REPORTER'S RECORD
DAILY COPY VOLUME 6
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 17th 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 17, 2012

PLAINTIFFS' WITNESSES

EXHIBITS OFFERED BY PLAINTIFFS

EXHIBITS OFFERED BY PLAINTIFFS

EXHIBIT NUMBER	DESCRIPTION	PAGE OFFERED	PAGE ADMITTED	VOL.
0372		7	8	6
0415		7	8	6
0441		7	8	6
0726		7	8	6
0760		7	8	6
0781		7	8	6
0939		7	8	6
0967		7	8	6
1373		7	8	6
1679		7	8	6
1680		7	8	6
1736		7	8	6
2123		7	8	6
2125		7	8	6
2126		7	8	6
2188		7	8	6
2243		7	8	6

EXHIBITS OFFERED BY DEFENDANTS

PROCEEDINGS

JANUARY 17, 2012

(Jury not present)

THE COURT: Thank y'all. Be seated. Mr. Jacks, you have some exhibits?

MR. JACKS: Yes, Your Honor. At this time, Your Honor, plaintiffs would offer exhibits that were associated with testimony presented last week by certain witnesses. We've reviewed these with defense counsel and are advised that apart from the objections that they filed in writing with the Court, they have no further objections to the admission of these exhibits.

First, from the testimony of Mr. Anderson, Plaintiffs' Exhibits 33-A and 33-D. From the testimony of Ms. Margaret Hunt, Plaintiffs' Exhibits 312, 1736, 2123, 2125, 2126 and 2243. From the deposition testimony of Mr. Leech, Plaintiffs' Exhibit 967. From deposition testimony of Ms. Bursch-Smith, Plaintiffs' Exhibits 266 and 1373. From the testimony of Mr. Allen Jones, Plaintiffs' Exhibits 180, 181, 182, 1679 and 1680. From the deposition of Laurie Snyder, Plaintiffs Exhibit 726.

From the deposition of Susan Stone, Dr. Stone, Defendants' Exhibit 441, which is a variation, I'm told, of Plaintiffs' Exhibit 48, which

has already been admitted. Do I have that right? Plaintiffs' Exhibit 372, Plaintiffs' Exhibit 415. From the deposition testimony of Dr. Schroeder, Plaintiffs' Exhibit 2188. From the deposition testimony of Percy Coard, Plaintiffs' Exhibits 760 and 781. And from the testimony of Mr. Friede, Plaintiffs' Exhibit 939.

THE COURT: With cognition of all defendants' previous objections, the exhibits are all admitted.

(Plaintiffs' Exhibits 33-A, 33-D, 180, 181, 182, 266, 312, 372, 415, 441, 726, 760, 781, 939, 967, 1373, 1679, 1680, 1736, 2123, 2125, 2126, 2188, 2243 and Defendants' Exhibit 441 all admitted)

MS. APPLEBERRY: Your Honor, defendants have some exhibits to admit as well.

THE COURT: Okay.

MS. APPLEBERRY: We have conferred with plaintiffs' counsel and they have no objections to the admission of these exhibits. So defendants move to admit Defense Exhibit 470, 428, 435, 441, 644, 745 and 751.

THE COURT: And they're all admitted.

(Defendants' Exhibits 428, 435, 441,

470, 644, 745 and 751 admitted)

THE COURT: Bring the jury in.

MR. JACKS: I have a correction, Your Honor. I apologize for this. I said that Defendants' Exhibit 441 was another version of Plaintiffs' Exhibit 48. It's actually Plaintiffs' Exhibit 98, which is already admitted.

(Jury present)

THE COURT: Good morning. Everybody be seated. Mr. Jacks.

MR. JACKS: Your Honor, at this time plaintiffs would call by deposition -- I'm sorry. We have one matter before we call the deposition, Your Honor. I'm sorry.

MR. MELSHEIMER: Your Honor, the parties have agreed on an organizational chart to be displayed to the jury as a demonstrative. I'll find a number for it and identify it for the record. The parties have also agreed as follows: That the chart we are showing you is representational. It is not time specific. And some of the individuals depicted on the chart may have had multiple different positions or promotions within the individual company.

Furthermore, as the chart is representational, there may be layers of corporate

structure not shown on the chart. For example, an individual's location on this chart may not be indicative of their rank within the company.

So with that explanation, this is an organizational chart that identifies many of the witnesses that have been previously talked about.

THE COURT: Mr. McConnico.

MR. McCONNICO: Your Honor, we agree at the proper time this chart may be shown to the jury as a demonstrative.

THE COURT: So he's indicating that now is not the proper time.

MR. MELSHEIMER: Your Honor, we're about to hear from Tiffany Moake, who's on this chart. We've heard from some other witnesses who are on this chart. I just think it would be fair to display it to the jury at this time for a demonstrative purpose.

MR. McCONNICO: We don't have any objection to that at all during this deposition.

THE COURT: Okay. Thanks.

MR. JACKS: Plaintiffs call by deposition as a witness identified with an adverse party Tiffany Moake, who shows up in the organizational chart.

THE COURT: How's the reflection off the screen? Okay?

(Video played as follows:)

TIFFANY MOAKE,

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

DIRECT EXAMINATION

Q. Would you please state your name.

A. Tiffany Renee Moake.

Q. Have you executed a consulting agreement with any law firm in connection with this lawsuit?

A. Yes.

Q. When did you do that?

A. It was executed a few weeks ago.

Q. And is that law firm the firm called Patterson, Belknap, Webb & Tyler, LLP?

A. Yes.

Q. What's your understanding of the terms of that consulting agreement in a broad sense?

A. Just that they are representing this -- the defendant side of the litigation, and I fall under that category. And according to the terms, I agreed to give testimony if subpoenaed, and they will serve as counsel for me.

Q. Do you have any understanding about your entitlement to receive compensation for any time you might spend working with their lawyers or doing other

activities related to the case apart from your testimony here today?

