kind of accordion-shaped. It goes on for
19 pages and pages, a lot of fine print. And it's got
20 various sections that are called out with bold
21 headlines. So right up at the top, because the FDA
22 wants doctors to see them, is warnings, precautions,
23 serious issues with the drug. And then much, much later
24 down are a laundry list of side effects.

25 Q. I notice, Doctor, that diabetes is mentioned

1 here.

2 A. So this -- we're now in the side effects
3 section. And the particular side effects are metabolic
4 and nutritional disorders. And this was what was in
5 Janssen's original label. This is the 1994 label. And
6 it says "infrequent," and it lists as a side effect
7 weight increase. But you can see why this is not
8 particularly helpful to doctors and not really a
9 warning, because just a few later it says weight
10 decrease --

11 MR. McCONNICO: Objection. We don't need
12 this constant narrative. He can just answer the
13 question.

14 THE COURT: Could I see y'all over here?
15 *(Discussion off the record between the*
16 *Court and counsel)*

17 Q. (BY MR. MELSHEIMER) Dr. Glenmullen, this is
18 from the label for Risperdal, correct?

19 A. The original label, yes.

20 Q. The original label. And this has a bunch of
21 different conditions, warnings -- or conditions and side
22 effects and things of that nature; is that right?

23 A. Side effects, not warnings.

24 Q. Right. And we've highlighted weight increase
25 and weight decrease.

1 A. Correct.

2 Q. And you were telling the jury that that's not
3 all that helpful to a doctor reading this. Can you
4 explain why?

5 A. Because this section of the label is not
6 calling out serious health concerns that have been
7 identified with the drug or the class of drugs that are
8 up in the warning section. It's a laundry list of side
9 effects. And it's difficult for a doctor to know how
10 much weight increase, what the significance of that is,
11 and especially when right after it it says weight
12 decrease. The doctor doesn't kind of know what to make
13 of that. That's very different from a warning saying
14 this class of drugs is associated with serious weight
15 gain and diabetes.

16 Q. Okay. So the types of information that might
17 be contained elsewhere in the label, how are they -- how
18 is that information different from what is contained in
19 the section of the label called warnings?

20 A. The FDA intends the warnings up at the top to
21 cause special health risks that have been identified
22 with the drug or the class to doctors' attention.

23 Q. And when was the first time that that kind of
24 warning about diabetes as opposed to a mention of it in
25 the label appeared in the Risperdal label?

1 A. That's the class label that the FDA required in
2 the fall of 2003.

3 Q. Dr. Glenmullen, we've talked a little bit about
4 this Dear Healthcare Provider letter. And you mentioned
5 in your analysis that you had looked at
6 misrepresentations concerning diabetes, and one of them
7 was this letter.

8 A. Correct.

9 Q. Are you with me? Okay. Did you also find this
10 letter or references to this letter being used by
11 Janssen's salespeople when they were out promoting
12 Risperdal to doctors?

13 A. Yes, call notes.

14 Q. And you found that in examples of what we've
15 all seen as call notes?

16 A. And in the sales training.

17 Q. Okay.

18 MR. MELSHEIMER: Can we see some examples
19 of that, Mr. Barnes, from Exhibit 145 for the record.

20 Q. (BY MR. MELSHEIMER) So this is Plaintiffs'
21 Exhibit 145, and we're going to try to go through this
22 quickly, Doctor. We have a few of these. So this is a
23 call note dated November 2003, November 17th, which is a
24 week after this letter went out. And what is in the
25 next call objective line?

1 A. So this sales rep is saying I put the diabetes
2 letter in every customer's box.

3 Q. Do you understand that to be the letter that
4 the FDA found false and misleading?

5 A. The Dear Doctor letter.

6 Q. Okay. Then what else was stated?

7 A. That every single one of the doctors that he or
8 she was calling on was -- this letter was going to be
9 delivered to them.

10 Q. Okay.

11 MR. MELSHEIMER: Do we have another
12 example, Mr. Barnes? I know -- or Mr. Roberts. I know
13 it takes a while for these to come up sometimes.

