REPORTER'S RECORD
DAILY COPY VOLUME 7
CAUSE NO. D-1-GV-04-001288

STATE OF TEXAS, ex rel. ALLEN JONES, Plaintiffs,	)	IN THE DISTRICT COURT
VS.	)	
JANSSEN, LP, JANSSEN PHARMACEUTICA, INC., ORTHO-McNEIL PHARMACEUTICAL, INC., McNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, JANSSEN ORTHO, LLC, and JOHNSON & JOHNSON, INC., Defendants.	)	TRAVIS COUNTY, TEXAS
	)	250TH JUDICIAL DISTRICT

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JURY TRIAL

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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

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JANUARY 18, 2012

PLAINTIFFS' WITNESSES

PROCEEDINGS

JANUARY 18, 2012

(Jury present)

THE COURT: Thank y'all. Be seated. We're continuing with the deposition.

MR. MELSHEIMER: May it please the Court, Your Honor. This is the continuation of the deposition of Tone Jones of Janssen.

(Video played as follows:)

TONE JONES,

having been previously duly sworn, further testified as follows by videotaped deposition:

DIRECT EXAMINATION (CONTINUED)

Q. Would any of the documents in Exhibit 2113 be examples of call notes?

A. Yes. All these examples are call notes and physician profiles.

Q. The box is kind of in the middle at the top of the page, and there's a -- the words "Call Date" appear to the right of that, and in a little box is the date 4th February 2004.

A. Okay.

Q. What's meant by the call date?

A. What is meant by the call date was that this was the date that the call was made.

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

A. Yes.

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

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

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

A. The sales rep who made the call.

Q. In this case, Laura Haughn?

A. Yes.

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

A. Yes, it does.

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

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

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

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

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

A. Yes.

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

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

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

A. Yes.

Q. Do you know Dr. Alice Mao?

A. Yes.

Q. And who is she?

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

private practice.

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

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

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

A. Yes.

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

Did I read that correctly?

A. Yes.

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

A. Child and adolescent.

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

A. Mm-hmm. Yes.

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

for doing so?

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

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

A. Yes.

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

A. Correct.

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

Did I read that sentence correctly?

A. Yes.

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

A. Okay.

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

A. Yes.

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

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

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

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

Did I read that correctly?

A. Yes.

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

A. Correct.

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

A. No, she was not the only one.

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

A. Correct.

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

A. Correct.

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

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

A. Correct.

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

A. Yes.

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

A. Yes.

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

A. Randle.

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

Did I read that correctly?

A. Yes.

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

A. Yes.
Q. All right. Is -- do you believe this is a document that you've seen before?
A. Yes.
Q. You testified earlier that -- I believe you said it was about 1 percent of the population who had been diagnosed with schizophrenia at any given time. Is that -- did I understand you correctly?
A. Correct.
Q. Now, if one were seeking to expand the market for Risperdal, if its only use is in patients with schizophrenia -- schizophrenia as a diagnosis, whether higher functioning or lower functioning, it's still 1 percent, true?
A. True.
Q. If all you're talking about is getting a bigger chunk of the 1 percent, would you think that would --
A. Got it.
Q. -- constitute the fastest growing market for this drug?
A. Can't be a $2 billion product and 1 percent marketing.
Q. Let me ask you, if you would, to skip over to the page that ends in the numbers 495. Do you see on this page what appear to me to be prints of information

from a slide presentation?

A. Yes.

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

A. "Child & Adolescent Physicians."

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

A. Yes.

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

Did I read that correctly?

A. Yes.

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

A. Mm-hmm.

Q. And what's that referring to?

A. Risperdal was not indicated for this patient --

Q. All right.

A. -- population.

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

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

A. Yes.

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

Did I read that correctly?

A. Yes.

Q. And what does that mean to you?

A. Focus on the associated symptoms of schizophrenia.

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

A. Yes.

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

A. Yes.

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

A. Yes.

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

A. Yes.

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

A. Yes.

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

A. Yes.

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

Did I read that right?

A. Yes.

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

A. Mm-hmm. Yes.

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

efforts."

Did I read that correctly?

A. Yes.

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

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

Did I read all that correctly?

A. Yes.

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

A. Yeah.

Q. Did I get that right?

A. You got it.

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

A. To the management team.

Q. All right. And you copied Laura Haughn?

A. Yes.

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

A. I sure did.

Q. We looked at this organization chart early on,

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

A. That's right.

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

A. Yes.

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

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

Did I read that correctly?

A. Yes.

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

A. No.

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

A. Yes.

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

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

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

A. Yes.

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

A. Yes.

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

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

you know, for other products as well.

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

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

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

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

Q. Do you know the name Valerie Robinson?

A. Yes.

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

A. Absolutely.

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

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

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

Q. Okay.

A. -- for Risperdal Oral.

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

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

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

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

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

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

A. Yes.

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

A. That it was equal to placebo.

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

A. Yes.

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

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

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

A. No.

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

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

A. Mm-hmm.

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

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

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

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

A. Yes.

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

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

Did I read that correctly?

A. Yes.

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

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

A. Yes.

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

A. Yes.

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

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

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

Q. Including on the issue of diabetes?

A. Yes.

Q. Is that something that your sales staff

communicated within the Houston area to physicians here?
A. Mm-hmm.
Q. Is that a yes?
A. Yes.
Q. Okay. With respect to Risperdal being -- having a low risk of diabetes and -- and diabetic ketoacidosis, was that a message that you were instructed to deliver to doctors within your area or region?
A. We had to deliver that on every call.
Q. And did you, sir, do so?
A. Yes.
Q. Now, I want you to pick back up the FDA letter authored by Dr. Mahmoud, and that's Exhibit 686; correct?
A. Yes.
Q. Now, approximately how -- how long after Mr. Walsman's voice blast was that letter sent by Ramy Mahmoud?
A. How long after?
Q. Yes, sir.
A. It was -- the voicemail was Friday, September 26, 2003, and Ramy Mahmoud sent the letter November 10, 2003, I mean. So Friday, September 26th, 2003, voicemail was out -- sent out by Mike Walsman, and

then two months after that the letter went out.

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

A. On every call.

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

A. May 7, 2004.

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

A. The doctor?

Q. Yeah, or the account.

A. Yeah, the account is Burke South.

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

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

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

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

Q. Is that a similar message to the one that

Mr. Walsman communicated early in September of '03?

A. Yes.

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

A. It's another call note from Seibel.

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

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

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

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

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

A. Yes.

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

A. Okay.

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

A. Laura Haughn.

Q. And can you tell me the physician she's calling on there, please?
A. James Buckingham.
Q. Okay. And can you tell me the date of the call?
A. May 7, 2004.
Q. And then if you could read for me the next call objective portion.
A. "Touch on how Risperdal addresses symptoms head-on instead of just sedating products with Seroquel and without weight gain or risk of diabetes with Zyprexa."
Q. Now, you mentioned that you've met with Mr. Sweeten and Mr. Jacks four times before today; is that correct?
A. Yes.
Q. What did y'all discuss during that meeting?
A. Just my background and also, you know, just promotion of Risperdal.
Q. Okay. Well, why did you meet with them at all?
A. Well, why I met with them at all, because of this situation with Risperdal and my, you know, involvement with Janssen. That's pretty much, you know, the reason. And when I received calls from the J&J legal department, you know, I just -- didn't really know

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

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

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

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

Does that answer your question?

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

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

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

Q. Okay.

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

Q. Uh-huh.

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

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

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

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

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

A. Correct.

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

A. Correct.

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

Did I read all of that correctly?

A. You did, yes.

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

A. Correct.

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

Did I read that right?

A. Yes.

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

A. Yes.

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

A. Dr. Del Campo, yes, sir.

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

Did I read that sentence correctly?

A. Yes, you did.

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

A. Correct.

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

A. Correct, yes.

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

child and adolescent population?

A. No.

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

A. It approves.

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

A. Correct.

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

A. Correct.

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

A. Correct. Yes.

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

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

A. Based on the dates of approval, yes.

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

A. No, there was no difference.

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

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

(Video stopped)

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

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

(Video played as follows:)

CROSS-EXAMINATION

Q. We've looked at several documents, compilation exhibits consisting of call notes.
A. Yes.
Q. Do you remember seeing those? We've seen some call notes by Laura Haughn?
A. Yes.
Q. Debra Crain?
A. Yes.
Q. And were these both sales representatives who reported to you during your tenure as manager?
A. Yes.
Q. And in preparing for your deposition, have you talked to any of them?
A. No.
Q. Have you reviewed their deposition testimony in this case?
A. No.
Q. So do you know what their explanation was as far as the substance that they've typed in the next call objective box?
A. No.
Q. So you don't know one way or the other whether or not they're reporting what they said or what somebody else said during a particular sales call?
A. Correct.

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

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

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

A. No.

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

A. No.

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

A. No.

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

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

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

sale of Risperdal?

A. No.

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

A. Yes.

(Video stopped)

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

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

THE COURT: Okay.

MR. MELSHEIMER: Thank you, Your Honor.

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

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

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

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

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

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

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

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

THE WITNESS: Yes, sir.

(The witness was sworn)

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

Okay, Patrick.

MR. SWEETEN: Thank you, Your Honor.

BILLY MILWEE,

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. SWEETEN:

Q. Good morning.

A. Good morning.

Q. Would you introduce yourself to the jury,

please?

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

Q. And what does that mean?

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

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

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

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

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

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

Big Spring?

A. Yes, sir, I did.

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

A. I left Big Spring in 1971.

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

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

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

A. A little over 20 years.

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

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

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

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

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

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

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

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

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

A. Yes, sir, I have.

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

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

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

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

Health Insurance Program director.

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

A. Yes, sir, that's correct.

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

A. January 1st, 2010.

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

A. About 15 years, I believe.

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

A. Yes, sir, I am.

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

A. About 300.

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

A. It's about $30 billion.

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

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

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

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

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

A. Yes, sir.

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

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

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

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

because of the associated disability.

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

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

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

A. Yes, sir, that's correct.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. Correct.

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

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

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

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

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

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

Q. Does every state have this same formulary

application process?

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

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

A. They submit an application.

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

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

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

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

THE COURT: Overruled.

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

THE COURT: You may.

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

THE COURT: You may.

MR. McDONALD: Thank you.

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

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

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

A. Yes, sir, it does.

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

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

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

Texas Medicaid?

A. Yes, sir, the company does.

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

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

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

A. Yes, sir, they did.

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

A. There were eight applications submitted.

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

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

Q. Okay. Formulations, is that --

A. Yes.

Q. Okay.

A. Or strength, yes.

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

A. Yes, sir, they were.

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

A. Yes, sir.

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

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

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

A. February 2nd, 1994.

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

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

Q. And who wrote this letter?

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

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

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

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

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

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

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

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

A. With Janssen Pharmaceutica.

Q. Okay.

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

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

A. This is information about the drug.

Q. Okay. Is this the actual application itself?

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

application.

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

A. Risperdal.

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

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

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

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

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

A. Yes, they are.

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

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

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

Q. And what's being certified to here?

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

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

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

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

A. Flora Bryant, Senior Information Coordinator.

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

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

A. Sure. Janssen Pharmaceutica Incorporated.

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

A. No, sir, it has not.

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

A. No, sir, they have not.

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

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

A. I believe that's the package insert.

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

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

Q. What is the date of this letter?

A. August 8th, 1996.

Q. And on whose letterhead was this written?

A. The Texas Department of Health.

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

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

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

A. Risperdal oral solution.

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

A. Yes, sir, it is.

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

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

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

Q. Who signed this document?

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

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

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

Q. And what's the date on it?

A. August 4th, 1999.

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

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

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

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

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

A. Yes, sir, it is.

Q. Was this signed?

A. Yes, sir, it is.

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

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

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

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

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

A. Yes, sir, it is.

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

A. May 22nd, 2003.

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

is?

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

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

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

Q. And was this letter signed?

A. Yes, sir, it was.

Q. And who signed this letter?

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

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

A. Yes, sir, it is.

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

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

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

A. Yes, sir, I do.
Q. And as Medicaid director, can you tell me whether that somehow invalidates the certification or holds any significance?
A. No, sir, I don't believe it does. It has -- we have the transmittal letter clearly communicating the intent, a signed transmittal letter.
Q. Okay. I've got two more of these documents to look at. One is Plaintiffs' Exhibit 1717. And can you tell me for what formulation and dosage of Risperdal this application was submitted?
A. This was submitted for Risperdal M-Tab three milligram and four milligram.
Q. And as I understand it, Plaintiffs' Exhibit 1717 is two VDP applications, correct?
A. Yes, sir, you're correct.
Q. Flipping through the next several pages of the application, I'll have you turn to Page 618, if you would, please. And is this a certification exactly the same as the others we've been looking at?
A. Yes, sir, it is.
Q. And is this signed?
A. Yes, sir, it is.
Q. What's the date of this one?
A. March 17th, 2006.

Q. Who signed this one?
A. Elizabeth Raney, Business Coordinator II, Johnson & Johnson.
Q. Okay. And then I'll have you turn to Page -- I think we're at 619. And can you tell us what this document is?
A. Yes. This is part of the Vendor Drug Program application.
Q. And what's the product name and drug strength listed here?
A. Risperdal M-Tab and the drug strength is four milligrams.
Q. And we'll turn to Page 622 of this document. And can you tell us who signed -- by the way, is the certification the same as the others?
A. Yes, sir, it is.
Q. Who signed this certification?
A. Elizabeth Raney, Business Coordinator II, Johnson & Johnson.
Q. And then there's one more we want to look at, which is 1718. Can you tell us what this is?
A. Yes, sir. This is also part of a Vendor Drug Program application. It's a letter to Elizabeth Raney from Don Valdes.
Q. And what formulation and dosage of Risperdal is

this application submitted for?

A. Risperdal CONSTA injectable 12.5 milligram vial.

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

A. Yes, sir, it is.

Q. Who signed and certified this?

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

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

A. Yes, sir, I believe we have.

THE COURT: Mr. Sweeten.

MR. SWEETEN: Yes, Your Honor.

THE COURT: We're taking a break.

MR. SWEETEN: Okay.

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

(Recess taken)

(Jury present)

THE COURT: Thank y'all. Be seated.

Mr. Sweeten.

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

applications signed by Janssen or Johnson.
A. Yes, sir.
Q. Okay. Now, can you tell me, who is it that processes all these VDP applications and reviews the information on them?
A. Staff in our formulary division.
Q. And how many employees are there in the formulary section of the Vendor Drug Program or VDP?
A. There's five or six. Right now I believe we have six people working in there.
Q. And approximately how many drugs are on the Texas Medicaid formulary?
A. We have 17,000 drugs on the Medicaid formulary.
Q. All right. And let me ask you, is Risperdal one of those drugs currently?
A. Yes, sir, it is.
Q. Are the conventional antipsychotics on the formulary?
A. Yes, sir, they are.
Q. Is Haldol on the formulary?
A. Yes, sir.
Q. Perphenazine?
A. Yes.
Q. Mellaril?
A. Yes, sir.

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

A. Yes, sir, that's correct.

Q. And how --

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

(Discussion off the record between the Court and counsel)

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

A. Yes, sir, it is.

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

A. I believe so.

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

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

Q. Why is that?

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

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

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

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

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

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

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

MR. McDONALD: Thank you, Your Honor.

THE COURT: You're welcome.

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

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

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

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

A. No, sir, we cannot.

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

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

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

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

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

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

Q. Are you familiar with the term open formulary?

A. Yes, sir, I am.
Q. Okay. And what does that term mean?
A. Open formulary simply means that a drug is listed on the Medicaid formulary.
Q. And does open formulary mean that once a drug is on the Texas Medicaid formulary, that there's no way to restrict its use?
A. No, sir, it does not.
Q. And can you tell the jury why not?
A. Once a drug is on the formulary, it's available for prescription, but limits can be placed on that drug. For instance, we can require a prior authorization. That means that a physician, before they can prescribe that drug, they'd have to contact the Medicaid Program to get that drug approved, or we can place edits on that drug that might deny it under certain circumstances.
Q. Does the State of Texas Medicaid Program monitor and manage the use and utilization of drugs that are on the Medicaid formulary?
A. Yes, sir, we do. And we're required to do so by our federal government.
Q. What are the ways that Texas Medicaid monitors and manages the use of drugs?
A. Well, let me talk a little bit about the Omnibus Reconciliation Act of 1990, also referred to as

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

Q. And what is a Drug Utilization Review program?

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

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

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

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

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

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

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

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

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

providers and testimony from advocates and clients.

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

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

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

A. No, sir, it cannot.

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

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

Q. And why are these educational letters sent?

A. To affect the utilization of that particular drug.

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

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

Q. Does that save the state money typically?

A. Yes, sir, it does.

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

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

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

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

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

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

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

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

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

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

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

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

A. Yes, sir.

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

A. Yes, sir.

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

A. Yes.

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

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

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

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

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

A. Utilization declined.

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

A. The consequential cost for those drugs went down.

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

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

Q. And who manages the preferred drug list?

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

Q. Can you tell us what the Pharmaceutical and

Therapeutics Committee does?

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

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

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

THE REPORTER: I didn't get that.

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

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

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

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

A. Yes, sir, I was.

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

A. I do recall that.

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

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

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

A. Yes, sir, it is.

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

A. Yes, sir, they do.

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

A. No, sir, it cannot.

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

A. No, sir, it cannot.

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

A. Yes, sir, it was.

Q. For what period of time?

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

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

A. No, sir, it's not.

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

A. Yes. Yes, there is.

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

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

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

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

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

A. Yes, sir, it is.

Q. Why?

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

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

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

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

A. Yes. It's Antipsychotics Review prepared by

Provider Synergies.

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

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

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

Did I read that accurate?

A. Yes, sir, you did.

THE COURT: May I interrupt? May I see

y'all down here a second?

MR. SWEETEN: Yes, sir.