A. Yes, I do.

Q. Okay. And what's your understanding about that?

A. Just that I will be compensated for my time, you know, spent with them.

Q. What was your territory at first?

A. At first, and always, it was just San Antonio Medical Center area, and part of downtown, some small outlying cities.

Q. At all times while you were working for Janssen between the last quarter of 2002 and the last quarter of 2004, did your job entail promoting Risperdal?

A. Yes.

Q. During those same years, did your responsibilities include promoting any other drugs?

A. Yes.

Q. Which ones?

A. Concerta.

Q. And what was Concerta?

A. Concerta is a medication for attention deficit hyperactivity disorder.

Q. During the full time of your employment with Janssen, was your compensation based upon your

performance of your job promoting those two products?
A. Yes.
Q. Throughout the time you were employed by Janssen, did either of those products have more weight in determining your compensation than the other?
A. Risperdal was weighted more than Concerta.
Q. Did anyone else work that territory along with you or did you work it by yourself?
A. I had a mirror partner.
Q. What's a mirror partner?
A. Someone with the exact same responsibilities and the same doctors to call on, same territory.
Q. Let's start with your mirror partner. Who was that?
A. His name was John Gaston.
Q. How did you and John Gaston divvy up the work?
A. We were required to create a territory operating plan so that we were in different offices at different times, but adhering to lists of physicians that were given to us by the company to see.
Q. Did you and John Gaston have the same names on your target list?
A. Yes.
Q. Did you or to your knowledge John Gaston ever call upon any physicians who you weren't told to call

upon by the company?
A. No.
Q. In selling Risperdal to your customers, did you ever convey sales messages that you hadn't received from someone else in the company?
A. No.
Q. That is to say did you ever craft your own sales messages?
A. No.
Q. Did you ever write your own script?
A. No.
Q. During the two years that you worked with Janssen, did you periodically receive reviews of your performance?
A. Yes.
Q. And how would you receive them?
A. I believe on field rides with the district manager, there was always a review process with how your territory was performing. And I can't specifically remember J&J's, but I'm sure there must have been a yearly performance review. That's standard.
Q. You used the expression field rides. What were those?
A. Field rides?
Q. Yes.

A. It's when the district manager rides with you in your car and goes on calls with you and records how you're doing.

Q. And about how often did that happen?

A. I want to say, you know, at least once a quarter, maybe once a month.

Q. And then there would be some sort of a written review you would receive from your district manager; is that right?

A. That's correct, a report.

Q. What were those reports called, if you remember?

A. A field report.

Q. All right. Field conference reports perhaps?

A. Field conference report, uh-huh.

Q. Were you ever told you had done anything that was questionable in terms of the ethics of your performance of your job?

A. No.

Q. Were you ever disciplined or reprimanded while you were at Janssen?

A. No.

Q. Do you have Exhibit 1953?

A. I do.

Q. And is it entitled Janssen Pharmaceutica Field

Conference Report?

A. It does.

Q. And does it contain a start date and an end date?

A. Yes.

Q. 9/24/2002 -- 9/23 and 9/24 of 2003?

A. Yes.

Q. Okay. And it has your district manager's name; is that right?

A. Yes.

Q. Shane Scott?

A. Yes.

Q. Is this generally the form of a report that you would receive each time you had a field ride with your district manager?

A. It looks like it, yes.

Q. And you described in a very broad way before what would happen on a field ride, but can you describe for the jury in somewhat more detail what would happen during the two days that you would have a field ride with your district manager?

A. Well, generally, we would have a meeting, an initial meeting upon working together where the numbers would be discussed, and then a general, you know, plan of things that are working and not working in the

territory, you know, ways that improvement could be had and things of that nature, and then the district manager would ride in the vehicle with the representative and go on calls to the doctors and the various institutions.

Q. Okay. And so the district manager would accompany you as you called upon your customers?

A. Yes.

Q. Was it your practice after calling upon physicians to make some entries into some part of Siebel?

A. It was my practice to do that because it was implemented by the company, a requirement to do that.

Q. Okay. So you were required to make entries after making a call --

A. Yes.

Q. -- and you did it?

A. I did.

Q. And the next sentence in this same area of the field conference report says, "Post-call planning was consistently utilized to enter accurate call notes for follow-up on future calls." Did I read that right?

A. Yes.

Q. Now, are call notes the same thing as what you were referring to a minute ago when you said you would make entries into Siebel after each call?

A. It looks like it, yes.
Q. All right. Now, and this says that that's something that was consistently utilized by you, at least during these field rides; is that right?
A. Right.
Q. When you didn't have your district manager along with you, was it also your practice consistently to enter call notes after you had made calls?
A. I think it was probably generally consistent --
Q. Okay.
A. -- based on the direction of the company.
Q. Okay. Again, you were told to do it so you did it?
A. Right. You can see we were judged on it, so...
Q. All right. And this entry says your call notes were accurate. Was it your practice to try to make them accurate?
A. I believe so, to the best of my ability.
Q. Did you take seriously the responsibility to convey accurately to your partner, John Gaston, what had happened to the call so that he would know when he next called on that same physician what had occurred?
A. I was required to record notes on each and every call, as deemed appropriate by the company, to depict what occurred in the conversation with the

physician and myself --

Q. Okay.

A. -- whether it be from the physician, what they told me, or information that I left.

Q. Do you have Exhibit 1965?

A. I do.

Q. Let me read the first two sentences under "Development" and then I'll ask you a few questions.

"Development. You have done a nice job focusing on your developmental opportunities in the territory as well as interaction with the district through conference calls and cycle meetings. As the Seroquel coordinator, you have provided useful information to help the team with overall product knowledge/selling strategies. Also you have taken the initiative to provide the team with useful information about child and adolescent customers and focusing on increasing efforts in the fall to maximize on back to school with Risperdal and Concerta."

Did I read all that accurately?

A. You did.

Q. Do you recall any efforts on your part to take an initiative to provide the team with useful information about child and adolescent customers?