14 Q. (BY MR. MELSHEIMER) So this is November 10th,
15 2003, a call by a Janssen salesperson on a doctor in
16 Houston. And what does this say?

17 A. So this sales rep is saying detailed, which I
18 think you've heard means tell the doctor details about,
19 the diabetes letter, which is the November 10th letter,
20 and sold the third paragraph. Again, just like
21 Dr. Reines is saying, that was the key paragraph from
22 the company's point of view, and --

23 Q. Let me stop you right there, Doctor. I'm
24 sorry. That's this paragraph here that begins
25 "Hyperglycemia-related adverse events" --

1 A. Correct.

2 Q. -- that has the middle sentence that we've
3 talked about?

4 A. Correct.

5 Q. And what does the call notes say about that?

6 A. And he, meaning the doctor, had no problems
7 with it.

8 Q. Does this all -- does this call note also have
9 a comment about the data of Risperdal and diabetes?

10 A. Yes. It says no data suggests Risperdal causes
11 diabetes.

12 Q. Doctor, we've had some discussion in this
13 case -- we'll leave that up, please -- some discussion
14 in this case about who said what in these call notes.

15 A. Right.

16 Q. All right. So is there -- is it -- did you
17 have any ambiguity in your mind when you were reading
18 this when you read he -- let's go back to the...

19 When it says he had no problems with it,
20 do you have any ambiguity about who that's referring to?

21 A. It's referring to the doctor.

22 MR. MELSHEIMER: Let's pull up just one
23 more example of a call note making reference to this
24 diabetes issue or the Dear Doctor letter.

25 And I'm sorry, Your Honor. It just takes

1 a while to scan through this database issue.

2 Q. (BY MR. MELSHEIMER) Doctor, how many call
3 notes are there that you've looked at in this case?

4 A. I've looked at thousands and thousands.

5 Q. Now, this is November 10th, 2003, right after
6 the letter was sent. It was a call made to a doctor in
7 San Antonio.

8 A. Right.

9 Q. And what does this salesman -- Janssen salesman
10 say about the diabetes letter?

11 A. Good core call and diabetes letter, positioned
12 as his safety/litigation, et cetera.

13 Q. Good core call and diabetes letter, positioned
14 as his safety/litigation. Is there any -- just listen
15 to my question. Is there any reference in there to what
16 litigation this salesman is referring to?

17 A. In the note?

18 Q. Yes, sir.

19 A. It doesn't say what kind of litigation.

20 Q. All right.

21 MR. MELSHEIMER: Your Honor, may it please
22 the Court. I'm --

23 THE COURT: About ready to go --

24 MR. MELSHEIMER: -- prepared to go forward
25 or I can stop now.

1 THE COURT: -- into a new area?

2 MR. MELSHEIMER: Yes, Your Honor.

3 THE COURT: I'll see y'all tomorrow
4 morning. Have a safe trip home.

5 *(Jury not present)*

6 THE COURT: I first would like to see
7 Winter and McDonald, and then I want to see the trial
8 team.

9 MR. MELSHEIMER: In that order?

10 THE COURT: In that order.

11 *(Court adjourned)*

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1 THE STATE OF TEXAS)

2 COUNTY OF TRAVIS)

3 I, Della M. Koehlmoos, Official Court
4 Reporter in and for the 250th District Court of Travis
5 County, State of Texas, do hereby certify that the above
6 and foregoing contains a true and correct transcription
7 of all portions of evidence and other proceedings
8 requested in writing by counsel for the parties to be
9 included in this volume of the Reporter's Record, in the
10 above-styled and numbered cause, all of which occurred
11 in open court or in chambers and were reported by me.

12 I further certify that this Reporter's
13 Record of the proceedings truly and correctly reflects
14 the exhibits, if any, admitted by the respective
15 parties.

16 WITNESS MY OFFICIAL HAND this the 18th day
17 of January, 2012.

18 /s/: Della M. Koehlmoos
19 DELLA M. KOEHLMOOS, TX CSR 4377
20 Expiration Date: 12/31/13
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