(Discussion off the record between the Court and counsel)

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

A. No.

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

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

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

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

A. It's not on the PDL today.

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

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

A. Yes, sir, I do.

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

A. Yes, it would.

Q. Why?

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

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

A. Yes, sir, it would.

Q. Why?

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

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

A. Yes, sir, it would.

Q. Why?

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

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

A. Yes, sir, it would.

Q. Why?

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

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

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

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

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

A. Yes, sir, I do.

Q. And are you familiar with that audit?

A. Yes, sir, I am.

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

A. 2004.

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

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

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

A. No, sir, it did not.

Q. Did it cover 1997?

A. No, sir, it did not.

Q. '98?
A. No.
Q. '99?
A. No.
Q. What year did it cover?
A. 2004.
Q. Also, we're going to have a witness testify at a later time, Ms. Sharon Dott. Did I ask you at some point to check to see if she was at any point a Medicaid provider for the State of Texas?
A. Yes, you did.
Q. And is Ms. Dott a Medicaid provider?
A. She is an enrolled Medicaid provider.
MR. SWEETEN: Pass the witness.

CROSS-EXAMINATION

BY MR. McDONALD:
Q. Good morning, Mr. Milwee. I see it's still morning.
A. Good morning.
Q. We met just a little bit ago at the last break.
A. Yes, sir.
Q. I understand you've been working with the Medicaid Program for a number of years, right?
A. Yes, sir, I have.
Q. But in truth, you've only had dealings with the

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

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

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

A. Yes, sir.

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

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

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

A. That's correct.

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

A. Yes, sir, I have.

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

A. Yes, sir.

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

A. I have not.
Q. Okay. And you've never actually been on that committee, right?
A. I am not on that committee.
Q. Okay. Also talked about the Drug Utilization Review Board.
A. Yes, sir.
Q. You've never been a member of that board, right?
A. No, sir, I'm not a member of that board.
Q. And you've attended, I think in your deposition you told us, two meetings?
A. Yes, sir.
Q. Okay. And it's the Drug Utilization Review Board, right?
A. Yes, sir.
Q. So they look retrospectively in the past, not in the future, right?
A. I believe that's an accurate characterization.
Q. Okay. You talked about the DUR board sending out intervention letters.
A. Yes, sir.
Q. Okay. The DUR board actually has no authority to impose or tell a doctor what to do through one of those intervention letters, correct?

A. That's correct.
Q. It's just a recommendation?
A. It's education.
Q. Okay. You also talked about clinical edits that you say the DUR board had the authority to implement.
A. Yes, sir.
Q. Do you recall that? Now, in 2003, 2004 time period, that's when the P&T Committee came into existence, correct?
A. Yes, sir, in 2004.
Q. And at that time the preferred drug list was created, right?
A. Yes, sir.
Q. And there were a number of drugs after the creation of the preferred drug list that were prior authorized or that had clinical edits for prior authorization, correct?
A. Correct.
Q. Now, that was the first time that the State of Texas had a fulsome prior authorization program, correct?
A. I believe we had some -- a limited number of drugs on prior authorization even before that, as I recall.

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

A. Yes.

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

A. Correct.

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

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

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

A. Yes, it was.

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

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

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

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

Q. And do you know what communications the

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

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

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

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

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

A. Yes, sir, I do.

Q. He runs the Vendor Drug Program at Medicaid?

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

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

A. Yes, sir.

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

A. Yes, sir.

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

A. Yes, sir.

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

Risperdal CONSTA has been approved?

A. Yes.

Q. Okay.

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

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

A. Yes, sir.

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

A. Correct.

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

A. Correct.

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

A. Correct.

Q. When was that communicated to pharmaceutical manufacturers?

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

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

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

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

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

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

A. Not to my knowledge.

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

A. Yes, sir, I do.

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

A. Yes, sir.

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

A. Yes, sir, I do.

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

A. Correct.

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

A. Correct.

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

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

Q. Okay. Not a provider, right?

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

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

A. Yes, it does.

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

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

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

A. Yes.

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

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

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

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

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

A. Well, your client's --

MR. SWEETEN: Objection, Your Honor --

A. -- not enrolled in Medicaid.

MR. SWEETEN: -- asked and answered.

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

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

A. Yes, sir.

Q. So nearly 17, 18 years ago?

A. Yes, sir.

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

A. Yes, they would.

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

A. No, sir, we have not.

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

A. No, sir, we have not.

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

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

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

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

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

Q. Okay.

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

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

A. I have seen this memo.

Q. Okay.

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

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

who ACS is?

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

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

A. Yes.

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

A. Yes, sir.

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

A. Yes, sir.

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

A. Yes, sir.

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

A. Yes, sir.

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

A. Yes, sir.

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

A. Correct.

Q. And it's nearly twice as expensive as

Risperdal, right?

A. Yes, according to this.

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

A. Yes.

Q. Again, nearly twice as expensive as Risperdal?

A. Correct.

Q. Geodon, another second generation antipsychotic?

A. Yes.

Q. More expensive than Risperdal?

A. Correct.

Q. And Symbyax, another second generation antipsychotic?

A. Yes.

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

A. Correct.

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

A. No, sir, we don't.

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

A. Not to my knowledge.
Q. I think Mr. Sweeten asked you also about misbranding of a drug. Texas Medicaid doesn't monitor misbranding of drugs, does it?
A. No, sir, we don't.
Q. And has Texas Medicaid ever removed a drug from its formulary because of alleged misbranding?
A. No, sir, we have not.
Q. We talked a little bit about the preferred drug list, and that was formulated in the late 2003, early 2004 time period, correct?
A. Yes, sir, 2004.
Q. And Risperdal was on the preferred drug list until about a -- nine months or a year after it went generic, right?
A. Yes, sir.
Q. And it went -- it's still on the list, but you have to have prior authorization to get the branded Risperdal, right?
A. Correct.
Q. But the generic Risperdal, there's no prior authorization for that, correct?
A. Correct.
Q. Okay. And the reason that the brand went to prior authorization and the generic was not is just from

a price standpoint, correct?

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

Q. Sure.

A. Yes.

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

A. Correct.

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

A. Not to my knowledge.

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

A. Correct.

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

A. Yes, sir, I have.

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

A. Correct.

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

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

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

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

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

A. Right.

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

A. Right.

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

A. Yes, sir, I do.

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

A. Correct.

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

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

A. Correct.

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

A. Correct.

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

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

A. Yes, I have.

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

A. Correct.

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

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

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

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

A. Correct.

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

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

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

A. Yes, we do.

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

A. I believe I have.

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

A. Yes.

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

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

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

A. He would have been my boss.

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

A. Yes, sir.
Q. All right. He only reports to the commissioner?
A. Yes, sir, he reports to the executive commissioner.
Q. One person above him. The subject is the DSHS Psychotropic Medication Guidelines. Do you see that?
A. Yes, sir, I do.
Q. And one other thing I want to point out: Mr. Bell is an actual -- he's an MD?
A. Yes, sir, he is.
Q. And I -- you're not?
A. No, sir, I'm not.
Q. And you're not a scientist?
A. No, I'm not.
Q. Okay. I'm not either, so I'm not disparaging you by any means.
Okay. Let's look at what this is that Mr. Bell is sending around, if you'll look at the second page. This is a memorandum to healthcare providers in the state of Texas, right?
A. Yes, it is.
Q. And it says, "The Texas Department of State Health Services has coordinated the creation of the accompanying best practice guidelines, *Psychotropic*

Medication Utilization Parameters for Foster Children."
Do you see that?

A. Yes, I do.

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

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

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

A. No, he was not.

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

A. Yes.

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

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

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

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

Q. Sure.

A. -- is the dosage recommendations.

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

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

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

antipsychotics in children, correct?

A. Correct.

Q. And this edit was implemented --

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

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

A. Yes, sir.

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

A. Correct.

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

A. Yes.

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

A. Yes, under the age of three.

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

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

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

right?

A. Correct.

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

A. Correct.

Q. And that's Medicaid, right?

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

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

A. Correct.

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

A. Yes, we are.

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

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

Q. The Medicaid Program --

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

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

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

A. Correct.

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

A. Correct.

Q. Did you have any involvement in this report?

A. No, I did not.

Q. You knew it was going on?

A. I believe so, yes.

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

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

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

A. Correct.

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

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

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

Do you see that?

A. Yes, I do.

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

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

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

A. Right, yes.

Q. Okay.

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

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

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

Did I read that correctly?

A. Yes, sir, you did.

Q. And that's a truthful statement?

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

Q. Okay.

A. I didn't write the report.

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

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

A. Correct.

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

A. Correct.

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

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

A. Correct.

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

A. Correct.

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

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

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

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

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

A. No, sir, I don't.

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

A. Yes, it is.

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

A. Correct.

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

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

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

A. It was in the literature in 2004 when the

report was developed.

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

A. (Nods head affirmatively).

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

A. That's what the report indicated.

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

A. No, sir.

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

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

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

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

Risperdal or risperidone clinical trials, right?

A. Correct.

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

A. No, sir, I don't.

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

A. Correct.

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

A. Correct.

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

A. Correct.

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

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

Q. After it went generic.

A. Correct.

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

three?

A. Correct.

Q. Thank you.

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

(Lunch recess taken)

(Jury not present)

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

(Jury present)

THE COURT: Thank y'all. Be seated.

John, you had passed, had you not?

MR. McDONALD: I have, Your Honor.

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

MR. SWEETEN: Yes, Your Honor.

THE COURT: Okay.

REDIRECT EXAMINATION

BY MR. SWEETEN:

Q. Okay. Mr. Milwee, I'm going to go over a few issues that Mr. McDonald discussed with you. The first is I'm going to ask that we pull up Defendants' Exhibit 346. Do you recall discussing this with Mr. McDonald?

A. Yes, sir, I do.
Q. At the time -- and this discusses the foster care children's guidelines that were sent in '05, correct?
A. Yes, sir.
Q. Okay. At the time these were sent, did your agency have access to an internal Janssen business plan?
A. No, sir, we did not.
Q. Had -- and the jury watched the deposition of Tone Jones earlier today. Had that deposition been taken?
A. No, sir, I don't believe it had.
Q. Did you have access to the deposition of Tiffany Moake?
A. No, sir.
Q. Did you have access to the back to school bashing programs?
A. No, sir.
Q. I want to ask you, if you would, to turn to the second page, please, of -- which is 660, and I want to focus on the last paragraph of this letter. And when they're transmitting these, it indicates that questions about the guidelines that are being disseminated may be directed to Steve Shon, Medical director of Mental Health Services, Texas Department of State Health

Services. Did I read that correctly?

A. Yes, sir, you did.

Q. I want to clarify a point. You remember defendants' counsel asked if pharmaceutical companies were, quote, providers, and you said not in the traditional sense. Can you tell us what you meant by that?

A. Certainly. Not in the traditional sense that they're physicians or pharmacies, but in the sense that they provide services for the Medicaid programs by listing their drugs on the formulary and those in turn are used in the Medicaid Program.

Q. You told us that -- during your direct examination that the DUR and P&T Committee look at three major factors. Can you tell us what those are again?

A. Certainly. Those are safety, efficacy and cost.

Q. Does a drug company marketing outside of an FDA approval impact any of these issues?

A. Yes, sir, I believe it could impact all three.

Q. And without full and accurate information, can a full review be done as to these issues?

A. No, sir, it cannot.

Q. Do the certifications that the defendants signed require disclosures by a drug company if they're

in violation of a federal law?

A. Yes, sir, they do.

Q. You heard questions about off-label promotion. Does Texas Medicaid rely on manufacturers to not violate state or federal law?

A. Yes, sir, we do.

Q. Do they rely on their certifications as to these issues?

A. Absolutely.

Q. We talked about the eight VDP applications that were signed, and I think one went from 1994. And Mr. McDonald showed you the one that had been entered in 2007, correct?

A. Yes, sir.

Q. So during this time period, Janssen Pharmaceutical or Johnson & Johnson certified to Texas Medicaid eight times that they were not in violation of federal or state law; is that right?

A. Yes, sir, that's correct.

Q. Does Texas Medicaid have the manpower or the resources to figure out if a drug company has marketing plans or is promoting the drug off label?

A. No, sir, we do not.

Q. And in the face of that, what do you rely upon?

A. Well, we rely upon the honesty and integrity of

the people who submit information to us.

Q. Did Janssen Pharmaceutical or Johnson & Johnson ever come to Texas Medicaid and tell them about the back to school bashing programs in San Antonio?

A. No, sir.

Q. Did Janssen or Johnson & Johnson ever come to Texas Medicaid and tell them of call notes relating to M-Tabs, pushing M-Tabs for children?

A. No, sir.

Q. With respect to the Provider Synergies issue, was there any way to know about Janssen's publication plans or what they chose to or not publish?

A. No, sir. Provider Synergies can only use what has been published and is in the public domain.

Q. I want to ask you about the Flood memo, which was DX 227. Do you recall discussing this document?

A. Yes, sir, I do.

Q. Does the Flood memo do an analysis of just Risperdal use?

A. No, sir, it does not.

Q. Does the Flood memo do an analysis of just antipsychotic use?

A. No, sir.

Q. In fact, what are the classes of medications that this addresses?

A. Antipsychotics as well as antidepressants.

Q. Did the Flood memo provide any sort of analysis as to the root cause of why these prescriptions of these three drugs were what they were?

A. No, sir, it did not.

Q. Did the Flood memo discuss -- provide an analysis of marketing efforts by pharmaceutical companies?

A. No, sir, it did not.

Q. I want to ask you -- I want to ask --

MR. SWEETEN: Jason, if you'd pull up PX 1819, please.

Q. (BY MR. SWEETEN) Mr. McDonald showed you these guidelines from HHSC, correct?

A. Yes, sir, he did.

Q. Okay. He read some portions from the HHSC, quote, guidelines, right?

A. Yes, sir.

Q. Okay. I'm going to ask if we can turn to page -- the bottom of Page 35. And on the -- the second to the last sentence starting with "Risperidone," all the way until right before "Prolactin." Can you read that for me, Mr. Milwee?

A. Certainly. "Risperidone, similar to other antipsychotics, has not been shown to be effective in

treating the core social deficits in autism. Weight gain consistently occurs in clinical trials with risperidone. The most rapid weight gain occurs early on and is not associated with a change in nutritional balance. Higher blood lipid levels are also seen as well as higher levels of prolactin."

Q. Okay.

MR. SWEETEN: I want to turn to the bottom of Page 56 if we would, please. And starting -- if we could highlight the paragraph on the bottom, "Recent research in adults."

Q. (BY MR. SWEETEN) Can you read that to the jury, please?

A. Certainly. "Recent research in adults has shown that the older antipsychotics, the first generation, are as effective as the much more expensive second generation medications. Growing literature in youth verifies the same finding."

Q. Now, this document was a -- what was this document?

A. In my mind, this document could be characterized as a report to the Legislature that's based on a review of the literature, available literature.

Q. Thank you. Is this considered official HHSC

policy?

A. No, sir, it is not.

Q. Was any criticism lodged in some quarters about the findings of this document?

A. Yes. Public comments were received criticizing the document.

Q. Were public comments appended to the report?

A. I believe so, sir.

Q. Do the passages that either I or Mr. McDonald read to you have any bearing whatsoever on the question of whether Janssen marketed in violation of federal or state law?

A. No, sir.

Q. Did the clinicians who authored this HHSC report have access to Janssen business plans?

A. No, sir, they did not.

Q. Knowledge of Janssen's marketing efforts in children?

A. Not to my knowledge, sir.

Q. You heard the suggestion that Texas is not active. Do you remember that?

A. I remember that, yes, sir.

Q. Okay. And I want to ask you, is that a true statement?

A. That's not a true statement.

Q. What has Texas Medicaid done with respect to the drug Risperdal?

A. Well, I think we've taken the most profound step that we can take in a civilized society, and that's why we're here in court today, seeking relief under the Texas Medicaid Fraud Prevention statute. Secondly, the TMAP no longer exists. That TMAP has been pulled down. It's no longer embraced by any state agency; and instead, PORT guidelines are used. The PORT guidelines are based on the, excuse me, National Institute of Mental Health standards, and those guidelines put the first generation and second generation antipsychotics on a level basis. There's no preference given. Thirdly, we have an age edit in place now for antipsychotics in children, children under three. And we no longer have Risperdal on the preferred drug list.

Q. Does this lawsuit to your knowledge seek to remove Risperdal from the formulary?

A. No, sir, it does not.

Q. What is your understanding of this lawsuit?

A. My understanding of the lawsuit is that but for some off-label marketing and some claims about -- comparative claims relative to the conventional antipsychotics, marketing for children and adolescents and some problems associated with diabetes, probably the

drug would not have been used to as great an extent as it was, and Medicaid would not have incurred as great a cost as it did in honoring prescriptions for this product.

MR. SWEETEN: No further questions. Thank you.

RECROSS-EXAMINATION

BY MR. McDONALD:

Q. Probably the drug would not have been used to the extent as possible. Those were your words you just used. In fact, you have no idea what would happen and what doctors would have done, right?

A. I would say the drug would not have been used to the extent as it has been had the off-label marketing not occurred.

Q. So tell me the name of any doctor that wrote a Medicaid prescription to a Medicaid recipient as a result of something my client did.

A. I can't give you that name, sir.

Q. You can't tell me a single name, can you?

A. No, sir, I can't.

Q. You can't identify a single prescription that was written by a Medicaid doctor to a Medicaid patient as a result of anything my client did, can you?

A. I can't identify a single prescription.

MR. McDONALD: Pull up, Chris, please, Defendants' Exhibit 227.

Q. (BY MR. McDONALD) This is the Flood memo we looked at before.

A. Yes, sir.

Q. And if we'll look at Page 6 again, please.

MR. McDONALD: If you'll blow up that chart, Chris.

Q. (BY MR. McDONALD) This is the information that we looked at about the price paid per claim by Medicaid for Risperdal as well as other second generation antipsychotics, right?