A. I do not.

Q. Do you recall any effort related to Risperdal and Concerta having to do with back to school?

A. I don't recall specifically any initiatives taken to do that.

Q. Ms. Moake, we're back after our break. Did you have an opportunity to visit with your attorneys during the break?

A. Yes.

Q. Do you have Exhibit 1966?

A. Yes.

Q. On the first page of 1966, is there an e-mail from you to some other individuals with the subject of conference call?

A. Yes, it looks that way.

Q. And does it appear that there also was an attachment to your e-mail that's referred to on the first page of Exhibit 1966 as Risperdal Back To School Bash, with a couple of periods, and then i-n-g dot PowerPoint?

A. Yes.

Q. Okay. And if you'll look at the second page of Exhibit 1966, do you see a -- what appears to be a PowerPoint title page with the title Risperdal Back To School Bash, and then three periods, ing, i-n-g?

A. I read that, yes.

Q. Okay. I believe when we were discussing the previous exhibit, I had asked you something about back to school, and you had testified you had no specific memory. Does this help refresh your memory?

A. It seems to coincide with that same statement that Shane Scott wrote.

Q. All right. And in Exhibit 1966, are we looking at an e-mail that you sent?

A. It looks like it was sent by me.

Q. And attaching a PowerPoint slide deck?

A. There is a PowerPoint slide deck attached, yes.

Q. The heading at the top of this PowerPoint slide says Conference Call Goals and Objectives. Did I read that right?

A. You did.

Q. Who are the individuals who are to whom this e-mail is addressed, that is, following the word "to" in your e-mail of August 17th, 2004?

A. All of those individuals are district members of the San Antonio district inclusive of our district manager, Shane Scott.

Q. Okay. The -- and then let me ask you to look at Page 7 of the PowerPoint deck which is entitled Back To School CSF's and Tactics. Are you with me?

A. Yes.

Q. Do you recall what CSF means in this context?
A. I don't.
Q. Okay.
A. Again, this slide deck was given to me and my name was put on it. I didn't create it.
Q. But you distributed it, true?
A. It appears that it came from my e-mail inbox, yes.
Q. Okay. And I understand you didn't write it, but you were given it and distributed it to others in your district; is that right?
A. It appears to be that way, yes.
Q. Okay. And in -- do you know who did prepare it?
A. I do not.
Q. Someone in Janssen I assume. Would you assume the same?
A. It has Janssen logos on it, so I would assume that the information came from within Janssen.
Q. Going back to Page 7 of the deck -- the slide deck, slide No. 7, where it says Back To School CSF's and Tactics.
A. Uh-huh.
Q. There are some bullet points. I won't go through all of them with you, but let me ask you about

some of them. The second bullet point -- actually, the first bullet point says effective partnering with McNeil. Do you have any idea what that's about?

A. I do.

Q. What's it about?

A. McNeil was a sister company of Janssen, and we partnered with them on our Concerta efforts.

Q. And Concerta did have indications for use in children -- FDA indications, correct?

A. Yes.

Q. Whereas at this time Risperdal did not?

A. Correct.

Q. All right. The second bullet point says, "Efficacy message - fast onset, mixed episodes, titration, sx" -- or symptoms -- "in children (behavioral problems, tantrums, aggression)." Do you see that?

A. I do.

Q. All right. Now, said words efficacy message, efficacy means what?

A. The ability of the medication to work at its fullest potential.

Q. All right. Do you recognize any of the features of efficacy listed here in this second bullet point as being ones that were contained in any sales

messages you ever used about Risperdal?

A. Some of those look familiar.

Q. All right. What about the mention of symptoms in children, "(behavioral problems, tantrums, aggressions)"; do you recall having seen that before?

A. I don't recall seeing that in any company-approved literature that I used for promotion.

Q. Going back to page -- or slide 7 of this particular PowerPoint slide deck that's included with your e-mail marked as Exhibit 1966, the last bullet point speaks of "Ice cream parties, snacks, lunches!!!"

A. I see that.

Q. All right. Now, we've talked about lunches before, and you sometimes used lunches --

A. Right.

Q. -- in the course of your work; is that right?

A. Yes.

Q. How about ice cream parties?

A. I've never hosted an ice cream party for an office.

Q. Ever been to one?

A. Not pharmaceutical related.

Q. Ever helped arrange one?

A. No.

Q. Ever invited anyone to one?

A. No.

Q. If I were to constitute the word social for the word party, ice cream social, is that a term you've ever heard?

A. An ice cream social?

Q. Yes.

A. I've heard the term.

Q. Did you ever employ ice cream socials to help sell Risperdal?

A. No.

Q. Did you ever invite customers to an ice cream social?

A. No.

Q. Did you ever put on an ice cream social?

A. No.

Q. Do you have Exhibit 1967?

A. I do.

Q. Now, the -- in this e-mail you say SA team, San Antonio team, "Hello all! First, I wanted to express my appreciation for the attentiveness and participation during Monday's conference call. We have a great opportunity moving forward for the next 60 days to remain #1 in CNS. In order to capitalize on our target audience, let's revisit some critical success factors in order to obtain our goal in child adolescent

psychiatry." And then there are four bullet points; is that right?

A. Yes.

Q. The first bullet point says "Efficacy message," correct?

A. Yes.

Q. The next bullet point says "Partnering with McNeil."

A. Yes.

Q. The third bullet point says "Call plan - extra calls on child psychs."

A. Yes.

Q. And the fourth bullet point says "Information - flood the clinics with Risperdal stuff."

Did I read all that correctly?

A. You did.

Q. You sent both e-mails, did you not?

A. I sent the e-mail with the PowerPoint presentation attached to it that I did not create. And this e-mail has an efficacy message written that looks to be the same in the PowerPoint presentation that I did not write.

Q. Okay. You sent both e-mails; is that true?

A. Yes.

Q. Okay. And back to the August 25th e-mail, the

second of these two e-mails, the one marked Exhibit 1967, and after the bullet points, the e-mail says, "The team who shows growth in the CHP market." Now, CHP is child and adolescent psychiatrists; is that not right?

A. Right. That is right.

Q. "The team who shows growth in the CHP market will receive 2 AwardsPerQs each." Did I read that correctly?

A. Yes.

Q. The next sentence says, "The contest will run from August 23rd to October 1st." Did I read that sentence correctly?

A. You did.

Q. What is 2 AwardPerQs? What does that mean?

A. I think it must have been a company-driven award system for -- in a contest.

Q. All right.

A. I don't know if it had any monetary value or -- I don't recall for sure.

Q. But it's a good thing, not a bad thing?

A. It looks like a good thing.

Q. And it's something the company can dispense.

A. Yes.

Q. Can award.

A. An award.

Q. And the contest involves, according to your e-mail in Exhibit 1967, and tell me if this is right or wrong, obtaining our goal in child and adolescent psychiatry. Is that true?

A. That's what the e-mail reads.

Q. All right.

A. Which I don't have any authority to delegate giving awards, so my interpretation to you is that this was given to me to present to someone as an assigned job or something.

Q. All right. You make a good point. The -- who does have the authority to give members of the C&A sales force sales awards within Janssen?

A. I'm not sure. The district manager, the regional business director, the field sales director. I'm not sure.

Q. But in any case, there was a contest going on?

A. It appears to be there was.

Q. And awards -- awards were be given -- were to be given to the winning team?

A. Yes.

Q. And the contest had to do with the child and adolescent market; is that right?

A. It looks like that, yes.

Q. Is it true that every time you called upon

child and adolescent psychiatrists on behalf of the company that employed you and spoke to them about Risperdal and its use in children and adolescents, you did so with your company's approval?

A. Every time I called on a physician, whether it be a child-and-adolescent-specific speciality or not, I delivered the company-approved message as per the FDA labeled indication for Risperdal and Concerta.

Q. Would you have ever engaged in a contest that had you calling upon child and adolescent psychiatrists to sell Risperdal without your company's approval?

A. No.

Q. Do you have Exhibit 1968?

A. I do.

Q. Is this a field conference report about calls that you made on the 1st and 2nd of September, 2004?

A. Yes.

Q. About a week after the more recent of these two e-mails; is that right?

A. Yes.

Q. At the bottom of the page, do you see where it says as Item No. 4, C&A/Seroquel coordinator? Do you see that?

A. Yes. And I don't know what C&A means.

Q. Well, haven't we established that C&A means

child and adolescent?

A. I guess so.

Q. Let me read what it says. It says, "Lead the district on conference calls on directive to grow Risperdal business in C&A offices. C&A blitz month of September, weekly voicemail/e-mails to district motivate their behavior." Did I read that correctly?

A. Yes.

Q. Do you see that -- the words "Lead the district on conference calls"?

A. I read those, yes.

Q. All right. Do you believe that that's likely the conference call discussing your two e-mails within the two weeks before this?

A. I don't believe so, no.

Q. You think it's a different conference call?

A. I don't believe it's an accurate representation of what's clearly on the PowerPoint presentation that you gave me to observe.

Q. Do you agree the PowerPoint had anything to do with Risperdal?

A. I do.

Q. Do you believe it had to do anything with growing Risperdal business?

A. I do.

Q. Do you believe it had anything to do with growing Risperdal business in child and adolescent offices?

A. I'm -- I'm -- I'm not sure. I don't know.

Q. Would you turn to the next page of Exhibit 1968. Does it -- does the next page bear your signature and a date?

A. It does.

Q. Would you have received a copy of this field conference report as you did the others?

A. It's very likely that I did.

Q. Okay. Let me ask you, if you would, please, look back at the page just before the one with your signature, the page discussing territory management. And if you'll look at about the middle of the page, do you see Texas Medicaid PDL?

A. Yes.

Q. There's a statement "Your territory has 71 percent of Medicaid patients, so focusing on your top Medicaid prescribers is resulting in generating increased Risperdal Oral sales."

Did I read that correctly?

A. You did.

Q. Was your territory one with a high percentage of Medicaid patients?

A. This is what Shane Scott has written, and I'm not sure if I would have known that information or not without that information being given to me.

Q. You may recall that in the PowerPoint deck that was disseminated by you by e-mail to the San Antonio team on August 17th of 2004, there was mention of ice cream parties.

A. I do recall.

Q. And I asked you about the ice cream.

A. Yep.

Q. All right. This Exhibit 1969 is, I'll represent to you, a group of your call notes, all dated in September and October of 2004. Do you recognize them as such?

A. I do.

Q. The first one on the first page of Exhibit 1969 concerns a call on Joel Schnitz, a registered pharmacist; is that right?

A. That's what it reads, yes.

Q. And they -- the next one down in the stack is for the same date, September 15th, 2004, and that's where I got Southwest Neuro Psych Institute, and then the one after that, same address, for Dr. Graham Rogeness. Am I pronouncing that right or not?

A. I'm not certain of the pronunciation of his

name.

Q. In the notes section is written "Ice cream social; big M-Tab push for extra orders." That's from the first call note involving --

A. The pharmacist?

Q. -- the pharmacist; is that right?

A. It looks like it.

Q. And the next note in this group all at the same address, same date, "Ice cream social; great response about mtab successes on inpatient." Did I read that correctly?

A. Yes.

Q. The next one going down the stack, this is Dr. Rogeness, "Ice cream social; mtab push in acute setting." Did I read that one right?

A. Yes.

Q. The next one reads, "Ice cream social; mtab push," for Dr. Michelsen. Did I read that right?

A. Yes.

Q. All right. Following those call notes, do you see a call date of September 16th -- of September 2004 for Dr. -- for actually an RN named Martha Espinoza with an address of 8026 Floyd Curl Drive?

A. Yes.

Q. And what's written is "Mtab push; ice cream

social 10/5," for October 5th. Did I read that correctly?

A. Yes.

Q. The next page, September 22, 2004, Dr. Margaret Farrell-Riedel. The note reads "Goodies to clinic, very appreciative ... set up ice cream social 10/29 ... core hirschfield study." Did I read that right?

A. Yes.

Q. Be it the 6th or the 8th of October, is the note "Ice cream social on 4th floor; good discussion to RN staff and docs for increased Risperdal use in hospital"?