A. Yes, sir.

Q. And if a Medicaid doctor would have written a prescription to another second generation antipsychotic instead of Risperdal, the State of Texas would have paid more money, right?

A. Yes, if the reimbursement rate were higher, correct.

Q. And, for example, in the case of Zyprexa, if a doctor would have written a prescription for Zyprexa instead of Risperdal, it would have cost the State of Texas nearly twice as much, right?

A. Yes, sir, it would have.

Q. Mr. Sweeten asked you about the -- sorry, I got

a little disorganized here.

Exhibit 346, these are the psychotropic medication guidelines. Do you recall that?

MR. McDONALD: Defendants' 346, Chris, please.

Q. (BY MR. McDONALD) Now we have the right one, right?

A. Yes, sir.

Q. Okay. These came out after this lawsuit was filed, correct?

A. Correct.

Q. After the allegations had been made against my client regarding TMAP and off-label use and all kinds of other things, correct?

A. Correct.

Q. These guidelines have been updated over time, correct?

A. I believe so.

Q. And the State of Texas has continued to tell doctors what dose of Risperdal should be used in children, correct?

A. I'm not a clinician, but I believe the memo suggests the dosage if they were to use it in children in these 2005 guidelines.

Q. Thank you. One of the things on the

applications that is submitted by my client as well as all other pharmaceutical manufacturers is the price of the drug, right?

A. Yes, sir.

Q. And there's no allegation in this case that the price that was given by my client was ever wrong, is there?

A. I don't believe so.

Q. Okay. Thank you. The State of Texas has never rejected an application or returned an application to a manufacturer because of alleged off-label marketing, right?

A. No, sir, not for off-label marketing.

Q. Or violation of any federal law, have they?

A. I'm not aware of any, sir.

Q. Okay. And despite the fact that this lawsuit's been around for ten years, been over 100 people deposed, my client's produced over five million pages of documents, you've taken no action to remove Risperdal from the formulary, have you?

A. Well, there never was a move to take Risperdal off the formulary.

Q. And you've never returned the applications to my client rejecting the applications, have you?

A. No, sir.

Q. In fact, we saw an application that was -- that was approved after this lawsuit was filed, right?

A. Yes, sir.

MR. McDONALD: That's all I have. Thank you.

MR. SWEETEN: I've got a few more.

THE COURT: Let me see y'all down here.

(Discussion off the record between the Court and counsel)

THE COURT: Thank you for your testimony. I'd get out of here if I were you.

Call your next witness, please.

MR. MELSHEIMER: Your Honor, may it please the Court. We call Dr. Valerie Robinson by video deposition.

THE COURT: Do y'all need to set the TV back up again?

MR. MELSHEIMER: We need a few moments. May it please the Court.

THE COURT: If y'all don't mind going back to the jury room or y'all can stay here, whichever.

MR. MELSHEIMER: It won't take long.

THE COURT: Why don't y'all relax while they set up the TV.

(Discussion off the record)

THE COURT: They're talking about tilting it toward where the jury can see. Watch this fellow down here on the first -- he'll give you all instructions you'll need.

Would y'all like to watch a different show than the one we've been watching? I'm thinking Judge Judy or something.

(Video played as follows:)

VALERIE ROBINSON,

having been first duly sworn, testified as follows by videotaped deposition:

DIRECT EXAMINATION

Q. Can you state your full name for us, please?

A. Valerie Ruth Robinson.

Q. And we're at the Texas Health Science Center here in Lubbock, Texas?

A. Yes.

Q. And is this where you work?

A. Yes.

Q. And how are you employed?

A. I'm an associate professor in the department of psychiatry, which will actually be official in September.

Q. And prior to becoming associate professor here at the Texas Health Science Center, what -- what was

your position?

A. Assistant professor in the department of psychiatry.

Q. And can you --

A. And I'm clinical director of child and adolescent psychiatry.

Q. But you are a medical doctor, correct?

A. That's correct.

Q. And you are a medical doctor that specializes in psychiatry; correct?

A. Child psychiatry.

Q. In child psychiatry?

A. Right. Child and adolescent, uh-huh.

Q. And what did you do in Fort Worth, Texas?

A. I was in private practice. I also worked for Cook Children's Physicians' Network, which is a children's hospital in Fort Worth, and I worked for Lena Pope Home.

Q. And what is that?

A. Lena Pope Home is an agency that helps foster care families with their children, and they also help with the regulations of therapeutic foster homes. They help children with adoption issues.

Q. And at some point, you left Fort Worth to come to Lubbock, correct?

A. That's correct.
Q. And that was in 2003?
A. That's right.
Q. And in addition to all that in 2003, you also became a member of the State's P&T Committee, correct?
A. That's correct.
Q. Which stands for the Pharmaceutical and Therapeutics Committee?
A. That's right.
Q. And you have served on the State's P&T Committee continuously since 2003?
A. That's correct.
Q. Through today?
A. That's right.
Q. And you currently also sit on the State's Drug Utilization Review Board; is that correct?
A. That's correct.
Q. Can you describe for us generally what the State's P&T Committee does?
A. It's made up of a committee of various physicians, backgrounds, and pharmacists. And it is to look at, for State Medicaid, various drug classes, keeping in mind safety, efficacy, cost and coming up with a preferred drug list.
Q. Is what is a preferred drug list?

A. These would be the medications that would be preferred by the physicians and patients so that they wouldn't have to necessarily ask for a prior authorization.

Q. Do you personally have any -- any knowledge of any information of anything Janssen has said that you believe to be misleading about Risperdal?

A. What year are you talking about?

Q. Any year.

A. Yes --

Q. Okay.

A. -- I do.

Q. And what would that be?

A. In the mid '90s, I worked for Cook Children's Physicians' Network, which is a Fort Worth-based children's hospital, 18 and under. I practiced there as an employee of the physicians' network services. I maintained an outpatient practice. I also did inpatient and partial hospitalization work and consult work for the pediatricians.

I remember a Janssen rep, pharmaceutical rep, visiting me numerous times with information about Risperdal. However, at that time, there was no indication for children for its use, but he would leave pharmaceutical studies that I didn't even know existed

or had in my possession whether -- these were adult trials. These would be adult indications for children.

I never practiced or saw adults as a child psychiatrist and treated them other than as the parent of a child. So I had -- what I mean by that, the parent of the child has to give me history, background information and permission to treat their child before I can do so, but I never treated adults during that time frame. My practice was exclusively child and adolescent.

Q. What in that information did you find to be misleading?

A. Why would a pharmaceutical rep who did not have an indication for childhood disorders come and see me, first off? I don't understand that.

Q. What did you find about that information to be false or misleading?

A. There was no childhood indication for the use of Risperdal in child -- child psychiatric conditions, and that's what I was, a child and adolescent psychiatrist.

Q. Right. But did this sales representative tell you that Janssen in fact did have an indication for use in kids?

A. No, he did not specifically say that.

Q. Did he suggest it?

A. I recall information from the rep regarding the use of Risperdal, stating that it was safer than our current neuroleptic medications that we used at that time, the main one being Haldol or Thorazine. And these are considered neuroleptic drugs or older medications for the use of psychotic disorders in children.

One of the main concerns we had was the condition called EPS, extrapyramidal side effects, which -- which did seem to occur in children at a higher rate than maybe the adult population. Risperdal was presented as a safer medication than what we were currently using in regard to EPS.

Q. I mean, as a result of the sales representative from Janssen who called on you in the mid 1990s, as a result of him sharing the adult trials or whatever information he was sharing with you, did that cause you to prescribe more Risperdal to your patients?

A. Yes.

Q. And what -- what drug would you have prescribed had you not prescribed Risperdal?

A. It depends on what the condition would be. There's a lot of things that go into the decision about prescribing a medication for a particular condition in a child.

Q. Would you have prescribed Haldol?
A. Yes.
Q. Would you have prescribed Zyprexa?
A. Yes.
Q. So insofar as there were other atypicals on the market, those would have been other drugs that you might have prescribed had you not prescribed Risperdal?
A. As I recall during this time frame, the only two atypicals on the market were Risperdal and Zyprexa.
Q. Would you have prescribed Thorazine?
A. Yes.
Q. Would you have prescribed perphenazine?
A. Yes.
Q. Dr. Robinson, before the break, we were talking about some statements that you believed were made to you by someone at Janssen in the mid 1990s that you thought to be misleading.
A. Correct.
Q. Do you recall who that sales representative was?
A. Yes.
Q. Jeff Dunham?
A. That's correct. That's who it was.
Q. What I'm trying to find out is: Do you recall the specific content or what he specifically said that

you believe to be misleading as it relates to Risperdal?

A. As far as the specific conversation we had, no, I don't necessarily recall every single word. What I do remember is enthusiasm about the medication, certainly it was safer than what we were currently using, and it covered a range of symptoms in child or in adolescents with mental illness.

Q. I'm sorry. Covered what?

A. A range of symptoms in children and adolescents, not a particular diagnosis.

Q. ... the record is clear. During this time period during which you say Jeff Dunham was telling that it -- Risperdal covered a range of symptoms in child and adolescent patients --

A. Correct.

Q. -- what did you understand to be the FDA-approved indication for Risperdal?

A. Schizophrenia in adults, psychosis disorders -- psychotic disorders in adults.

Q. And you said among the things that you recall Mr. Dunham saying to you was that Risperdal was safer than the other drugs that you were currently using?

A. In particular to a side effect that was very bothersome in children.

Q. Okay. All right. So it was safer than drugs

that you were currently using as it pertains to a specific side effect that you believe to be particularly problematic in children?

A. That's correct.

Q. And what side effect is that?

A. Extrapyramidal side effects.

Q. Sometimes --

A. That's EPS, which leads to tardive dyskinesia, or TD.

Q. Anything else?

A. Weight gain.

Q. And what did Mr. Dunham tell you about weight gain as it relates to Risperdal?

A. That it could occur, but not a significant problem in most children.

Q. What do you mean "significant"?

A. A 20 or 30-pound weight gain after its onset -- after the onset of the use of the drug.

Q. Okay. So --

A. A 20 or 30-pound weight gain in a month or two.

Q. Okay. So he did not tell you during this time period sometime in the mid 1990s that Risperdal would cause patients to gain 20 to 30 pounds --

A. Correct.

Q. -- following onset or use of the drug?

A. Correct.

Q. Within -- within how long after use of the drug did the 20 or 30 pounds set in?

A. Within a month.

Q. And specifically, what you recall him telling you or the information that he shared with you is that Risperdal had better -- or was better with respect to the side effects of EPS?

A. Yes.

Q. Relative to what?

A. Haldol, Thorazine, in particular.

Q. And what I'm trying to find out is what did Dr. -- what did Mr. Dunham tell you about weight gain in the use of Risperdal in kids, if anything?

A. He didn't tell me about the fact that it could be this high. I guess if you're looking at a pharmaceutical rep to give you information about a new product, I want to know what have you -- what have you studied, what do you know about this particular side effect in child and adolescents? If you're calling on me with a new medication to be prescribed for children and adolescents, what do you have to share with me about what I'm seeing clinically? Who -- what am I seeing clinically in my own experience? Address that for me. Let me talk to your medical liaison -- scientific

liaison people about this particular issue, because I am concerned.

Q. And based on your use of the drug Risperdal in treating child and adolescent patients, you found it to cause weight gain in patients?

A. Yes.

Q. In all of your patients?

A. Majority. 80 percent or more.

Q. And prior to the 1992 to 1996 time period that we've been talking about, you had experience prescribing Haldol?

A. Yes.

Q. Thorazine?

A. Yes.

Q. Perphenazine?

A. Yes.

Q. Well, let me ask it this way: When Risperdal became available -- and during which time Haldol, Thorazine and perphenazine continued to be available, correct?

A. Correct.

Q. Did you switch all of your patients who were receiving Haldol to Risperdal?

A. At least half were switched.

Q. What about your patients who were on Thorazine?

A. Same, were switched.
Q. Four to six months after you started using Risperdal --
A. Right.
Q. -- you determined that some of the information that Mr. Dunham shared with you, at least you thought to be false and misleading?
A. Correct.
Q. Can you remind me what it is that you recall Mr. Dunham communicating to you about EPS as it relates to Risperdal?
A. That there was a lower incidence of EPS with Risperdal over neuroleptics, neuroleptics such as Thorazine and Haldol.
Q. And neuroleptics, is that the same thing as the conventional antipsychotics that were --
A. Right. Correct.
Q. -- available at the time?
A. Uh-huh. Correct.
Q. And you believe that statement to be misleading?
A. Do I believe it now or did I believe it then?
Q. Well, let's start with then.
A. No. I believed what he said. I mean, if he said it had a lower incidence, since he was the one who

knew about this new drug and I was just being introduced to it, I believed him.

Q. Okay. And sitting here today in 2010, do you believe that to be a misleading statement?

A. Yes.

Q. Why?

A. Because it's based on the dosage in children. Basing on the dosage in children, you will definitely get EPS.

Q. Do you think Risperdal is better than Haldol generally as it relates to EPS?

A. No.

Q. You talked some about Mr. Dunham visiting you in the '90s, and I want to show you what has previously been marked in this case as Exhibit 1875 in Mr. Dunham's deposition. And I want to represent to you that Mr. Dunham indicated these were call notes kept in the course of his work for Janssen. First, I want to ask you to look at the first call note and the date on that call note and then the very last date on the call note on the back page.

A. Okay. The first date is 8/26/1994.

Q. Okay. And then if you'd look at the one on the last page.

A. Is it November 18th, '02?

Q. That's -- that's what it looks like to me. If this document -- if, in counting, it has either 96 or 97 call notes reflecting different dates when Mr. Dunham visited you during this time period, do you have any reason to dispute that's the amount of times Mr. Dunham saw you?

A. No.

Q. Okay. When Mr. Dunham talked to you, what drug was he talking with you about during these visits?

A. Risperdal.

Q. During the time period 1994 through 2002, did you see any patients other than children and adolescents?

A. No.

Q. Did you -- during the course of your many visits with Mr. Dunham, did you make clear to him who your patient population was?

A. Yes.

Q. When Mr. Dunham or any other Janssen salesperson would come visit you, were you left samples of Risperdal?

A. Yes.

Q. And can you describe generally what a presentation of EPS looks like?

A. In children, primarily it's in the upper part

of their body in which they have involuntary motor movements.

Q. Okay. Per EPS or TD, are those reversible conditions?

A. EPS can be. Tardive dyskinesia is more difficult.

Q. Okay. Given the fact that your patients are children and adolescents, is EPS a concern for you?

A. Yes. It's a big concern.

Q. Can you give us your -- can you tell us what diabetes is?

A. Well, there's two types. There's Type 1 and there's Type 2. One is insulin dependent, like juvenile onset; and the other one is more of an adult onset that has to do with obesity.

Q. Is diabetes a permanent condition?

A. Yes.

Q. Okay. Is diabetes a concern when you treat the patients within your practice?

A. Yes.

Q. I want to ask you: Have you -- over the course of your career as a physician and a child and adolescent psychiatrist, have you received Dear Healthcare Provider letters from pharmaceutical companies?

A. Yes.

Q. And I'm going to hand you what's previously been marked in the deposition of Ramy Mahmoud Exhibit 686, and I want to ask you if you've seen that document before.

A. Yes, I've seen this.

Q. Okay. Were you sent this Dear Healthcare Provider letter addressed by Dr. Mahmoud?

A. Yes.

Q. Does this information provide you information regarding diabetes?

A. Yes, it's in here.

Q. Okay. Do you -- when you receive Dear Healthcare Provider letters, do you read them?

A. Yes.

Q. Do you rely upon them?

A. Yes.

Q. Earlier you were asked a couple of questions about usage of the TMAP algorithm in clinical practice.

A. Yes.

Q. Was there a time when you utilized the TMAP algorithm or had access to it?

A. Yes.

Q. When did that occur?

A. Shortly after coming to Texas Tech. So I would say starting in 2004.

Q. Did the TMAP guidelines in any way -- did they influence, in your view, prescribing behavior here during your practice at Texas Tech?

A. Yes.

Q. In the event you deviated from the -- the TIMA or TMAP decision trees, was there a requirement that you document any sort of deviation?

A. Yes.

Q. Okay. I want you to turn, if you would, please, to the diabetes letter dated -- or that's Exhibit 686, if you would. And I want you to turn specifically to Paragraph 4 which starts with "Hyperglycemia-related adverse events have infrequently been reported in patients receiving Risperdal."

Did I read that sentence correctly?

A. Yes.

Q. Did you read this in 2003 --

A. Yes.

Q. -- when you received the letter?

A. Uh-huh.

Q. Did you also read the next sentence that says "Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that Risperdal is not associated with an increased risk of diabetes when compared to untreated

patients or patients treated with conventional antipsychotics"?

Did you also review that sentence when you received it?

A. Yes.

Q. Were you aware that the FDA sent a warning letter to Janssen Pharmaceuticals actually in April of 2004?

A. No.

Q. I want to ask you to turn, if you would, please, to Busti Exhibit 1839, and specifically Page 4 of that exhibit. I'm going to ask you to look above at Dr. Stanis -- it says "Stanislaw," but I'll represent to you that it's Dr. Steve Stanislav.

A. Okay.

Q. And this is testimony that he provided to the P&T Committee; is that correct?

A. Yes.

Q. At the bottom of the first paragraph, it says, "And we've demonstrated in a long-term study up to two years, which was published in the *New England Journal of Medicine* when patients are randomized to either Risperdal or comparator, active comparator, relapse actually is reduced and the timed relapse is extended."

Did I read that sentence correctly?

A. Yes.

Q. And in -- did Mr. Stanislav, in discussing or referencing this *New England Journal of Medicine* study, disclose Janssen Pharmaceuticals' funding of that study, if any?