A. Yes.

Q. The next with a call date of 6 October, it says, "Ice cream social at MST." Is that the same hospital?

A. I guess so.

Q. We've gone through a number of call notes in September and October of 2004 that would --

A. Yes.

Q. -- with entries under your name --

A. Yeah.

Q. -- with customers that you called on, all talking about ice cream socials and about promoting Risperdal, or specifically it being on these occasions

Risperdal M-Tabs. Are these your call notes?

A. They -- they look like they could be my call notes, yes.

Q. Do you have Exhibit 1970?

A. I do.

Q. Do these appear to be your call notes?

A. Yes, they have my name on them.

Q. The -- I believe these are arranged -- the effort was to arrange them in chronological order.

A. Okay.

Q. The earliest date is the 13th December 2002 and concerns a call on a Dr. Enrique Trevino; is that right?

A. I see that.

Q. The last page bears a date of October 6th, 2004; is that right?

A. Yes.

Q. And concerns a call on a Dr. Patrick Holden; is that right?

A. Yes.

Q. Your note on the call to Dr. Holden in October -- on October 6th of 2004 is "Big M-Tab push in kids and advantages " -- "and advantages special population."

Did I read that correctly?

A. You did.

Q. All right. The one immediately preceding that call note -- and now I'm on the next to the last page of Exhibit 1970 -- it's the page that has the numbers 397 in the bottom right-hand corner -- is Dr. Surya; is that correct?

A. Yes.

Q. All right. The note says, "Had an entire waiting room of foster kids; Rosemary said she sees at least 10 Risperdal prescriptions go out a day."

Did I read that correctly?

A. Yes.

Q. The call note before that one -- you'll have to go two pages back to see the beginning of it -- bears the numbers 136 on the bottom right-hand corner. Are you with me?

A. 136?

Q. Yes, ma'am.

A. Uh-huh.

Q. And this is a doctor named Robert Stevenson. Do you remember him?

A. In Hondo. Vaguely.

Q. All right. The note says, "Continued selling Risperdal for bipolar and mood in mono- and combo-therapy; agreed to using more after hard close; used mtab in a child and encouraged increased use here."

Did I read that part correctly?

A. Yes.

Q. The one before that was May 7th of 2004 for the doctor named Maria Chavez. The number in the right-hand corner ends in 075. Are you with me?

A. Yes.

Q. The note says, "One of the best calls with her!! Discussed the core M&M message vs Zyprexa/ Seroquel; really pushed Texas PDL vs Zyprexa because the office is having major problems with wait time and gathering info for the PA process ..... Use this to our advantage!! This office is all Medicaid!! She prescribed Ris while I was there," Risperdal while I was there, "maybe show the combo effect of Concerta/Risperdal and the JAACAP next call as lots of kids are on both stimulants and antipsychotics."

Did I read that correctly?

A. Yes.

Q. Do you know what the JAACAP refers to?

A. I don't recall.

Q. Okay. The -- do you know whether the CAP refers to child and adolescent psychiatry?

A. I can draw that conclusion.

Q. All right. Ms. Moake, the -- we've gone through the 2004 call notes. There are many others

going back to as early as the 13th of December 2002, shortly after you joined the company, but is it true that at least -- if these call notes are accurate -- that on each of the occasions in 2004 we've covered, there was discussion between you and the physicians to whom you were promoting Risperdal about the use of Risperdal in children?

A. I don't know.

Q. Would you agree with me that in each of these call notes, at least the words child or children or adolescents or kids appears in your description of your discussion with these customers of yours?

A. I see the appearance of those words in the notations.

Q. All right. The next one is dated the 29th of April 2003, and again is Dr. Enrique Trevino; is that correct?

A. Yes.

Q. The note begins "Continued with John's call and spoke of new areas to use Risperdal."

Did I read that part right?

A. Yes.

Q. And would John be John Gaston do you believe?

A. I believe.

Q. And you continue, after three dots you put

"Used JAACAP to show augmentation to stimulants with low dose -- low dose Risperdal for hostility/aggression. This seemed to spark some interest, so we might need to elaborate here since he sees so many kids."

Did I read that part correctly?

A. You did.

Q. The next, after the semicolon it says, "Also reminded of oral solution for hospital patients and kids ... agreed." Did I read that correctly?

A. Uh-huh. You did.

Q. The next one is dated May 13th, 2003 and concerns a visit with a nurse named Martha Espinoza. Do you recognize her name?

A. I don't.

Q. All right. But she's in the medical center; is that correct?

A. According to the address, yes.

Q. All right. And do you remember that her name was one of those that showed up in the -- in one of the ice cream social --

A. I do.

Q. -- call notes?

A. I remember.

Q. Okay. The note reads "Introduced M-Tab with demo and was well received ... she said to speak with

Dr. Feruzzi to start using immediately ... will be very helpful to the unit and for the kids."

Did I read that correctly?

A. You did.

Q. The next note is dated the 30th of May 2003 and concerns Dr. Claudio Cepeda, and -- are you with me on this page?

A. Yes.

Q. Okay. "Core M&A with m-tab intro .. really need to push utilization in his population of kids and on inpatient." Did I read that correctly?

A. Yes.

Q. The next page is on a call dated June 6th, 2003 to Dr. Jose Hernandez. The first part of the note seems to relate to Concerta; is that correctly -- before the semicolon?

A. Yes.

Q. After the semicolon the entry is "Discussed m-tab for ease of care with children and closed here over Seroquel." Did I read that correctly?

A. You did.

Q. Well, the next one is dated the same date, 1st of July 2003, and here the doctor is Dr. Steven Pliska; is that right?

A. Yes.

Q. And Dr. Pliska is a child and adolescent psychiatrist at the University of Texas Health Science Center; is that true?

A. I believe so.

Q. And the note reads CGC -- by the way, is that Child Guidance Center?

A. I don't remember CGC. It could be.

Q. At any rate, it says, "CGC breakfast/orientation ... full intro to new child fellows and quick plug on Risperdal." Did I read that right?

A. Yes.

Q. The next one is dated the 8th of July 2003 with Dr. Rolando Rodriguez again. And the note begins "Core both." Does that mean both drugs?

A. I don't know.

Q. Okay. But the doctor is "Back from vacation in SF ... pushed m-tab for kids." Did I read that right?

A. Yes.

Q. The next one is the 20th of August and the doctor's name is Ronald Brenz. The note on that day reads "Good core for M&A with receptor binding chart/KAPUR;" K-a-p-u-r semicolon, "need to be better in identifying Seroquel use; full m-tab and agreement to push on parents for new starts with their kids." Did I

read that correctly?

A. Yes.

Q. Next on the 14th of October 2003, Dr. Abel Hipolito, picking up about the middle of the first line after the dots, "Doctor will be seeing kids from St. PJ's on Friday, so might be an opportunity for more business." Did I read that correct?

A. Yes.

Q. Do you recognize all of the documents in Exhibit 1970 as being call notes of yours?

A. I recognize them looking at them today with my name on them and having the notation read to me.

Q. My question to you is, do you have any reason, as you sit here today, to doubt that you saw these doctors --

A. No, I do not.

Q. -- these customers and wrote these notes?

A. I don't.

Q. During the years you were with Janssen, did you ever engage in any promotional activity concerning Risperdal that you kept secret from your superiors?

A. No, I did not.

Q. Did you ever specifically engage in any promotion of Risperdal during the years you were with Janssen that you kept secret from your district manager?

A. No, I did not.

Q. Or from your regional business representative Rob Kraner?

A. No.

Q. Did -- during the years you were with Janssen, was every promotional activity you engaged in done with the permission and approval and knowledge of your superiors?

A. Every promotional activity that I was engaged with was done under the direction of the company that fell within the guidelines and the indication of Risperdal with the approved sales aids and messages.

Q. Let me show you an exhibit that's been marked previously in another deposition. It's marked as Dunham Exhibit -- and the exhibit number is 1884. It's -- the subject line reads "Voice mail message on safety data - Risperdal." And the date is shown as being -- at the top of the page it says September 29, 2003, and then below the guideline it says, "Voicemail message confirmation Friday September 26, 2003." Are you with me?

A. I read it, yes.

Q. Okay. And the first line of the body of the voicemail message confirmation at the bottom half of the first page of Exhibit 1884 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 management teams."

Did I read that part correctly?

A. Yes.

Q. Was there someone named Mike Walsman?

A. Mike Walsman, yes.

Q. All right. And do you remember what his position was at that time?

A. I believe that he oversaw the entire CNS sales force.

Q. Okay. It states, "As you think, the FDA recently sent us a request for a Risperdal label revision to address the issue of diabetes. This request was sent to ALL" -- and the words "all" -- the word "all" is in all caps -- "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. The data DOES NOT" -- and the words "does not" are in all caps -- "show an association between Risperdal and an increased risk of diabetes. However, the data DOES SUGGEST" -- and the words "does suggest" are in all caps "a greater

association with some of the other products. We are in the process of submitting this data to the FDA for their review and anticipate that they will respond asap. As always, patient safety is our first priority as we share FDA's interest in ensuring that physicians and patients have accurate safety information about our products. You should also be confident that you will be the first to know if and when the FDA makes any decision regarding this issue. 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 this class utilizing our diabetes reprint carrier combined with our new sales brochure."

Now, did I read all that correctly?

A. Yes.

Q. Do you have Exhibit 1975?

A. Yes, I do.

Q. All right. Do these appear to be call notes of yours?

A. Yes.

Q. I believe they're arranged chronologically, and the earliest date of these is October 17th, 2003, and the latest is October 30, 2003; is that correct?

A. Yes.

Q. All right. The next one is meeting with Dr. Zenaida whose last name we had trouble with before --

A. Oh, yes.

Q. -- is that right?

A. Uh-huh, yes.

Q. And do you say in this message that you "went through the weight of evidence and Gianfresco to distinguish diabetes difference"?

A. Yes.

Q. All right. The next one is a call at the Bexar County Jail. And is there mention of the diabetes reprint carrier in this call as well?

A. Yes.

Q. And did you discuss diabetes the next day on the 30th of October with Dr. Stevenson?

A. Yes, it reads that.

Q. All right. And on the same date, the 30th of October, with Dr. Cepeda, that you also mentioned the reprint carrier on diabetes?

A. It reads that, yes.

Q. All right. Now, in all of these -- all of these call notes in Exhibit 1975, by the way, do fall after the time of the late September voicemail from Mike Walsman; is that true?

A. Yes, it does.

Q. Okay. In that voicemail Mr. Walsman said, "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 of this class utilizing our diabetes reprint carrier combined with our new sales brochure."

Is that a direction you would have followed as you met with these customers in October 2003?

A. It seems to be consistent with what was directed by Mike.

Q. Let me ask you to look at another exhibit that's been marked previously. It's Exhibit 686. Do you have it in front of you?

A. Yes.

Q. It's dated November 10th, 2003. It's written over the signature of Dr. Ramy Mahmoud, MD, Vice President CNS Medical Affairs Janssen Pharmaceutica; is that right?

A. Yes, that's what it reads.

Q. And specifically, does it seem to relate, according to the first sentence, to a request by the FDA that "All manufacturers of atypical antipsychotics include a warning regarding hyperglycemia and diabetes

mellitus in product labeling"?

A. That's what it reads, yes.

Q. All right. Now, is that the same subject matter of the labeling change requested by the FDA that Mike Walsman discussed in the voicemail back in late September?

A. It appears to be the same discussion about diabetes.

Q. Do you have Exhibit 1976 in front of you?

A. I do.

Q. Does it contain call notes of yours?

A. Yes, they do.

Q. As you look through these -- I won't go through each of them, but as you look through these calls dated in November 2003 --

A. Yes.

Q. -- is there mention in each of them of the diabetes letter?

A. There is.

Q. All right. And is it your belief that that diabetes letter would be the Dear Healthcare Provider letter dated November 10th, 2003?

A. It does.

Q. Now, to your knowledge, based both on the letter itself, November 10, 2003, and the voicemail from

Mike back in late September 2003, was there any difference between manufacturers and products and what the warning label was supposed to say?

A. I don't know if there was any difference. This letter states that Risperdal has a lower incidence, and that looks like the letter that I was asked to deliver.