A. Not that I remember.

Q. In his testimony that's transcribed here, does Mr. Stanislav disclose any role by Janssen Pharmaceutical in helping either fund or conduct the study that's referenced in the *New England Journal of Medicine*?

A. No.

Q. I want to ask you to turn to the bottom paragraph. Here it says, "Risperdal is first line in terms of antipsychotics in national guidelines and national algorithms. If you look at the EPA guidelines, if you look at the TMAP guidelines in Texas" -- and I want to stop there and ask you, does Mr. Stanislav anywhere in his testimony disclose Janssen Pharmaceuticals' funding of the TMAP algorithm?

A. No.

Q. Why is it -- for a physician, why is it a problem if a pharmaceutical company who knows the risks associated with a drug either misrepresents the truth about that or doesn't tell the whole truth about it in

communicating with the medical community?

A. When you look at adverse events with any medication, and in particular with Risperdal -- remember, these weren't related to children and adolescents. These are adult studies. So we had no idea how this would play out in children. And we found out through basically trial and error that some of these adverse events were alarming. I felt that I was putting patients at risk and that it was basically up to my clinical expertise to figure out what was wrong or how to undo it or how to fix it, if you will, for the benefit of the patients.

Q. And so with respect to weight gain, you found out that what Mr. Dunham had told you wasn't true how?

A. Because the majority of the children, even at low doses, gained significantly within a month.

Q. And with respect to EPS side effects, you found out that what Mr. Dunham told you wasn't so in the same way, by observing?

A. I found that out by the times when maybe I used a little bit higher dose, not much -- a little bit higher dose, and EPS would develop just like I saw with Haldol or Thorazine and had to treat -- treat it.

Q. And how high of doses are we talking about here?

A. Oh, two to three milligrams per day. Two to three milligrams per day.

Q. With respect to hyperprolactinemia, what is that?

A. That means there's an increase in prolactin levels which can result in a condition called galacturia, which means there's actually leakage of breast milk in boys and girls.

Q. Boys and girls?

A. Boys -- males can have it as well, but typically adolescent females.

Q. All right.

A. And also affect -- can affect their menstrual cycle.

Q. And is that a side effect that you've seen with patients taking Risperdal?

A. Yes.

Q. Did Mr. Dunham or anybody else from Janssen ever tell you anything about that --

A. No.

Q. -- side effect?

A. Not -- no, he did not.

Q. Have you ever heard the expression "fair balance" as it relates to what drug company representatives are supposed to present to physicians

when they meet with them about a drug? Does that term mean anything to you, "fair balance"?

A. Yes.

Q. When Mr. Dunham and other sales representatives from Janssen have met with you about Risperdal, did they devote as much time and energy and attention and enthusiasm in discussing the adverse effects the drug could cause as they did their touting its effectiveness?

A. No.

(Video stopped)

MR. MELSHEIMER: That concludes Dr. Robinson's testimony.

MR. McCONNICO: Your Honor, the defendants have a tender.

(Video played as follows:)

CROSS-EXAMINATION

Q. When were you first -- you have a board certification, you've told this jury, correct?

A. Correct.

Q. When were you first board certified and in what?

A. Adult psychiatry.

Q. Okay. Well, what -- what I'm trying to figure out is: What did you find to be misleading about -- putting aside why -- why a Janssen sales rep would have

called on you if you were only treating kids, as far as the actual information that he or she gave you about Risperdal --

A. Uh-huh.

Q. -- what did you find about that information to be false or was misleading?

A. There was no childhood indication for the use of Risperdal in child -- child psychiatric conditions, and that's what I was, a child and adolescent psychiatrist.

Q. Right. But did this sales representative tell you that Janssen in fact did have an indication for use in kids?

A. No, he did not specifically say that.

Q. When prescribing medications to patients in the mid 1990s, child and adolescent patients, insofar as those drugs were not yet FDA approved for use in children and adolescents, that's something you knew?

A. Yes.

Q. Okay. I mean, as -- as a licensed physician, you generally stay abreast as to what are the FDA-approved indicated uses for particular medications as set forth in the drug's or the medication's package insert?

A. Yes.

Q. And just so everybody's clear, what -- what is a package insert or a label for a drug?

A. A package insert is a product of the pharmaceutical companies that has to do with everything and anything concerning a drug as far as, for example, contraindications, adverse reactions, dosing range, things of that nature.

Q. And while that is a product of the pharmaceutical companies, that is something that is FDA approved, isn't it?

A. Yes.

Q. In fact, the FDA requires pharmaceutical companies to include that package insert?

A. That's right.

Q. And when your patients would gain 10 to 20 pounds within the first month of the use of Risperdal, would you stop prescribing it?

A. It -- it depended on many factors if I would stop it or not.

Q. Okay. So you didn't stop it in all instances?

A. No.

Q. Why not?

A. I lowered the dose. I added something else to it.

Q. Why not -- why not stop prescribing Risperdal

and go back to using Haldol or Thorazine?

A. Sometimes I did.

Q. And sometimes you did not?

A. Sometimes I did not.

Q. Why not?

A. Because it was effective in the conditions I was using it for on those children.

Q. You thought it was working?

A. Yes.

Q. But you made a determination as a -- as a clinician as to which patients you would switch or start a treatment on Risperdal who had been previously receiving Haldol, Thorazine or perphenazine, correct?

A. That's correct.

Q. And how did you determine which patients you would start on Risperdal and which ones you would leave on the conventionals that they were currently receiving?

A. The ones that were on the conventionals and the drug was effective, the patient was compliant and the side effect profile was tolerable and safe, would stay. The ones that were not compliant, the ones that had difficulty with adverse events, I switched.

Q. To Risperdal?

A. To -- uh-huh, to Risperdal.

Q. Let me make sure I understand what you're

saying. If a patient was on Haldol and was doing well and you were monitoring for adverse events and side effects, you didn't just switch them over to Risperdal just because it was the new drug on the market?

A. No.

Q. Kind of if it isn't broke, don't fix it?

A. That's correct.

Q. However, if a patient -- if a patient's needs were not being met, at least in your opinion as their treating physician, by the current treatment with the conventional, you would explore other treatment options?

A. Yes.

Q. Which at that time included Risperdal --

A. Yes.

Q. -- as well and later? That included Zyprexa or olanzapine?

A. Yes.

Q. Do you think Risperdal is right for all patients?

A. No.

Q. Do you think Haldol is right for all patients?

A. No.

Q. Do you think any single antipsychotic medication is right for all patients?

A. No.

Q. And in new patients, brand-new patients who come through the door to see you for the first time and you're left with the choice of selecting a medication to start them on, has it been your practice to never start them on Risperdal?

A. No.

Q. So you -- you, in fact, started brand-new patients on Risperdal?

A. Yes.

Q. Did you believe that to be a good drug choice for those patients?

A. Yes.

Q. And in follow-up visits -- well, let me ask you this: When you start a new patient on an antipsychotic medication, do you give them enough refills to get them through the year before you see them again, or do you expect to see them again in short order?

A. They get enough for a month.

Q. Because when you're dealing with patients suffering from mental illness, whether it be schizophrenia, bipolar disorder or any other abnormality out there, it's important as a doctor to see them frequently?

A. Yes.

Q. And the importance of that is -- is what?

A. Safety and efficacy.
Q. So if they're not responding well, you can change therapies, right?
A. Yes.
Q. Sure, but I mean, one of the things -- one of the reasons why it's important to see these patients within a month fairly regularly is to monitor and keep track of side effects?
A. True.
Q. Adverse events?
A. Yes.
Q. Make sure the drug is working?
A. Yes.
Q. And if any of those things send off a red flag to you as their treating physician, you'd do something about it, wouldn't you?
A. Yes.
Q. And if that meant stopping the current therapy, whether it be Risperdal or any other drug, you'd do that, wouldn't you?
A. Yes.
Q. You'd try another therapy, wouldn't you?
A. Yes.
Q. Maybe another atypical antipsychotic, maybe a conventional antipsychotic, right?

A. Yes, or maybe no medication.
Q. Or maybe no medication at all?
A. Correct.
Q. But that's something that would be left to your discretion, right?
A. Right.
Q. And it would be dependent upon the individual patient and whatever symptomology that patient is presenting to you?
A. Yes.
Q. Because if a patient comes in and tells you "Dr. Robinson, I don't like this drug; it's making me feel bad," you'd take that into account in whether to renew or refill a prescription for whatever drug that patient is on?
A. Yes.
Q. And that's not unique to Risperdal?
A. No.
Q. That's not unique to Zyprexa?
A. No.
Q. That's not unique to Haldol?
A. No.
Q. Or Thorazine or perphenazine?
A. No.
Q. It's not even unique to antipsychotic

medications, is it?

A. No.

Q. That's just good medicine?

A. Yes.

Q. You work in child and adolescent psychiatry?

A. Yes.

Q. And has it been your practice from time to time to prescribe medications to patients for whom the drug is not FDA approved?

A. Yes.

Q. And is that an off-label use?

A. Yes.

Q. And in your practice, is that something that you do fairly often or is that uncommon, the off-label use of a medication?

A. Now, in 2010 --

Q. Okay.

A. -- it's more common for me to use FDA indications because we have them for child and adolescent. Ten years ago, more off-label use --

Q. Okay. And --

A. -- because indications weren't there.

Q. Right. And in some cases, you haven't necessarily changed the -- the selection of drugs that you use; it's just that the drugs that you choose from

now have additional indications that include use in child and adolescent patients?

A. Because they have indications for child and adolescent, they will be oftentimes my first line drugs that I will consider.

Q. And, in fact, today Risperdal has child and adolescent indications, doesn't it?

A. Today, yes, it does.

Q. But as of, you know, when it first came out, that wasn't the case?

A. No.

Q. Zyprexa, it didn't have a child and adolescent indication?

A. No.

Q. Conventionals, they didn't either, did they?

A. Which drugs in particular are you talking about?

Q. Well, first, Thorazine.

A. Oh, no.

Q. Perphenazine?

A. No.

Q. Haldol?

A. No.

Q. Okay. So the conventional antipsychotics, at least those three, those -- those did not have an

FDA-approved indicated use in children and adolescents?

A. Correct.

Q. But you prescribed them anyway --

A. Yes.

Q. -- because you thought those were the right drug choices for your patients?

A. In many cases they were like the only choices we had. We were very limited.

Q. Have you ever prescribed an antipsychotic conventional or atypical to a patient under the age of 12?

A. Yes.

Q. How about under the age of eight?

A. Yes.

Q. Under the age of six?

A. Yes.

Q. Why?

A. Because of severe symptomatolgy that may require even a hospitalization or the behavior is dangerous, the child is exhibiting dangerous behavior to themselves or to others.

Q. And during this time period, I mean, these medications were not FDA approved for use in patients that young, correct?

A. What time frame?

Q. Any time before 2006.
A. No. No, there wouldn't have been indications approved.
Q. Right.
A. Right.
Q. But nevertheless, you -- you would from time to time prescribe antipsychotic medications to patients as young as six?
A. Yes.
Q. And would you monitor the patient?
A. Yes.
Q. Closely?
A. Yes.
Q. And if the patient was not reacting well to the -- to the therapy, would you do anything to change it?
A. Yes.
Q. And did you in fact from time to time, from patient to patient, change their therapy?
A. Yes.
Q. Today do you prescribe Risperdal to any patients you treat?
A. Yes.
Q. Have you used TMAP in any of your clinical work?

A. I was aware of TMAP guidelines after Dr. Stanley came to the Health Science Center and would work with the residents who were seeing our adult outpatients. So I was aware of it. Did I use it exclusively? Not necessarily.

Q. Are the atypicals on the preferred drug list today?

A. Yes.

Q. Is Risperdal?

A. Yes.

Q. As of February of 2010, Risperdal is on the State's preferred drug list?

A. Yes.

Q. Do you know if there's generic versions of Risperdal available?

A. Yes.

Q. Do you know how many?

A. How many different generics?

Q. Uh-huh.

A. No.

Q. Do you know if they're on the State's preferred drug list?

A. Yes.

Q. But in any event, if you-all wanted to, the DUR board, you-all could -- could put in a -- a restriction

so that any time a doctor fills a prescription for Risperdal in a patient who's a child or adolescent for which there's not yet an indication, you-all could put that restriction in place so that that claim doesn't get reimbursed?

A. Correct.

Q. He asked you a question to the effect of knowing now -- knowing today what you know now, would you have put in a place restriction on -- on Risperdal on the P&T Committee.

A. Uh-huh.

Q. Do you remember that?

A. Correct.

Q. And you said yes?

A. Yes.

Q. Y'all haven't done that, have you?

A. No.

Q. Dr. Robinson, isn't it fair to say sitting here today in 2010, looking back at this letter in 2003, you can't tell this jury with any reasonable certitude in what way, if any, you changed your prescribing behaviors as a result of this letter, right?

A. Right.

Q. Dr. Robinson, you mentioned in response to Mr. Jack's questions that Mr. Dunham didn't tell you how

Risperdal's use would play out in children. Do you remember that?

A. Yes.

Q. Did you expect him to?

A. Well, if he was in my office and I was a child and adolescent psychiatrist, yes.

Q. Did you ask him how -- how is Risperdal going to play out in treating child and adolescent patients?

A. Yes.

Q. Did he -- did he not answer your questions?

A. He didn't know.

Q. He didn't know?

A. No.

Q. Did he tell you that he didn't know?

A. Yes.

Q. Did he suggest that you could call somebody at medical science, a medical science liaison and ask them?

A. Yes.

Q. Did you do that?

A. I don't remember.

Q. My question is: Sitting here today, is it your belief that Risperdal ought not to be prescribed to patients between the ages of six and 18?

A. No. It should be prescribed.

Q. Based upon what the doctor thinks?

A. Yes.

(Video stopped)

MR. McCONNICO: Your Honor, that is the end of the defense tender.

MR. MELSHEIMER: Your Honor, may it please the Court. At this time we would call -- it's a short deposition of Sharon Dott.

THE COURT: When you say short --

MR. MELSHEIMER: Thirteen minutes.

THE COURT: Okay.

(Video played as follows:)

SHARON DOTT, M.D.

having been first duly sworn, testified as follows by videotaped deposition:

DIRECT EXAMINATION

Q. Dr. Dott, could you please state your full name for the record?

A. My name is Sharon Gail Dott.

Q. And then upon graduation --

A. I --

Q. -- you attended which medical school?

A. I attended the University of Texas Medical Branch in Galveston.

Q. And after you graduated from medical school, where did you do your residency?

A. I did my internship at the University of Texas Medical Branch and my residency also at UTMB.

Q. And then associate professor in 1995; is that correct?

A. That's correct.

Q. While you held these professor positions, what were your duties and responsibilities?

A. For a number of years I was the medical director at the acute inpatient units. In addition to that, I was medical director of the Gulf Coast Center, which is the MHMR authority for Galveston and Brazoria County.

Q. Tell us what involvement you still have with the UTMB.

A. I am retired faculty --

Q. Uh-huh.

A. -- in the department of psychiatry at a clinical associate professorship. I am not salaried.

Q. Okay.

A. I am asked to teach seminars on occasion or supervise residents.

Q. And in addition to the patient being able to pay for the medication, what other payor sources did you encounter?

A. Well, I can X off private insurance because we

did not have patients with private insurance. Medicare did not provide medication. So that leaves patients' resources and Medicaid.

Q. Do you know if pharmaceutical companies communicated directly with the executive formulary committee members?

A. Well, I was an executive committee member. I had pharmaceutical reps communicate directly to me. So I think the answer to the question is yes.

Q. Just generally, do you recall any other instances of speaking with Janssen sales representatives relating to Risperdal?

A. Oh, I've spoken to Janssen reps on many occasions in the 17 years I've been here.

Q. And you as a psychiatrist taught -- I'm sorry, treated patients suffering from mental illness; is that correct?

A. Correct.

Q. Have you ever prescribed an antipsychotic medication to a patient?

A. Yes.

Q. Have you prescribed a conventional or a traditional antipsychotic medication?

A. I used both.

Q. Do you have any specific example of some

Janssen advertising that you think may have in some way victimized a member of NAMI?

A. Sadly, when family members ask about new medications with advertisements of being the best or a better medicine than anything before and essentially side effect free, which clinicians know is not the case and does not exist, family members are given false hope only to have what little strength they have kind of blown away by the lack of response because every medication is not for every person and they come with that expectation based on what they interpret, and I say they interpret from the advertisements.

Q. Is there a specific one that comes to mind, a specific Janssen advertisement that may have resulted in this sort of response?

A. In some of the advertising, Risperdal was advised as effective for positive and negative symptoms with little to no side effects.

Q. Can you identify any decision you made relating to Risperdal that was a result of something my client said or did?

A. Yes. The pharmaceutical representative from Janssen informed me that Risperdal was a potent drug that treated both negative and positive symptoms of schizophrenia, which I didn't find in clinical practice

to treat the negative symptoms over time.

And more disconcerting was the promise that it had lower EPS, extrapyramidal symptoms side effects, which prompted residents under my supervision to listen to and be fairly aggressive with treatment which, for lack of a better term, blew up in their face when patients encountered severe EPS.

Q. Okay. And --

A. And may I add one last thing?

Q. Sure.

A. That is the most disconcerting, the -- promise is not the particular word, but the stance that Janssen took that Risperdal was weight neutral was of particular disconcern -- of particular concern when patients gained weight. So there are three examples that were very negative in my opinion.

Q. The second instance that you mentioned was a representation that Risperdal had lower EPS?

A. Yes.

Q. First of all, you didn't clarify. Lower than what?

A. Lower than what was available.

Q. Typical antipsychotics or other atypicals or both?

A. Typical.

Q. Okay. Do you remember who made the representation to you that Risperdal had lower EPS than typical antipsychotics?

A. Dan Skarke.

Q. And as a result of Dan Skarke's representation to you, did it cause you to prescribe more Risperdal?

A. Initially, yes, until I encountered that what he was representing was not accurate.

Q. In your practice, did you have patients who gained weight?

A. Yes, I did.

Q. And once the patients began gaining weight, what did you do?

A. Without destabilizing them, you try to remove the offending agent, so lowering the dose, trying to switch medicines.

Q. So you made some adjustments to their treatment?

A. Yes.

Q. And how long would it take you as a treating physician to realize that a patient was gaining weight on an agent?

A. Sometimes just weeks. That was alarming.

Q. And again, these -- these were -- the majority of these patients were inpatient?

A. No. These -- the majority -- these that I'm speaking of are outpatients.

Q. The -- the weight gain patients --

A. Yes.

Q. -- were outpatients. So you would see them less frequently?

A. Not necessarily. They may have been in our day hospital program where they were seen --

Q. Okay.

A. -- every day.

Q. With those three, how long do you think could have elapsed between you prescribing a medication to a patient and then you noticing a weight gain?

A. Oh, we took weights every visit, every doctor's visit.

Q. So just the next -- the next visit you might notice --

A. Yes.

Q. -- that there was some weight gain. And if there were a significant amount of weight gain, you would alter the treatment program, either with a reduce of dosing or a different agent?

A. Sometimes a patient wouldn't tolerate that and they would decompensate, so --

Q. Can you tell me what you mean by they wouldn't

tolerate that and they would decompensate?

A. Sometimes changing patient's medication was not in their best interest because they were so fragile --

Q. Okay.

A. -- and any alteration in their medication would destabilize them to the point that they would relapse.

Q. Can you think of a specific instance where you had a patient who was exhibiting what you would consider to be an unacceptable amount of weight gain on Risperdal that you did not change their treatment?

A. No. That I did not change their treatment, no. They had considerable weight gain, and psychotic patients do not make good diabetic patients, so --

Q. I understand.

A. -- they are just dreadfully difficult in that situation. So that was one situation where we really struggled to be very proactive.

Q. Other than these three examples that we've just gone through, is there anything else that someone from Janssen told you relating to Risperdal that you later learned was false?

A. I'm sure there was, but at this time that's what I can recall.

Q. No more specific examples?

A. You want more?

Q. If you have more, yes.
A. Let it suffice at that point.
Q. Other than the examples that we've previously discussed, do you recall any information that they gave you that you thought was misleading?
A. Well, it only takes a little bit of information to then wonder about the rest, so it became a dubious situation.
Q. Do you mean that you thought maybe there was information you did not receive?
A. Yes.
Q. Was there any -- did you ever ask any of these sales reps about the omitted -- or the information you perceived to be omitted?
A. Many of us were concerned about the effect on prolactin and we received none of that information.
Q. Did you ask the Janssen sales reps about it?
A. Yes.
Q. And what was their response?
A. They didn't have any response.
Q. And in this instance, did you ask the senior rep about prolactin?
A. I had asked him, yes.
Q. And what was his response to you?
A. It has no effect.

Q. Did you question his response?
A. Same as with weight gain. Weight neutral was not a good answer to me when my patients were gaining weight.
Q. Other than the representations that we've discussed today, do you have any knowledge of anything that my clients may have done that you consider to be untruthful?
A. Representing a medication to a population of patients that are severely impaired is, in my opinion, bad enough. And to withhold information from the prescriber about side effects from medication really twists the knife in the families that have to take care of these patients. I think that speaks for itself.
Q. When you make these two points about representing lack of side effects and withholding information about them, are you referring to the representations made to you by the sales representatives?
A. Yes.
Q. When Janssen sales representatives would visit you, did the Janssen sales reps disclose to you information that was negative about Risperdal?
A. No, they did not.
Q. Did they disclose to you the results of drug

studies that were negative about Risperdal?

A. No, they did not.

Q. Did they disclose to you results of drug studies showing problems with the drug Risperdal?

A. I asked, but they never did.

Q. Did they disclose to you the results of drug studies showing -- showing problems with side effects with Risperdal?

A. No, they did not.

Q. When the Janssen sales representatives visited you, did they talk to you about treatment algorithms?

A. They did talk some about treatment algorithms.

Q. Do you remember which treatment algorithm they talked with you about?

A. Specifically schizophrenia.

Q. Did they show you information about TMAP?

A. An early form of TMAP was shown to me.

(Video stopped)

MR. MELSHEIMER: That concludes the plaintiffs' offer.

MR. McCONNICO: Your Honor, the defendants have a tender.

(Video played as follows:)

CROSS-EXAMINATION

Q. You just mentioned that you performed these

services prior to retirement. Does that mean you are retired today?

A. I have been retired 11 years.

Q. Dr. Dott, you -- you've participated as the lead investigator in several -- several studies funded by pharmaceutical companies throughout your career, haven't you?

A. Yes.

Q. And did you believe you were doing anything inappropriate by participating in these studies?

A. No.

Q. Just generally, do you recall any other instances of speaking with Janssen sales representatives relating to Risperdal?

A. Oh, I've spoken to Janssen reps on many occasions in the 17 years I've been here.

Q. After speaking with any of them, do you -- did you change your prescribing of Risperdal to your patients?

A. Not that I recall.

Q. And just to be clear, you did not adopt his dosing strategy?

A. Just to be clear, I'd like to reiterate his dosing recommendations were nonclinical and I did not follow them.

Q. Do you typically rely on people who aren't clinicians to give you information regarding drugs that you may prescribe?

A. Generally not. I do look to the pharmaceutical reps as knowing their drugs and being knowledgeable about their drugs to some degree.

Q. Okay. And ultimately, do you -- if you were to review a published study, would you rely on a pharmaceutical company rep to explain it to you or would you use your own understanding?

A. I would use my own judgment.

Q. And when you were treating your patients, which set of information did you use, the information you received from the pharmaceutical company or the outcome of your clinical experience?

A. As a physician, I have to abide by do no harm, and that is precisely that. So it overrode the pharmaceutical -- pharmaceutical information provided to me.

(Video stopped)

MR. McCONNICO: That is the end of the defendants' tender.

THE COURT: Thank you. Ladies and gentlemen, let's take our ten-minute afternoon break.

(Recess taken)

(Jury present)

THE COURT: Be seated, please. Yes, sir.

MR. MELSHEIMER: May it please the Court. Your Honor, at this time -- I'm going to return to my demonstrative chart. And the plaintiffs call Dr. Scott Reines, a witness associated with Janssen.

(Video played as follows:)

SCOTT REINES, M.D.

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

Q. Can you please state your full name, please, sir?

A. It's Dr. Scott Reines.

Q. Can you briefly tell the jury what your educational background is?

A. Yes. I graduated Cornell University as an under -- undergraduate. I received a Bachelor of Arts in chemistry. I have a Ph.D. from Columbia University in chemistry, molecular biology. Sort of a combined sort of study thesis. I have my medical degree from Albert Einstein College in New York and my psychiatric residency training from Montefiore Hospital, which is part of Albert Einstein.

Q. And then you joined Johnson & Johnson in July of 2003 and stayed with Johnson & Johnson Pharmaceutical

Research & Development until September of 2008; is that correct?

A. Yes.

Q. Once you became involved with the CNS component, explain what your responsibilities were once CNS came under your umbrella.

A. I was responsible for the conduct of the clinical trials for interactions with regulatory agencies for personnel issues. I was responsible for regulatory submissions.

Q. Can you tell the jury what you mean by regulatory submissions?

A. Yes. When the company collects data and -- and -- and the data are important either because they involve safety issues or because the company is seeking a new indication, more summarizing what it's been doing with a certain drug. Those data are put together. They're written up, and they're submitted to the FDA, if we're talking about the U.S. And those -- that's what I mean by regulatory submissions.

Q. All right. And am I correct in understanding that the regulatory submissions you might have dealt with at any given time might have been either just voluntarily submitted and/or requested by the FDA depending on the circumstance?

A. Yes.

Q. And when it came to Risperdal, you were performing those responsibilities for a drug that was marketed by a Janssen entity, correct?

A. Correct.

Q. Do you have general familiarity with the rules about off-label promotion of a drug?

A. Yes.

Q. And so you've heard the phrase "off label" or "off-label marketing"? You've heard that before?

A. Yes.

Q. Can you explain to the jury in your understanding and experience what that means?

A. In my understanding, off-label promotion would be communications or dissemination of information that is outside of the product label or inconsistent with the product label.

Q. You are aware of the November 2003 Dear Doctor letter that Dr. Mahmoud sent out regarding the class label issue?

A. I'm aware of a letter that was sent, yes.

Q. Okay. Were you involved in drafting that letter before it went out or reviewing it?

A. No, I was not aware of that letter until after it had been sent.

Q. And what was your reaction when you saw the November 2003 Dear Doctor letter from Dr. Mahmoud concerning the class label issue?

A. I was upset.

Q. Why were you upset?

A. Because in my opinion, the letter was something that was -- was inconsistent with the regulatory -- it was inconsistent with the regulations that -- that governed the types of communications that were permissible.

Q. And that upset you why?

A. Because there are regulatory consequences that follow that type of communication, assuming that the FDA were to agree, and I thought they would, that that communication was inconsistent with their regulations.

Q. Okay. And when you say there are regulatory consequences that follow, what do you mean by that?

A. Well, as -- as actually played out in this case, there was a letter that was issued by the DDMAC division of the FDA some months later that was critical of the company for having issued that communication.

Q. Did you think that the letter violated FDA rules and regulations?

A. I thought that the statements in the paragraph we discussed were inconsistent with the product label

that was being disseminated and that therefore there was a potential regulatory consequence.

Q. Would you have approved the Dear Doctor letter to go out had you reviewed it before it went out?

A. No.

Q. Exhibit 2292 appears to be an e-mail chain starting with the September 16th e-mail and ending with the September 7th, 2003 e-mail, which, again, is about a week or so after the FDA request for a class label change, correct?

A. Yes.

Q. And do you see where he says "From our perspective, we looked at some rough financial scenarios to put into perspective," and then he lists three scenarios?

A. I see that.

Q. And the title of this e-mail, when it's talking about financial scenarios, it's talking about the Risperdal bipolar mania and diabetes labeling in the U.S., correct?

A. Yes.

Q. And the first scenario that Mr. Pruden lists is to accept the current label and launch bipolar, and he puts next to that that it has approximately a 55 to 100-million-dollar downside based on final assumptions.

Did I read that correctly?

A. Yes.

Q. The second scenario that Mr. Pruden lists is to submit further data to agency to strive for revised wording, but agency fails to accept post review. Cost of delaying bipolar approval until January is approximately five to seven-million-dollar downside.

Did I read that correctly?

A. Yes.

Q. The third scenario that Mr. Pruden lists in Exhibit 2292 as follow-up from that teleconference with the FDA is to submit further data to the agency, meeting in December for review, FDA accepts revisions. And he states in parenthesis, i.e., low risk for Risperdal. We get precaution versus warning for others. Other competitors get class label. And then he lists in bold an upside approximately 100 million in incremental sales.

Did I read that correctly?

A. All of the numbers are in bold.

Q. Do you see anything -- any discussion whatsoever in this e-mail that's Exhibit 2292 of how this class label issue concerning diabetes impacts use of Risperdal in vulnerable populations such as children and adolescents?

A. No.
Q. Do you see anything in Exhibit 2292 when you're discuss -- when Mr. Pruden is discussing financial impact to the company of various scenarios associated with the label change that discusses how the diabetes warning impacts patient welfare?
A. This is a financial -- as I read this, it -- it has financial estimates only.
Q. Do you think it's appropriate to have this kind of a financial impact discussion without also evaluating the safety issue involved and how that might impact public welfare?
A. I don't have an opinion.
Q. You can't tell the jury one way or the other whether you have an opinion on that?
A. Correct.
Q. Okay. In Exhibit 1884, there appears to be a number of people copied on this, but it states that it's a voicemail message on safety data Risperdal, and it's dated September 29th, 2003, correct?
A. Yes.
Q. And then it has a voicemail message confirmation for Friday, September 26th, 2003?
A. Yes.
Q. And that's within two or three weeks of

receiving the requested label change from the FDA, correct?

A. Yes.

Q. Mr. Walsman goes on to state, "The data does not show an association between Risperdal and an increased risk of diabetes."

Is this statement that Mr. Walsman sent to the entire CNS sales force consistent with the language of the warning the FDA suggested just a couple of weeks earlier?

A. The FDA warning does -- does not address the question of what the company's data showed.

Q. And nowhere in that suggested warning does it state that the data does not show an association between Risperdal and an increased risk of diabetes, correct?

A. Correct.

Q. Okay.

A. The FDA does not make that statement.

Q. Okay. That's not a statement that would have been permitted under that particular label suggestion, right?

A. It was not included in that label.

Q. And the FDA label did -- did not say, though, that there was a greater association of diabetes with some products versus others such as Risperdal?

A. The FDA label did not say that, correct.

Q. Okay. Later in this paragraph, Mr. Walsman states in his message to you and the entire CNS sales force, quote, "In the meantime" -- do you see where I'm at? Still on the first page, kind of --

A. Yes.

Q. -- second -- okay. "In the meantime, you should follow our company position and sales direction and continue to emphasize that Risperdal has a low risk of diabetes and DKA compared to other drugs in the class utilizing our diabetes reprint carrier combined with our new sales brochure." Did I read that correctly?

A. Yes.

Q. Have you seen the acronym DKA used before?

A. Yes.

Q. And what does that typically stand for in your experience?

A. Diabetic ketoacidosis.

Q. Okay. Can you identify and read for the jury the paragraph of Exhibit 686 that upset you when you saw the Dear Doctor letter?

A. "Hyperglycemia" -- and this is the second -- well, actually, one, two -- it's the third or fourth paragraph of the letter. "Hyperglycemia-related adverse events have infrequently been reported in patients

receiving Risperdal. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research," and there's footnotes one through eight, "suggests that Risperdal is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that Risperdal is associated with a lower risk of diabetes than some other studied atypical antipsychotics."

Q. And how about the next sentence that says "Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that Risperdal is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics."

Did that statement in Dr. Mahmoud's Dear Doctor letter concern you at the time that you read the letter?

A. Yes.

Q. Why?

A. Because that statement is not consistent with what the FDA had imposed in the class label.

Q. And turning back to the first page of the Dear

Doctor letter, the last sentence, "Evidence also suggests that Risperdal is associated with a lower risk of diabetes than some other studied atypical antipsychotics."

My first question is: Is the statement that Risperdal is associated with a lower risk of diabetes than some other studied atypical antipsychotics a statement that was contained in the class warning for diabetes that was ultimately put in the Risperdal label?

A. That is not in the class labeling.

Q. So then can we agree that this letter is conveying at least some information that is not in the FDA-approved label for Risperdal?

A. Yes.

Q. All right. What is Exhibit 2302?

A. This is a response from J&J to Dr. Katz.

Q. Dr. Katz with the FDA, correct?

A. Yes.

Q. Okay.

A. And it says, among other things that that the Dear Doctor letter has -- that he's requesting has been voluntarily mailed.

Q. Okay. And it explains that Janssen had already voluntarily mailed a medical communication concerning the new hyperglycemia and diabetes mellitus labeling to

more than 600,000 physician and healthcare providers.
A. Yes.
Q. Did I read that correctly?
A. Yes.
Q. Okay. It apparently encloses a copy of a letter, although that's not attached to this exhibit, and it also states that Janssen has individually informed over 70,000 physicians of this label change for Risperdal.
Did I read that correctly?
A. Yes.
Q. Okay.
A. Well, that -- I think you read most of that sentence.
Q. Yes. And then it goes on to explain a complete copy of the package insert including the new warning was provided as part of both communications to physicians?
A. Yes.
Q. Okay. Did you have any input or review or approval or anything of this letter that went to Mr. Katz?
A. No.
Q. Okay.
A. I wasn't aware of it.
Q. What is Exhibit 2304?

A. It's an e-mail string including Jack Grebb and me and a number of other people.

Q. You take the e-mail and it eventually gets forwarded to you and you send a separate e-mail to Fred Grossman and Jack Grebb and Garry Neil that says, "Fred, Jack, what was the internal clearance procedure for Ramy's letter? Did PRD have any signoff?"

Did I read that correctly?

A. Yes. I believe this is the first time that I saw the November 10th letter.

Q. So what was the response you received to your questions?

A. So do you want me to read Jack Grebb's note back to me.

Q. Sure.

A. "Scott, The letter would have been approved by the CDT leader and the CDT regulatory leader, Jack."

Q. And then what do you respond to Jack?

A. "Jack - Do you think that's sufficient? I'm troubled by the liberties they've taken. To me it seems like off-label promotion of differences among the atypical agents."

Q. Do you have any regrets for expressing your opinions on this letter?

A. I don't have any regrets about my attempt at

the time and after that to be sure that the company to the best of its ability was compliant with the regulations.

Q. And what is Exhibit 2306?

A. It's e-mail correspondence between Fred Grossman and me.

Q. And it's dated January 8th, 2004, correct?

A. Yes.

Q. On the second paragraph he states to you, "Ris diabetes - I recognize why JPI wants to push improving the diabetes label for Ris, but it may not be advantageous to us with respect to our relationship with the FDA in the long run. If a meeting with the FDA does take place, it should be with the intention to share additional data and analysis that the FDA hasn't seen. I believe that the FDA will not reverse their class labeling without very compelling data (which we do not have)."

Did I read all that correctly?

A. Yes.

Q. You respond to his e-mail: Thanks for the update, Fred. Ris diabetes is another example of agreeing with the FDA and then trying to back out which is going to hurt us.

Did I read that correctly?