Q. Would it be fair to say that with respect to diabetes, that any message you delivered was a message that the company directed or at least approved for you to deliver?

A. Yes.

Q. And would that be true at all times throughout the time you were with Janssen?

A. Yes.

Q. We've looked at some different call notes today, a lot of call notes, and some have of them that we've gone through have indicated your awareness that the doctors or the facility you were visiting were Medicaid doctors or the facility contained a lot of Medicaid customers; is that correct?

A. Yes.

(Video stopped)

MR. JACKS: That concludes the plaintiffs' offer from Ms. Moake's deposition, Your Honor.

MR. McCONNICO: Your Honor, the defendants

will now make their offer.

(Video played as follows:)

CROSS-EXAMINATION

Q. You were a sales rep from 2002 through 2004; is that correct?

A. Yes.

Q. When you were a sales representative selling Risperdal, how did you determine what information you would share with your customers?

A. I only used the company-approved sales aids that were delivered to us and the labeling set forth in the PI.

Q. Did those sales aids change from time to time?

A. Yes, they did.

Q. How were new sales aids delivered to you?

A. Sometimes at meetings or different training sites.

Q. What products did you detail on your sales call while at Janssen?

A. Risperdal and Concerta, and at the end Risperdal CONSTA.

Q. And did you promote Concerta and Risperdal concurrently?

A. Yes.

Q. Do you ever recall deviating from your

company-approved sales aids during any calls in your position?

A. No.

Q. During a particular sales call, was it your practice to discuss both Risperdal and Concerta?

A. Yes.

Q. We've had some conversations today about off-label promotion. In your work as a sales representative promoting Risperdal, would you discuss or promote Risperdal beyond its label?

A. No.

Q. While you were a sales representative, do you ever recall representing to a doctor that Risperdal was FDA approved for a particular indication that it was not yet approved for?

A. No.

Q. Do you ever recall telling a doctor that Risperdal was approved for use in children or adolescents?

A. No.

(Video stopped)

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

THE COURT: May I see y'all briefly here?

(Discussion at the bench as follows:)

THE COURT: What's your next area?

MR. JACKS: We have next her manager Mr. Scott's deposition, Your Honor. The plaintiffs' portion is about 22 minutes and the defendants' is a minute or so.

THE COURT: Let me take a ten-minute break here.

MR. JACKS: Sure.

(End of bench discussion)

THE COURT: Let's take our ten-minute morning break. We're in recess.

(Recess taken)

(Jury not present)

THE COURT: Since we have a news blackout because we can't use our electronic devices, I gathered three stories that have a lesson for us all. First story, Paula Dean has been diagnosed with diabetes. She says it's not going to influence the way she cooks. You start with two sticks of butter. The second story is that Betty White has turned 90, and so this ought to be for you and Mr. Jacks, that somebody so nice can live so long. And then the third story is Romney says he actually pays close to 15 percent on his income tax because he gets it off of the capitalization thing. Somehow, I don't think that was helpful.

Well, let's bring them in and see what happens.

MR. JACKS: All right.

(Jury present)

THE COURT: Mr. Jacks.

MR. JACKS: Yes, Your Honor.

THE COURT: Your next witness, please.

MR. JACKS: Plaintiffs at this time call by deposition, Your Honor, as a witness associated with an adverse party, Mr. Shane Scott who appears on the organizational chart as district manager above where Ms. Moake's position is on the chart. Thank you.

(Video played as follows:)

SHANE SCOTT,

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

DIRECT EXAMINATION

Q. State your full name and business address for the record.

A. Shane Thomas Scott, 1000 Route 202 in Raritan, New Jersey.

Q. I'm going to ask you about then your move from Ortho-McNeil Pharmaceuticals. You then took a job at Janssen CNS franchise; is that correct?

A. Correct.

Q. Were you in San Antonio during the time you held that position?
A. I was.
Q. The dates that you worked there were November 2002 through September 2007; is that correct?
A. Correct.
Q. Did you undergo management -- centralized management training during that time period?
A. When you first start, yes.
Q. And can you tell me where -- where you underwent that training?
A. In New Jersey.
Q. And Titusville is the home office of Janssen; is that correct?
A. Correct.
Q. Was it Johnson & Johnson and Janssen management training?
A. Yes.
Q. All one thing?
A. Yes.
Q. During the -- and your title as district manager, can you tell me who was -- who did you directly report to as district manager, sir?
A. Rob Kraner.
Q. As far as the number of prescriptions that

were -- the volume of prescriptions that were written in your region, what was the number one drug that was sold while you were a district manager in the Janssen CNS franchise?

A. Risperdal.

Q. Okay. In November of 2002 when you took the position of district manager for the Janssen CNS franchise, what FDA indications were there for the drug?

A. Schizophrenia.

Q. Okay. And was that for adults or for children, sir?

A. Adults.

Q. Okay. There in describing your tenure from November '02 to September '07 as the district manager of the Janssen CNS franchise, you say, "The number one ranked territory in the region came from the San Antonio District 3 of 4 years (2004-2006) and also ranked #1 nationally two times."

Is the statement that you've -- that you wrote in this resume, which is Exhibit 2196, is that a correct statement?

A. That's correct.

Q. During your tenure as district manager for the San Antonio district, were you -- were any of your sales representatives ever reprimanded for off-label promotion

of Risperdal?

A. No, they were not.

MR. SWEETEN: Are we on 2203?

Q. This is another work session follow-up sent to you by Rob Kraner on September 3rd, 2004. Is that what this is?

A. Yes, you said that correctly.

Q. And did you attend that two-day meeting with Mr. Kraner?

A. Yeah, I must have.

Q. Okay. I want to ask you to turn to Page 2 and starting at the top, which is the business review. And he says, "Congratulations on the President's Trophy results through June. The San Antonio District has a June TPQ of" 153.08 "with a rank of" 1 out of 58, "- Great job!!" Second quarter '04 "PQ is" 196.74 "- Again, Great Job!"

You have turned this district around as district manager at this point; is that right?