A. Yes.
Q. Okay. What did you mean when you said that it was another example of agreeing with the FDA and then trying to back out which is going to hurt us?
A. Well, I don't -- I don't recall what I meant by another example, if there were any other examples. I think looking at that now, that's kind of an unfortunate characterization written at 11:01 p.m.
Q. And one -- you're saying that RIS diabetes is an example of agreeing with the FDA and then trying to back out. What specifically are you referencing?
A. Well, from the context of this e-mail, I -- I must be referencing the class label.
Q. Do you recognize Exhibit 687?
A. Yes.
Q. Okay. What is it?
A. It's a warning letter from the DDMAC division of the FDA --
Q. Okay.
A. -- to J&J --
Q. Okay.
A. -- concerning Risperdal.
Q. And did you agree that it conveyed a different impression than what the class label had stated?
A. It was inconsistent with the label.

Q. Do you agree that the claims that Risperdal is safer than other atypical antipsychotics would be a claim that is not consistent with the Risperdal label at that time?

A. Yes.

Q. And it goes on to state, "Instead, as discussed below, the letter minimizes risks associated with Risperdal and claims that Risperdal is safer than other atypical antipsychotics when this has not been demonstrated by substantial evidence or substantial clinical experience."

Did I read that correctly?

A. Yes.

Q. Okay. Do you agree with any part of that conclusion from the FDA?

A. I agree that the letter claims that Risperdal is safer than other atypical antipsychotics, at least in terms of the context that we're talking about of diabetes hyperglycemia.

Q. And certainly the FDA's position was that the statements in Dr. Mahmoud's Dear Doctor letter were false or misleading, correct?

A. That was the FDA's position.

Q. Do you recognize Exhibit 2308?

A. Yes.

Q. What is it?
A. It's e-mail correspondence including a number of people but also myself and Joanne Waldstreicher.
Q. Okay. And the e-mail correspondence is in the April 28th, 2004 time frame, roughly a week or so after the warning letter from the FDA, correct?
A. Correct.
Q. Okay. You go on to state, "Also, I think it's ironic that Christine is so purist about the database, after JPI wrote such a flagrant letter about Risperdal that the whole management team almost got canned. I'm sure you've seen the DDMAC warning letter."
Did I read all that correctly?
A. Yes.
Q. Okay. And when you -- you've been using the term JPI in your e-mails. Can you explain to the jury what you are referencing when you say JPI?
A. It's the same as Janssen. It's Janssen Pharmaceutica Inc.
Q. And it was your opinion at this time when you wrote to Ms. Waldstreicher that the Dear Doctor letter that Dr. Mahmoud sent out was a flagrant letter about Risperdal, correct?
A. Yes.
Q. And did you characterize it as a flagrant

letter because of the reasons we've already discussed today?

A. Because of the regulatory compliance issue, yes.

Q. When you're addressing the warning letter in the second paragraph, tell the jury what you stated about it.

A. Do you want me to read the second paragraph?

Q. Yes, sir.

A. "The warning letter is ugly. As soon as I saw the JPI letter last November, I called Garry and asked how it could have gone out, but it was too late. They never consulted the team or anyone in PRD except some unnamed regulatory and legal people whom they say reviewed it. But no competent person would have let it go out. If you're interested, I can send it. It's really a black mark for J&J. The *Wall Street Journal* and other media slammed us yesterday. Regards."

Q. And was that how you felt in April 2004?

A. Yes.

(Video stopped)

MR. MELSHEIMER: That concludes the plaintiffs' offer.

MR. McCONNICO: Your Honor, the defense has an offer.

(Video played as follows:)

CROSS-EXAMINATION

Q. And was there anything at this time in the fall of 2003 -- was there anything in this particular paragraph that I just read under the warning section suggested by the FDA that you disagreed with?

A. Yes.

Q. Okay. What did you disagree with at that time?

A. I disagreed with the -- the lumping of all of the atypical antipsychotics studied and the -- the statement that epidemiological studies suggest an increased risk, and I'm paraphrasing, in patients treated with the atypical antipsychotics, because our own epidemiological data and all of the data we could find from the literature did not substantiate that statement.

Q. Did you have any understanding when you worked for the company of how a label change such as the one suggested by the FDA would -- whether it would advantage or disadvantage Risperdal compared to other manufacturer drugs?

A. You're asking me whether the class label that the FDA was proposing would give Risperdal either a competitive advantage or a disadvantage? The problem with the class label was that in our opinion it was

incorrect. So a class label is designed to blur distinctions across the drugs that are covered by the class label. And in our opinion, there were distinctions among the drugs. And the distinction in particular was that Risperdal was different from olanzapine in terms of these types of risks.

Q. And then it misleading -- it also states that the Dear Doctor letter misleadingly claims that Risperdal is safer than other atypical antipsychotics. Did I read that correctly?

A. Yes.

Q. Okay. Did you agree with that conclusion?

A. No.

Q. And why didn't you agree with that conclusion?

A. Because I understand in their letter they're using the term misleadingly to mean that there's a statement made that's inconsistent with the product label. That's their definition of misleading. But my definition of misleading has more to do with the accuracy of the data. And after my review of the data, my opinion was that the information conveyed was not misleading.

Q. Okay. And where do you get the understanding that when they say misleading, they're specifically using that term in reference to the label?

A. Well, from the experience I've had in the pharmaceutical industry, including participation on medical/legal boards, crafting labels, negotiating labels, my impression is that the terms false or misleading are regulatory terms that they use for communications that they consider to be inconsistent with the label.

Q. Do you have Exhibit 686 in front of you? That's the November 10th, 2003 Dear Healthcare Provider letter?

A. Yes.

Q. And can you tell us when -- when did you first see this letter?

A. Approximately November 26th.

Q. 2003?

A. Correct.

Q. All right. So about two weeks after it had gone out?

A. Yes.

Q. Okay. And at that time, did you have an opportunity to assess the scientific validity of the statements contained within the letter, specifically the paragraph that starts with hyperglycemia-related adverse events?

A. Yes, I did.

Q. And what did you do?
A. I reviewed the references cited in this letter, as well as other information that the company had, including literature and the company's database.
Q. Okay. And upon that -- that review, did you reach any conclusions?
A. Yes, I did.
Q. And what were they?
A. I concluded that based on that review, that the statements in the letter were accurate and -- and represented the -- the data that we had.
Q. And -- when did -- when did you reach those conclusions?
A. It was sometime in December, I'd say, late 2003.
Q. And we've seen some e-mail communications where you were critical of Exhibit 686, correct?
A. Correct.
Q. And with those criticisms did you try to retract the November 10, 2003 letter?
A. You mean did I -- did I work within the company to somehow change or retract the letter that had gone out?
Q. Yes, sir.
A. No.

Q. Why not?

A. Because after I reviewed the data, I was completely satisfied that the data that had been communicated were accurate, and therefore, there was not a patient safety issue at stake. Given, though, as we've discussed during this day many times, that there was an issue from a regulatory compliance perspective, but no issue from a patient safety perspective in my opinion.

Q. Do you know if the FDA was provided a copy of the November 10th, 2003 Dear Healthcare Provider letter at or about the time that it went out?

A. Yes. The documents we have reviewed show that there was a letter. The letter was provided to the FDA shortly after it went out.

Q. Do you have a copy of Exhibit 2302 in front of you?

A. Yes.

Q. And that's a letter sent from Susan Merchant, Manager of Regulatory Affairs at Johnson & Johnson to Dr. Katz with the Division of Neuropharmacological Drug Products at FDA, correct?

A. Yes.

Q. And do you see there on the front page, the bottom paragraph?

A. Yes.

Q. And let me read that. There she states to Dr. Katz, quote, "We request that you review the proactive efforts already undertaken by Janssen to inform and educate the medical community, consider the overall level of information already provided to the public and physicians concerning the issue and concur that no additional communication on this topic is necessary."

Do you see that?

A. Yes.

Q. Do you have an understanding as to what's being referred to there?

A. My understanding is that she's referring to the November 10th letter.

Q. And when was the first time that you or others at Janssen heard of any criticism from the FDA regarding that letter?

A. The first time was the April warning letter from the DDMAC division.

Q. And how many months later was that?

A. Five.

Q. Do you know if Exhibit 686 was sent out as -- as just this two-page letter?

A. It also included the new class labeling

warning.

Q. That was an enclosure with this letter?

A. Yes.

Q. Okay. And also turn your attention back to Exhibit 697 in your e-mail to Mr. Frost and Al. I'm sorry, is that Al --

A. Derivan.

Q. Derivan. In -- in your e-mail, your July 25th, 2004 e-mail, you write: Al - this stems from a "Dear Doctor" type letter that Janssen sent to physicians after we included a class warning about diabetes in the label. DDMAC objected to the letter and required the company -- that the company send a corrective document, which is the source of the, quote, misleading, closed quote, statement, referring to the original communication.

In your e-mail, you've put misleading in quotation marks?

A. Yes.

Q. Why?

A. That was to indicate that this was a regulatory definition. And as I testified earlier, that I did not think that the information was misleading.

Q. The last sentence in that paragraph reads, quote, the first letter was by no means optimal, but it

did contain the new warning. What did you mean there?

A. That refers to the November 10th letter. And I meant that from a regulatory perspective, it was not optimal because of the issues we've discussed today, but I did want to point out to Al Derivan that that warning -- the most current class labeling warning had been included in that letter.

Q. You mentioned earlier that Risperdal CONSTA was a very important product. Do you remember that?

A. Yes.

Q. What did you mean?

A. Risperdal CONSTA was the first atypical antipsychotic drug available by injection, and the -- the population treated is schizophrenia, which is a very vulnerable population and a population that does not typically comply well with medication. The opportunity for a physician to provide an injection of Risperdal CONSTA meant that the patients could be treated without the uncertainty of whether they were taking their medication or not.

(Video stopped)

MR. MELSHEIMER: Your Honor, at this time we call Dr. Joseph Glenmullen.

THE COURT: Doctor, may I get you to raise your right hand for me, please.

THE WITNESS: Yes, sir.

(The witness was sworn)

THE COURT: I appreciate it. Thank you. There is a front door.

MR. MELSHEIMER: May it please the Court, Your Honor.

JOSEPH GLENMULLEN, M.D.

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. MELSHEIMER:

Q. Doctor, tell the jury who you are.

A. I am Dr. Joseph Glenmullen.

Q. Where do you live, sir?

A. Cambridge, Massachusetts.

Q. How long have you lived in Cambridge?

A. Oh, about 30 years.

Q. Do you have children?

A. I do.

Q. How many?

A. Three grown children, daughter and two sons.

Q. What do you do for a living, Doctor?

A. I'm a psychiatrist.

Q. All right. And what is your practice as a psychiatrist?

A. I do a number of things. I see patients in a

private practice. I research and write books on psychiatric issues. And I teach at Harvard Medical School.

Q. Tell the jury about your practice as a psychiatrist.

A. I see all kinds of patients. I trained in the public sector. And I've always treated severely mentally ill patients and also very high-functioning patients, too.

Q. How many patients -- private patients do you see currently?

A. Currently I'm seeing about 10 to 20 patients.

Q. How long have you been doing that?

A. Oh, about 30 years now.

Q. All right. You also mentioned that you're an author and a researcher in psychiatric issues.

A. Right.

Q. Have you written any books?

A. Four.

Q. What are they?

A. Well, two of the books were on antidepressants and their side effects. Another book was on psychotherapy. And the most recent one was on death and dying issues.

Q. Was one of the books you wrote called *Prozac*

Backlash?

A. It is.

Q. What was *Prozac Backlash* about?

A. It was a book about Prozac-type antidepressants. So that would include Zoloft, Paxil, Celexa, the whole class. And half the book was about the side effects that I didn't think doctors and patients were being told enough about at the time. And the other half was how to make a reasoned decision as a prescriber or a patient when it would be appropriate to use them.

Q. Did that book receive any honors or awards, Doctor?

A. Yes. I got the annual Achievement Award from the American College for Advancement of Medicine for that book.

Q. Now, you mentioned that you work as a clinical instructor at Harvard Medical School.

A. That's correct.

Q. What does that mean?

A. So I have been teaching at Harvard Medical School since I finished my residency, and I typically teach psychiatric residents late in their training and supervise their case loads, advise them about treating their patients.

Q. How many psychiatric residents do you supervise every year?

A. Typically, it's two or three, and I'll meet with each of them weekly, individually.

Q. How many patients are they seeing?

A. They're seeing hundreds of patients.

Q. Are some of the psychiatric residents you're overseeing treating patients with schizophrenia or other severe mental illnesses?

A. Yes, sir. The -- I teach at Cambridge City Hospital, which again is a public hospital, so lots of people with no insurance or Medicaid, street people, a lot of patients with very serious mental illness.

Q. I want to talk to you a little bit about your educational background, all right?

A. Sure.

Q. Did you go to college?

A. I did, sir.

Q. Did you graduate?

A. Yes, sir.

Q. Where did you graduate from?

A. Brown University.

Q. Did you go back to school -- when did you graduate?

A. 1972.

Q. Did you go back to school in 1978?
A. I did.
Q. Why?
A. I took a number of years off, and then I decided I wanted to try to go to medical school. So in 1978, I went back and did the pre-med requirements hoping to get into medical school.
Q. You got into a pretty good one?
A. I went to Harvard Med.
Q. All right. And when did you graduate from Harvard Medical School?
A. 1984.
Q. What type of courses -- tell the jury, what kind of courses did you take in medical school?
A. Well, in medical school, they really want you to sample all of medicine, so really everything, anatomy, physiology, biochemistry, general medicine, surgery, pediatrics, psychiatry, something of everything, so you can make the decision what you would like to do.
Q. After you graduated, did you decide to specialize in a particular area of medicine?
A. That's when I decided to specialize in psychiatry.
Q. All right. In order to specialize in

psychiatry, did you have to take some specialized training?

A. I did.

Q. Tell the jury about that.

A. So for that, you have to do a one-year internship, followed by three years of specializing in psychiatry.

Q. Where did you do your internship and residency?

A. Those I did at one of the Harvard teaching hospitals, Cambridge City Hospital, the same one I've been teaching at ever since.

Q. What kind of internship did you complete?

A. So I did a general medical internship, which meant I spent time in the emergency room, intensive care, medical wards. I did a month of pediatrics, again, kind of the spectrum of medicine.

Q. After you completed your internship, how long was your residency?

A. It was three additional years. The first one is inpatient work. The second one is outpatient work. And the last year I was the chief resident in the outpatient department.

Q. So during your residency, did you see patients with serious mental illnesses?

A. Oh, very much so. Again, because this was a

public hospital, the city hospital, a lot of schizophrenics, a lot of bipolar disorder, a lot of severe depression, many patients with no insurance, many patients with Medicaid.

Q. Now, we've heard some testimony about this before, Doctor, but what does it mean when you say a public hospital, so therefore you were likely to see a lot of patients with severe mental illnesses? What do you mean by that?

A. Well, that's in contrast to private hospitals where most of the patients would have insurance. This is a city hospital specific -- with a specific mission to treat poor patients, indigent patients, people with Medicaid or no insurance at all.

Q. When did your formal education conclude, sir?

A. 1988.

Q. What did you do after you completed your formal training in 1988?

A. So I did a number of things. I started my private practice. I took the teaching position at Harvard Medical School. And I was also offered a job at the Harvard Student Health Services where I saw students, staff and faculty.

Q. Are you still doing all those three things except the student health services?

A. Yeah. I retired from the student health services a little over three years ago.

Q. You don't look enough to be retired?

A. Thank you, sir.

Q. All right. Now, from the time you started practicing as a psychiatrist until very recently, how many patients would you say you saw a month?

A. Probably about 200 appointments a month with my patients.

Q. Is that a combination of private patients and students?

A. Exactly.

Q. Okay. Now, as a psychiatrist, have you had an occasion to prescribe antipsychotic drugs?

A. Oh, absolutely.

Q. How long have you been doing that?

A. Pretty much the whole 30 years.

Q. Which ones?

A. All of them, both the older less expensive drugs that I'm sure the jury has heard a lot about and the newer more expensive ones.

Q. Have you, Doctor, ever participated in any medical studies?

A. I have.

Q. What kind of studies?

A. The ones that I've done are called epidemiological studies.

Q. What's that?

A. It's when you look back in time, retrospectively, at a patient population and you're looking at a particular issue. It might be a disease. It might be a side effect of a drug. And you're looking backwards in time in a particular defined population.

Q. Now, in addition to your private practice and your teaching, have you ever been engaged in consulting work on psychiatric issues?

A. I have.

Q. Describe how you first became involved with that kind of consulting work.

A. So that book that I talked a little bit about, *Prozac Backlash*, half of it about side effects, some of those side effects then became the subject of lawsuits, and I was asked to consult in those lawsuits.

Q. Have you been hired or retained as an expert in other legal cases?

A. Yes, sir.

Q. And what was the subject matter of your expert testimony and opinion offered in those cases?

A. I have expertise and typically testify on either psychiatric medications or other kinds of

medications that have psychiatric side effects.

Q. Now, in those other cases, do you conduct what's called a forensic analysis?

A. I do.

Q. What is that?

A. That involves typically looking through lots and lots of pharmaceutical company documents, what the pharmaceutical company's internal company reports said about their studies, what they submitted to the FDA, the FDA's reviews back to the company of those studies, all of which is confidential but comes available in the lawsuits, then the published versions of the studies, what the company's public face about those studies was to doctors and patients, internal company memos, e-mails, business plans, marketing plans, sales training, call notes. As the cases go on, as you know from some of these videotapes, there's deposition testimony, and I will read some of that.

Q. What about medical studies?

A. Oh, all -- not only the company studies, but other medical studies on the same class of drugs or the same side effects.

Q. Have you given sworn testimony in lawsuits as an expert witness?

A. I have.

Q. Have you testified in both depositions and in jury trials?

A. That's correct.

Q. Have you issued or provided in most of those cases written reports of your analysis and conclusions?

A. Yes. Typically I have to write a report before I get deposed.

Q. Dr. Glenmullen, did one of your reports in one of your cases become the basis for a request for an inquiry to the FDA by Senator Grassley of Iowa into the practices of another large pharmaceutical company called GlaxoSmithKline?

A. Correct. Two judges made that report public, and then Senator Grassley's office got it and he initiated an investigation by the FDA into that pharmaceutical company's practices.

Q. In the experience you've had as an expert consultant, has it always been in psychiatric issues?

A. Correct.

Q. Has it sometimes involved antipsychotic drugs like the ones that we're talking about in this case?

A. It has.

Q. Have you been retained by the United States Department of Justice, the justice department, to consult on psychiatric issues?

A. Correct.
Q. How much of your time currently is spent doing this kind of forensic analysis in legal cases?
A. In recent years, it's been over half my time.
Q. Can you tell the jury why that's changed over the last couple of years?
A. What's happened is that cases like this one are so large and require so much time to go through all of what -- all these documents and all the science, that I haven't had as much time left to see patients.
Q. Can you give the jury an idea of how much time you've personally spent working on this case?
A. I have spent over 3,000 hours on this case in four and a half years.
Q. Did you review sworn testimony?
A. About 114 depositions taken in this case.
Q. Did you review documents?
A. I reviewed documents in the database with over ten million documents in it.
Q. Did you have some help doing that?
A. I did, sir.
Q. How many medical studies did you review?
A. Hundreds.
Q. Let's talk about an example of one of the studies you reviewed and analyzed.

MR. MELSHEIMER: Can we pull up PX 94?

Q. (BY MR. MELSHEIMER) Dr. Glenmullen, is PX 94 one of the studies you reviewed as part of your analysis in this case?

A. Correct. This is Study 35, one of Janssen's studies of new patients in the early stages of psychosis.

Q. Why did you review and analyze this particular study which we'll call Study 35?

A. This was an example of where the internal company report did not match the published version of the study. The results were different.

Q. What do you mean by that?

A. Well, the internal study report made it clear that when Risperdal was compared to Haldol on the primary measure and most of the other measures, the two drugs were comparable. And then by the time it appeared in print, the published version said that Risperdal was superior.

Q. Are we going to talk a little bit more about that study later?

A. Correct.

Q. Now, did part of your work in this case to get ready to come to court involve reviewing the expert reports from the pharmaceutical company?

A. The defense reports, yes.
Q. Did the defendants provide just one report to rebut your analysis or more than one?
A. More than one.
Q. How many defense expert reports did you review from defense experts who responded to your conclusions?
A. I reviewed about a dozen defense reports.
Q. Now, during your review of those reports, was it possible for you to determine just from the reports how much time those folks spent doing their work?
A. No, not from their reports.
Q. Now, so the kind of review and analysis that we've talked about, is that the kind of work that makes up the bulk of the more than 3,000 hours you spent on this case?
A. Correct.
Q. Okay. Now, it's been said at the very beginning of trial -- it seems a while ago -- that all you did was flip through or look through some documents. Have you heard that?
A. I have.
Q. Does that sound right?
A. I don't think that's a fair characterization.
Q. Why is it unfair?
A. Well, these are dense medical studies and very

complicated. I really had to read hundreds of thousands of pages word for word and in many instances check the data, check the analyses with a lot more than just flipping through.

Q. Did you bring your medical expertise, your experience and training to bear when you reviewed those studies?

A. Exactly.

Q. And your own experience as a practicing psychiatrist?

A. Yes.

Q. Now, when were you first contacted about this lawsuit?

A. In the fall of 2000 -- fall of 2007.

Q. Who contacted you?

A. The Texas State Attorney General's Office.

Q. What happened next?

A. They invited me to come down here to Austin.

Q. Did you?

A. I did.

Q. What did you talk about?

A. Well, they told me some about the case and I told them some about my qualifications.

Q. What did the attorney general of Texas ask you to do in this case as an expert?

A. They asked me to review this issue of off-label marketing, whether or not Risperdal had been off-label marketed. They asked me to review the effectiveness in Ris -- of Risperdal, and in particular, whether or not Janssen had made superiority claims that it was more effective. They asked me to review the safety of Risperdal, and again, particularly whether or not Janssen had made claims that it was superior when it came to safety. And the attorney general also asked me to review the whole TMAP process, the way in which TMAP came into existence and was adopted in Texas.

Q. Did they also ask you to evaluate whether the TMAP algorithm resulted in -- the TMAP algorithm was based on valid medical science as opposed to drug company marketing?

A. That was the heart of it, yes.

Q. Did you do all those things?

A. I did.

Q. And you agreed to act as an expert?

A. I did.

Q. Now, did you tell them the kinds of documents that you think you needed to see to perform your analysis? I think we have a demonstrative to illustrate that. Did you tell the Attorney General's Office the kind of documents you thought you would need?

A. I did.

Q. And review for us, if you would, sir, what you told them.

A. Well, there's a voluminous -- in this case of this drug, there was like around 300 volumes of material submitted by Janssen to the FDA. It's called a new drug application. I told them I would need everything in the new drug application, all the original studies, the internal company reports on those studies, the FDA's review of those reports, the FDA's correspondence with the company about the studies, then the published versions, internal company e-mails, memos, the depositions as they were taken. I also wanted to look at the business plans, the marketing plans, sales training, call notes. That's what made up the database of over ten million documents.

Q. Did you write a report, Doctor, that included the results of your analysis and your conclusions?

A. I did.

Q. Why did you do that?

A. Well, two reasons. One, it's actually required in cases like this. And two, I personally find that a very useful exercise, because for me it's when I write it down that I have to really cross all the T's and dot all the I's and make sure that I have the science right.

Q. Is your report in this case short or long?
A. It's a long one.
Q. How long is it?
A. It's 400 pages.
THE COURT: 444.
THE WITNESS: Thank you, Your Honor.
Q. (BY MR. MELSHEIMER) You're under oath, Doctor. Here's a softball. Does it have more than a thousand footnotes?
A. 1300.
Q. So you've worked on this case for over four years, almost five years. You've spent 3,000 hours -- over 3,000 hours. You wrote a 400-page report. I take it you charge for your time, sir.
A. I do.
Q. All right. And what's your hourly rate for this kind of forensic work?
A. $550 an hour.
Q. Dr. Glenmullen, I want to talk about the issue of diabetes.
A. Sure.
Q. All right. Is that one of the issues that you looked at in your analysis?
A. Yes, sir.
Q. Okay. And is one of the issues about diabetes

that you considered was a review of the scientific evidence and the evidence from Janssen's own files surrounding the issue of Risperdal's risk for diabetes?

A. Yes.

Q. Okay. So, Doctor, we're not going to get through all your testimony today, so we're going to focus on diabetes, and hopefully we can get -- we can get through that. Did Janssen make representations in one form or another that Risperdal did not cause diabetes?

A. That's correct.

Q. Is that true or false?

A. That's false.

Q. All right. So let's look at some examples of what you've concluded are Janssen's false representations. Is this one of them?

A. That's the November 10, 2003 Dear Doctor letter which I think the jury has heard quite a lot about.

Q. Okay. And this is actually -- it's labeled DX 441. I think we've got it as a plaintiffs' exhibit.

MR. MELSHEIMER: What is it, Mr. Roberts?

Q. (BY MR. MELSHEIMER) Does this contain false representations about Risperdal and diabetes?

A. It does.

Q. Okay. And what are some other -- I want to

talk about that in just a moment. But what are some other examples of other false statements that you found that Janssen had made about Risperdal and diabetes?

A. Well, it wasn't just this letter. The company business plans, marketing plans made it very clear that the company was taking the position that Risperdal caused very little or no diabetes. The sales training reflected that. And then the call notes made it clear that that was what was being communicated in the field to doctors. And I think the jury heard earlier in the week, or maybe it was -- well, from Mr. Friede that this is one way to really look through the whole process, what did the company intend to do, what did they plan --

Q. Let me stop you. So that's in their business plans?

A. Correct.

Q. And what's the next one?

A. What did they actually implement. That would be the training, the sales training. And then what actually happens in the field, what do the call notes that the sales reps wrote indicate.

Q. All right. So you looked at all those things?

A. I did.

Q. Did you find out any way to make those call notes easier to read?

A. Not yet.

Q. Okay. Did you come to a conclusion about whether the medical science supported Janssen's representations that Risperdal was either no or low risk for diabetes?

A. I concluded that the science did not support that claim.

Q. Okay. Let's take a look at the November 10th, 2003 Dear Doctor letter that we've heard so much about, and this is Plaintiffs' Exhibit 938. It's also displayed here in our demonstrative in front of the jury. So is this the letter that -- the so-called Dear Doctor letter that you reviewed?

A. It is.

Q. So where in this letter -- let's just cut right to it. Where in this letter does Janssen say that Risperdal does not cause diabetes?

A. Well, you heard Dr. Reines say just a little while ago that the key paragraph is the middle paragraph, and the key sentence is the middle sentence that Risperdal is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics.

Q. So I just want to focus on that for a minute. So they're saying that -- when they say Risperdal is not

associated with an increased risk of diabetes when compared to untreated patients, in other words, are they saying that when you compare somebody that's never gotten Risperdal at all?

A. Exactly.

Q. Okay. So that sounds like a pretty good comparison. If you're not -- if you're not causing diabetes compared to someone that doesn't even get your drug, is that a pretty powerful statement?

A. That's essentially saying Risperdal doesn't cause it.

Q. Okay. And then "or patients treated with conventional antipsychotics."

A. Correct.

Q. All right. That would be like the Haldol.

A. Thorazine, perphenazine.

Q. Let me ask you a question. At the very end of Dr. Reines' testimony he talked about the injectable form of Risperdal called CONSTA.

A. Correct.

Q. Was there an injectable form of Haldol as well?

A. Injectable Haldol. There was an injectable Prolixin. There were injectable forms of the older drugs.

Q. Okay. So that really wasn't all that big of a

deal?

A. No, sir.

Q. Okay. So let's talk about -- this is the claim that you're saying is not supported by the science?

A. Correct, that Risperdal is not associated with an increased risk compared to untreated patients.

Q. Okay. But there's eight footnotes.

A. That's correct.

Q. One to eight.

A. Again, we heard -- we just heard Dr. Reines refer to those eight footnotes.

Q. Now, what are those eight footnotes?

A. On the back of the letter, there are eight references which Janssen was citing to support that claim.

Q. All right. So these are the eight footnotes. I've never actually seen a sentence that had eight footnotes, but this -- it says one through eight, and these are -- these are they?

A. Those are the studies.

Q. Okay. So did you check these references and review them closely?

A. I did. I got all of those papers and read them.

Q. Now, Dr. Reines said he checked them, too, but

let's figure out -- or let's hear what you found out. First of all, do these eight references support Janssen's claims that Risperdal is not associated with diabetes?

A. No. Two of the eight do not.

Q. Okay. Let's talk about that. No. 1, Buse?

A. That's the Buse study, and No. 8, the Sernyak study.

Q. Let's take a look at Buse, all right? That is Plaintiffs' Exhibit 1920. Plaintiffs' Exhibit 1920 is a retrospective cohort study of diabetes and antipsychotic treatment in the United States, and the first author is a man named Buse, correct?

A. Correct.

Q. What was this study trying to look at?

A. So this was one of those epidemiological studies looking at a large insurance database retrospectively and comparing the incidence of diabetes in patients treated with different antipsychotics.

MR. MELSHEIMER: And if we could go to the highlight, Mr. Barnes.

Q. (BY MR. MELSHEIMER) What is the bottom line of the Buse study? Let's wait until we get it pulled up.

A. Well, you can see here that this study is actually saying of the atypical newer more expensive

antipsychotics, only Risperdal was associated with a significantly greater risk of diabetes than the Haldol -- haloperidol is another name -- cohort.

Q. So this is Footnote 1?

A. This is Footnote 1.

Q. It's offered in support of the claim that Risperdal is not associated with diabetes?

A. Correct.

Q. And it actually shows just the opposite?

A. That's right, sir.

Q. All right. Was there another study in the eight footnotes -- let's go back to our eight footnotes -- that did not support Janssen's claim that Risperdal was not associated with diabetes?

A. Footnote No. 8, Sernyak.

Q. Okay. Let's take a look at the cover of the Sernyak study. What was that?

A. This was, again, an epidemiological retrospective study comparing antipsychotics for the risk of diabetes.

Q. What did it conclude?

A. It concluded that in patients under 40 years of age who are not normally at an elevated risk, all of the antipsychotics, including Risperdal, increased the risk of diabetes.

Q. Dr. Glenmullen, a doctor or healthcare provider reading that letter referencing these studies, how would they know that a quarter of the studies cited say just the opposite?

A. They wouldn't know. You would assume that all of the studies cited supported the statement that was being made.

Q. Now, let's take a look at the warning letter.

MR. MELSHEIMER: Can you pull up the warning letter, Mr. -- oh, there it is, Plaintiffs' Exhibit 138.

Q. (BY MR. MELSHEIMER) And here's a big copy of it. In fact, Doctor, is what you just told the jury about, that two of these studies don't even -- support the opposite of what the assertion was in the letter, is that one of the criticisms that the FDA leveled at Janssen in this warning letter?

A. That's correct. The FDA identified the same two studies as not supporting Janssen's claim and criticized them for that.

Q. Is that good medical science to cite a study for a proposition that's just the opposite?

A. Bad medical science.

Q. How about citing two? Twice as bad?

A. Twice as bad.

Q. All right. Now, are there any -- now, those -- let's go back to the footnote, though, the studies. So we've got two of them we've got to cross out, but let's go back and look at the other six. So 1 and 8 are gone. Of the remaining six, are any of those Janssen funded or related studies?

A. Four of the six are.

Q. How do you know that?

A. Again, from checking the papers and internal Janssen documents.

Q. Now, there's nothing wrong with a drug company funding a study, right?

A. That's correct.

Q. And there's nothing wrong with people associated with drug companies being involved with studies, right?

A. Correct.

Q. And you're not here to criticize that or say that's a bad practice?

A. No.

Q. But is there anything wrong with any of these six -- or four Janssen funded or involved studies?

A. Well, from the internal Janssen documents, at least one of these studies, No. 3, Fuller, the results had been manipulated before the study was published.

Q. Okay. Is that the study No. 3, Fuller, also known as -- another name there is Shermock?

A. Correct.

Q. Now, that's a pretty sharp claim, Doctor. How do you know that Janssen manipulated the results of this study before it was published?

A. From internal Janssen documents saying that originally the study had shown there was no difference between Risperdal and Zyprexa, and by the time it was published the claim was that Zyprexa was worse.

Q. Well, let's take a look at it. Let's take a look at Plaintiffs' Exhibit 232. Do you see that, sir?

A. Yes.

Q. Now, this is an e-mail from someone named Amy Grogg who's on our organizational chart. Maybe you can help me find here. Right there. Okay. She's a director of Outcomes Research, actually is right -- on our chart is right below Dr. Mahmoud, who was the author of the letter that the FDA found was deceptive.

A. Correct.

Q. Okay. So let's take a look at this e-mail dated October 15th, 2001 from Ms. Grogg. And this is this VA diabetes study. Is that the study that became the Fuller study?

A. Correct.

Q. And what does she say?

A. So she's saying here "Hot off the presses." This is the original unmanipulated results. The general gist is there is not a difference between Risperdal and olanzapine, which is Zyprexa, in diabetes risk.

Q. Now, let's go to Plaintiffs' Exhibit 1960. And is 1960 the published version of this Fuller study?

MR. MELSHEIMER: Just -- Mr. Barnes or Mr. Roberts, if you could show -- just go back to the very top of the article and see that this is in fact Mr. Fuller or Dr. Fuller.

Q. (BY MR. MELSHEIMER) All right. So this is the Fuller/Shermock study that was cited in the footnote, right?

A. And you can see that Amy Grogg was actually a co-author of the published version.

Q. Oh, she got on it, too?

A. She did.

Q. Okay. So what does this published version conclude? And we've got that highlighted.

A. So the published version said Zyprexa therapy was associated with a significantly higher risk of development of diabetes compared with Risperdal.

Q. So let's go back to the e-mail. And in the e-mail she says the gist is that there's no -- she says

not difference -- no difference between Risperdal and olanzapine to diabetes risk.

A. Correct.

Q. All right. So how did they manipulate the data to get the result for the published study that they cited to the FDA?

A. What they did was they actually threw out some of the data. They dropped female patients. They took all the female patients out. They took all of the Hispanic patients out. They took all of the Asian patients out. They removed about 12 percent of the percent from the study, which included about 13 percent of the patients who had developed diabetes. And when those patients were taken out, that changed the result in favor of Risperdal.

Q. Let me focus on this for just a second, because I think we're going to hear from Janssen -- indeed we have heard that, well, you know, many years later, many years later, it turned out that a lot of people agreed that Zyprexa was a little worse with weight gain than Risperdal. Are you aware of that?

A. I am aware of that.

Q. As a doctor and as a scientist, does that justify throwing out the data that didn't support their conclusion back in 2001?

A. No, it does not.

Q. Do you know of any accepted scientific standards that would permit that kind of manipulation of data?

A. No, I do not.

Q. Now, in addition to this Fuller study before it was manipulated, had Janssen done any other studies showing that Risperdal was associated with diabetes?

A. Actually, they had. I discovered that they had done three additional studies.

Q. All right. Now, were those studies cited by Dr. Mahmoud in this letter?

A. None of them were in the eight footnotes.

Q. Okay. Not even generally mentioned or referred to in any way?

A. Not at all.

Q. Okay. Now, did Janssen tell the FDA -- separate from this letter, did Janssen tell the FDA about these three studies?

A. No. In this time frame, the FDA had written to all the companies in 2000 saying we're examining this closely because it's so serious, send us everything you have, and Janssen made a mission several months later and did not tell them about any of these studies, two of which had been completed by that time.

Q. What are the studies you're referring to that Janssen concealed from the FDA?

A. They're called 113, ERI and 275.

Q. All right. What was Study 113?

MR. MELSHEIMER: Let's pull up Plaintiffs' Exhibit 115, please, sir.

A. 113.

Q. (BY MR. MELSHEIMER) It's Exhibit 115.

A. Oh, sorry about that.

Q. The study is 113, correct? That's a little confusing. So this -- tell us what Exhibit 115 is, sir.

A. So this is the first of these three studies. This is actually an extremely high-quality study, much higher than any of the eight in the footnotes.

Q. Why do you say that?

A. Because the eight in the footnotes were epidemiological studies, looking backwards at a population. That's considered a lower level of science than when you specify prospectively, "I'm going to do a study." And I think you heard something about it in the last week about blinding the study so that neither the patients nor the doctors doing the study can have any bias about who's taking what. So this was one of those high-quality blinded studies. It was a year. It was large with a lot of patients. This was a superb study.

In the Fuller article, the company had said we're not aware of any prospective studies like this, and they had actually already done one.

Q. Well, what does this study purport to evaluate?

A. Comparing the risk of medically serious weight gain for diabetes in patients taking Risperdal or Zyprexa.

Q. So did Risperdal cause weight gain in this 113 study?

A. It did, medically serious weight gain.

Q. Let's take a look at Plaintiffs' Exhibit 71. What is this, sir?

A. So these are the results for the -- what's called medically serious weight gain, which means a weight gain -- the FDA and scientists define that as weight gain of more than 7 percent of your body weight.

Q. Okay. And does the study conclude that -- first, that there appears to be no difference in the incidence of 7 percent weight gain in the two groups?

A. Correct.

Q. And then does it say both support the finding of significant weight gain in the risperidone treated patients, especially at week 52?

A. So about half the Risperdal patients had medically serious weight gain in this study during a

year.

MR. MELSHEIMER: Let's take a look at the next slide from this exhibit, Mr. Barnes.

Q. (BY MR. MELSHEIMER) Did Risperdal cause diabetes in this study?

A. So this study used as a marker of diabetes what's called hemoglobin A1c. That's the abbreviation HbA1c. And you can see in the table that 2.8 percent of the Risperdal patients got diabetes during the one year of this study.

Q. A couple things I want to ask you about that. So that's actually more than under olanzapine?

A. Zyprexa, correct.

Q. Now, 2.8 percent doesn't sound like very much to the average person. Is it significant in a medical study?

A. It is. Pharmaceutical companies themselves actually define any side effect that occurs in more than 1 percent of patients as a frequent side effect. And this side effect is very serious. It can be life-threatening.

Q. So 1 percent is the threshold for frequent, and this is nearly triple that?

A. That's correct.

Q. Okay. Now, when did Janssen have the results

of 113?

A. In 1999.

Q. This is before the FDA had asked for all this information about diabetes?

A. That's correct, the previous year.

Q. Now, tell the jury how it is that the FDA became aware that there was this issue with these newer more expensive antipsychotics like Risperdal, Zyprexa and other drugs, how they became aware that there was this diabetes problem.

A. Well, you've heard multiple doctors testify like Dr. Dott earlier, Dr. Robinson, you heard Dr. Van Norman last week, that shortly after these drugs came on the market and psychiatrists started prescribing them for patients, it was just so obvious that they were gaining huge amounts of weight. And there started to be reports in the medical literature. The FDA started to get reports into their adverse event database, meaning side effect database. And so by the late 1990s, it was a very big issue. This study was completed by Janssen in 1999, and it's in 2000 that the FDA formally writes to all the companies in the spring and says we would like everything you have on this subject by August.

Q. Did Janssen provide Study 113 to the FDA at any time during this time frame when the FDA was

investigating the serious risk between these newer antipsychotics and diabetes?

A. The company did not.

Q. Did they actually -- in addition to not telling the FDA about it, did they in fact tell -- well, did they in fact represent that they had no long-term comparison studies even available?

A. Correct. So this --

Q. Let me stop you there. This is -- just for the record, this is DX 671. This is the submission from Janssen to the FDA. And tell us -- with regard to this diabetes issue, tell us where you're directing our attention, Doctor.

A. So there was a sentence in the summary at the front. This was a huge submission of about 18 to 20 volumes. And there's typically a summary, like 30 to 50 pages at the front. And in the summary, Janssen said there were no long-term, double blind trials with either placebo or Zyprexa, because again, they would have been considered the gold standard, and the company was representing that they didn't have any, even though they had completed one the previous year.

Q. Well, but what we've heard in the trial, Doctor, I think -- or not evidence, but argument, I think, that this 113 was a broken study that should

never have been submitted to anyone.

A. I have heard that.

Q. I want to talk to you a little about that. First of all, did -- did Janssen -- broken or no, did Janssen actually end up publishing the results of this study that they didn't give to the FDA?

A. As best I could determine, they've never published it.

Q. Okay. Now, the notion that a study can have problems with the patients getting the drug or similar issues, is that a common or an uncommon problem in medical studies?

A. It's actually quite common. When you do studies at multiple sites with hundreds of patients, there's very often problems with some of the data.

Q. So does the notion that some of the data has problems -- does that render a study broken or unusable?

A. No, not at all.

Q. And in fact, does it happen pretty often in studies that there's some glitch with the data that has to be corrected for or dealt with?

MR. McCONNICO: Excuse me. Counsel doesn't need to constantly lead the witness. That's the objection.

MR. MELSHEIMER: I'll rephrase, Your

Honor.

Q. (BY MR. MELSHEIMER) Can you tell the jury if there -- if there ever is an issue with studies being run and published even with data problems?

A. Again, it's very common. What you typically do is identify the small amount of data that's problematic and you calculate the results with and without, and if it makes no difference to the results, then you're quite clear that it's not a broken study.

Q. Dr. Glenmullen, did you find evidence -- tell us if you found evidence that that exact problem had happened to Janssen in studies that they did submit to the FDA to get Risperdal approved in the first place.

A. Yes, and that they had published.

Q. All right. Let's take a look at Plaintiffs' Exhibit 118. What is Plaintiffs' Exhibit 118, Doctor?

A. So this is, again, one of Janssen's internal reports on a study called 79.

Q. Was this one of the studies that Janssen submitted to the FDA to get Risperdal approved?

A. This was a study that was specifically submitted to the FDA for what was called a long-term approval. The original approval were six- to eight-week studies for approval for the drug. And then at a later stage, they went for what's called a long-term

maintenance approval, and this was their key study.

Q. Did this study have a data issue in it?

A. It did.

Q. Can you direct the jury's attention to that, please, sir?

A. So you can see here during the trial audit, it was determined that the data from one site did not meet the Janssen Pharmaceutica quality standard; therefore, analyses were performed with all sites, 395 patients, and without site No. 8, 365 patients. That's a 30-patient difference.

Q. So the 30-patient difference here did not render this study broken?

A. No, sir.

Q. How many patients were at issue that got the wrong medication in Study 113?

A. Nine patients.

Q. Did they publish this study in addition to submitting it to the FDA, Plaintiffs' Exhibit 118?

A. The company did publish it.

Q. Did they ever represent that it was broken or couldn't be used?

A. No. They became the centerpiece. This was Csernansky, and it became the centerpiece of their marketing.

Q. Now, you said there were three studies that the FDA did not get from Janssen. One of them was this Shermock. One was this 113. What's the last one?

A. No, the first one is 113.

Q. I'm sorry. 113. What's the second one?

A. It's called the ERI study.

Q. And what's that?

A. Epidemiological Research Institute was a company that Janssen had contracted with to do one of these retrospective epidemiological studies.

Q. And what did the ERI study look at?

A. It again compared the incidence of diabetes in patients taking the antipsychotic drugs.

Q. What were the results of it?

A. The results of this study were that there was no difference between Risperdal and Zyprexa.

Q. Now, when did Janssen have the results of this ERI study?

A. They had the results of this study in late July 2000, early August, just a little before the submission to the FDA, which was on August 8th.

MR. MELSHEIMER: Let's take a look at Plaintiffs' Exhibit 238, Mr. Barnes.

Q. (BY MR. MELSHEIMER) Is this an e-mail in which the ERI report is forwarded or sent by Ms. Grogg who

we've talked about earlier?

A. Correct.

Q. And in the subject line, what does she say about this study and the FDA?

A. She says do not include in FDA submission. And this is August 1, just a week before the submission.

Q. Now, Doctor, had Janssen planned to submit this ERI study to the FDA before the results turned out bad for their argument?

MR. McCONNICO: Objection. This is argumentative and continues to lead. He doesn't need to lead the witness, doesn't need to make argument with questions.

MR. MELSHEIMER: Let me rephrase, Your Honor.

Q. (BY MR. MELSHEIMER) Did you find evidence that Janssen had originally planned to submit this ERI study to the FDA?

A. Internal company documents showed that in July when they were waiting for the results, they did plan to submit it.

MR. MELSHEIMER: PX 546, Mr. Barnes.

Q. (BY MR. MELSHEIMER) This is an e-mail again from Ms. Grogg of Janssen dated July 19th, 2000. What does this say about the ERI study?

A. That it will be available July 28th, 2000 in order to be incorporated into the response to the FDA, due August 10th.

Q. So just so we're clear, the first sentence before that says "I have also enclosed table shells from the second project from ERI, the vendor for the project." Is that this epidemiological study you've told us about?

A. Correct, the ERI, Epidemiological Research Institute study.

Q. All right.

MR. MELSHEIMER: And then can we just go back to 238, Mr. Barnes?

Q. (BY MR. MELSHEIMER) And this is the same study that is now stated about a couple of weeks later "do not include"?

A. Correct. It says just before the highlighting, "ERI report and tables."

Q. Is either the 113 study or the ERI study mentioned in the November 10th, 2003 healthcare provider letter?

A. No, they are not.

Q. And you mentioned a third study --

A. Correct.

Q. -- Janssen had. What study was that?

A. This study was called 275.

MR. MELSHEIMER: Plaintiffs' Exhibit 100, please, Mr. Barnes.

Q. (BY MR. MELSHEIMER) What is Plaintiffs' Exhibit 100, Dr. Glenmullen?

A. This is another internal Janssen company report on the study. And you can see the trial number -- trial stands for study, RIS-USA-275.

Q. Describe what this study was --

A. So this was another one of these higher standard studies, double blind, prospectively designed, again, an extremely high-quality study. It was long term, in this case six months. And it was a very sophisticated sensitive study with multiple levels -- multiple measurements of blood glucose regulation, which is what ultimately when it goes awry can cause diabetes.

Q. When did Janssen have the results of Study 275?

A. They had the earlier results in September 2003.

Q. What were the results of 275?

A. Once again, in this study, Risperdal and Zyprexa were comparable.

Q. Did Janssen share the results of this study -- in this time frame when the FDA was investigating the diabetes risk, did Janssen share this study with the FDA in any way that you can tell?

A. Not as best as I could tell.
Q. Do they in any way cite them in the letter?
A. No, they do not.
Q. Now, I want to ask you about this issue, Dr. Glenmullen, that diabetes was already in the label of Risperdal. There was already warnings about diabetes in the Risperdal label. Do you -- have you heard that argument made?
A. I have.
Q. All right.
MR. MELSHEIMER: Can we pull up the Plaintiffs' Exhibit 13, Page 5?
Q. (BY MR. MELSHEIMER) Now, tell the -- tell the jury what we are showing in Plaintiffs' Exhibit 13.
A. So I think you've heard a lot about the label, which is a technical term for the prescribing guidelines. I think Mr. Jacks unfolded one in front of you. It's kind of accordion-shaped. It goes on for pages and pages, a lot of fine print. And it's got various sections that are called out with bold headlines. So right up at the top, because the FDA wants doctors to see them, is warnings, precautions, serious issues with the drug. And then much, much later down are a laundry list of side effects.
Q. I notice, Doctor, that diabetes is mentioned

here.

A. So this -- we're now in the side effects section. And the particular side effects are metabolic and nutritional disorders. And this was what was in Janssen's original label. This is the 1994 label. And it says "infrequent," and it lists as a side effect weight increase. But you can see why this is not particularly helpful to doctors and not really a warning, because just a few later it says weight decrease --

MR. McCONNICO: Objection. We don't need this constant narrative. He can just answer the question.

THE COURT: Could I see y'all over here?

(Discussion off the record between the Court and counsel)

Q. (BY MR. MELSHEIMER) Dr. Glenmullen, this is from the label for Risperdal, correct?

A. The original label, yes.

Q. The original label. And this has a bunch of different conditions, warnings -- or conditions and side effects and things of that nature; is that right?

A. Side effects, not warnings.

Q. Right. And we've highlighted weight increase and weight decrease.

A. Correct.

Q. And you were telling the jury that that's not all that helpful to a doctor reading this. Can you explain why?

A. Because this section of the label is not calling out serious health concerns that have been identified with the drug or the class of drugs that are up in the warning section. It's a laundry list of side effects. And it's difficult for a doctor to know how much weight increase, what the significance of that is, and especially when right after it it says weight decrease. The doctor doesn't kind of know what to make of that. That's very different from a warning saying this class of drugs is associated with serious weight gain and diabetes.

Q. Okay. So the types of information that might be contained elsewhere in the label, how are they -- how is that information different from what is contained in the section of the label called warnings?

A. The FDA intends the warnings up at the top to cause special health risks that have been identified with the drug or the class to doctors' attention.

Q. And when was the first time that that kind of warning about diabetes as opposed to a mention of it in the label appeared in the Risperdal label?

A. That's the class label that the FDA required in the fall of 2003.

Q. Dr. Glenmullen, we've talked a little bit about this Dear Healthcare Provider letter. And you mentioned in your analysis that you had looked at misrepresentations concerning diabetes, and one of them was this letter.

A. Correct.

Q. Are you with me? Okay. Did you also find this letter or references to this letter being used by Janssen's salespeople when they were out promoting Risperdal to doctors?

A. Yes, call notes.

Q. And you found that in examples of what we've all seen as call notes?

A. And in the sales training.

Q. Okay.

MR. MELSHEIMER: Can we see some examples of that, Mr. Barnes, from Exhibit 145 for the record.

Q. (BY MR. MELSHEIMER) So this is Plaintiffs' Exhibit 145, and we're going to try to go through this quickly, Doctor. We have a few of these. So this is a call note dated November 2003, November 17th, which is a week after this letter went out. And what is in the next call objective line?

A. So this sales rep is saying I put the diabetes letter in every customer's box.

Q. Do you understand that to be the letter that the FDA found false and misleading?

A. The Dear Doctor letter.

Q. Okay. Then what else was stated?

A. That every single one of the doctors that he or she was calling on was -- this letter was going to be delivered to them.

Q. Okay.

MR. MELSHEIMER: Do we have another example, Mr. Barnes? I know -- or Mr. Roberts. I know it takes a while for these to come up sometimes.

Q. (BY MR. MELSHEIMER) So this is November 10th, 2003, a call by a Janssen salesperson on a doctor in Houston. And what does this say?

A. So this sales rep is saying detailed, which I think you've heard means tell the doctor details about, the diabetes letter, which is the November 10th letter, and sold the third paragraph. Again, just like Dr. Reines is saying, that was the key paragraph from the company's point of view, and --

Q. Let me stop you right there, Doctor. I'm sorry. That's this paragraph here that begins "Hyperglycemia-related adverse events" --

A. Correct.
Q. -- that has the middle sentence that we've talked about?
A. Correct.
Q. And what does the call notes say about that?
A. And he, meaning the doctor, had no problems with it.
Q. Does this all -- does this call note also have a comment about the data of Risperdal and diabetes?
A. Yes. It says no data suggests Risperdal causes diabetes.
Q. Doctor, we've had some discussion in this case -- we'll leave that up, please -- some discussion in this case about who said what in these call notes.
A. Right.
Q. All right. So is there -- is it -- did you have any ambiguity in your mind when you were reading this when you read he -- let's go back to the...
When it says he had no problems with it, do you have any ambiguity about who that's referring to?
A. It's referring to the doctor.
MR. MELSHEIMER: Let's pull up just one more example of a call note making reference to this diabetes issue or the Dear Doctor letter.
And I'm sorry, Your Honor. It just takes

a while to scan through this database issue.

Q. (BY MR. MELSHEIMER) Doctor, how many call notes are there that you've looked at in this case?

A. I've looked at thousands and thousands.

Q. Now, this is November 10th, 2003, right after the letter was sent. It was a call made to a doctor in San Antonio.

A. Right.

Q. And what does this salesman -- Janssen salesman say about the diabetes letter?

A. Good core call and diabetes letter, positioned as his safety/litigation, et cetera.

Q. Good core call and diabetes letter, positioned as his safety/litigation. Is there any -- just listen to my question. Is there any reference in there to what litigation this salesman is referring to?

A. In the note?

Q. Yes, sir.

A. It doesn't say what kind of litigation.

Q. All right.

MR. MELSHEIMER: Your Honor, may it please the Court. I'm --

THE COURT: About ready to go --

MR. MELSHEIMER: -- prepared to go forward or I can stop now.

THE COURT: -- into a new area?

MR. MELSHEIMER: Yes, Your Honor.

THE COURT: I'll see y'all tomorrow morning. Have a safe trip home.

(Jury not present)

THE COURT: I first would like to see Winter and McDonald, and then I want to see the trial team.

MR. MELSHEIMER: In that order?

THE COURT: In that order.

(Court adjourned)

THE STATE OF TEXAS)

COUNTY OF TRAVIS)

I, Della M. Koehlmoos, Official Court Reporter in and for the 250th District Court of Travis County, State of Texas, do hereby certify that the above and foregoing contains a true and correct transcription of all portions of evidence and other proceedings requested in writing by counsel for the parties to be included in this volume of the Reporter's Record, in the above-styled and numbered cause, all of which occurred in open court or in chambers and were reported by me.

I further certify that this Reporter's Record of the proceedings truly and correctly reflects the exhibits, if any, admitted by the respective parties.

WITNESS MY OFFICIAL HAND this the 18th day of January, 2012.

/s/: Della M. Koehlmoos
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