A. We improved our rankings, yes.

Q. Okay. You improved it to the point where as of these -- as these numbers were given you were number one out of all the districts in the entire United States?

A. That's what it reads.

Q. Under the columns it says, "Risperdal. Xponent

share change is significantly higher than the nation. The San Antonio Team has done an excellent job of executing on the Texas Medicaid PDL opportunity and this is having a positive impact on" all "the overall Xponent market."

Did I read that correctly?

A. Yes, you read that correctly.

Q. And what Texas Medicaid PDL opportunity were you executing on during this time period?

A. Just that Risperdal was on the Texas Medicaid PDL.

Q. So you were communicating to customers, to physicians that Texas had a PDL and that Risperdal was on it?

A. Correct.

Q. The Medicaid market was obviously a focus?

A. Yes, absolutely.

Q. Approximately how many days a week was one of your sales representatives calling on customers?

A. How many days a week?

Q. Mm-hmm. On average.

A. They were -- unless they were not working, they were calling on customers every day.

Q. And did you -- you or anyone else within the company that you're aware of advise your sales

representatives to set a target of approximately how many specific individuals they should call on on any given day?

A. From what I can remember, I mean, you know, eight to ten doctors or customers a day. Forty to 50 customers a week is kind of -- they would focus on from a call plan standpoint.

Q. You listed child and adolescent psychiatrists among the different types of customers you called on in the retail marketplace; is that correct?

A. That's correct.

Q. Have you heard of M-Tab?

A. Yeah.

Q. All right. Can you tell the jury what M-Tab is?

A. Risperdal M-Tab is a dissolvable tablet.

Q. And is that a formulation of Risperdal that you and your sales representatives discussed with your customers?

A. Absolutely when we -- you know, once we launched it. I don't remember exactly when we launched it.

Q. Is there anything called M-Tab in relation to Concerta?

A. No, I don't believe so.

Q. Did you ever become aware of any of your sales representatives selling Risperdal to any of your customers specifically for use in the child and adolescent population prior to 2006?

A. No.

Q. All right. I want to talk a little bit about Tiffany Moake. How long did you supervise Tiffany Moake?

A. Probably two years.

Q. Do you recall the approximate time period?

A. When I started through the end of 2004-2005 time period.

Q. When you reviewed information provided to you that was created by Tiffany Moake, did you always find it to be accurate?

A. Yeah, I would say -- I would say yes.

Q. Do you recall anything specifically she did that was inconsistent with what you had instructed her to do?

A. Not that I can remember, but I can't remember specifically what was...

Q. But as far as you know, were there any times that you disciplined her for violation of company policy either verbally or through a written reprimand?

A. No, not that I can remember.

Q. Did you encourage Ms. Moake to promote Risperdal for use in the child and adolescent population?

A. No.

Q. Do you recognize Exhibit 1952 as a personnel review for Tiffany Moake?

A. Yes.

Q. Okay. Did you create this personnel review?

A. Yes, I would have been the one that --

Q. Okay.

A. -- created this, yes.

Q. The comments you wrote are "Overall performance for 2003 consistently meets and sometimes exceeds job standards." Did I read that correctly?

A. Yes, you read that correctly.

Q. Exhibit 1959 is an e-mail chain in the May 2003 time frame titled "Child & Adolescent Advisory Board Request," correct?

A. That is correct, yes.

Q. All right. And there's a May 8th, 2003 e-mail at the bottom of Exhibit 1959 from you to the sales representatives in your San Antonio region with a request concerning this ad board, right?

A. That appears to be correct, yes.

Q. You write: Hi SA -- "Hi Team SA, We have the

opportunity to send Child and Adolescent Psychiatrists to an Advisory Board" meeting "in LA this coming fall. Please send me 5 C & A Psychiatrists from each territory with the following criteria NLT Tuesday, May 13, 2003," and then you set forth some criteria.

Did I read all of that correctly?

A. You read that correctly.

Q. What were the criteria that you listed for this particular advisory board meeting?

A. High decile physicians.

Q. Does high decile have to do with how frequently they prescribe antipsychotics or Risperdal in particular?

A. It can mean various certain things, but it's, you know, how much antipsychotics they use.

Q. Okay. Specifically in this e-mail where you're making this request for recommendations for a -- child and adolescent psychiatrists to attend advisory board meeting, you state, the first bullet point, "HVP." What does HVP stand for?

A. High volume prescriber.

Q. All right. High volume prescriber "(70-90 Decile) Child and Adolescent Psychiatrists" slash General "Psychiatrists (70-90 Decile) with over 40% Child & Adolescent patient population. If the above is

met, you can submit 90 Decile Psychiatrists."

Did I read that correctly?

A. Yes, you did.

Q. And in response to your request, Ms. Moake sent you a list of some child and adolescent psychiatrists, correct? If you'll turn to Page 118, it starts on there and continues to the second and then on.

A. Yep.

Q. Specifically, you were requesting to send child and adolescent psychiatrists or general psychiatrists with over 40 percent child and adolescent patient population, correct?

A. That's what it says here, yes.

Q. I'm going to hand you what's been marked as Exhibit 1962, and specifically I'm going to focus on comments on Page 254. This exhibit is a field conference report of Tiffany Moake when you were her district manager that you prepared in the June 2004 time frame, correct?

A. Yeah, that's the date.

Q. And then the "Selling Effectiveness" section on the page ending 254, I'm looking under the comments. Are you with me?

A. Yep.

Q. In the next paragraph you write: "During the

work session closing for increased Risperdal business was observed although closing for specific patients would provide greater commitment. For example, with Dr. Samaniego the advantages of using" Risperdal "MTAB for adolescent patients vs Seroquel/Zyprexa was demonstrated with faster onset of" action "to control depressive/manic symptoms. This resulted in closing for increase use of Mtab in place of "Seroquel/Zyprexa "and he committed to use more. To take this call to the next level continue to close vs. the competition, but first identify a specific patient by painting a patient profile and close for that patient in place of the compensation."

And those are your words, correct?

A. It is included in this field conference report.

Q. That's what you wrote, right?

A. Yes.

Q. Okay.

A. From what I can remember.

Q. So were you encouraging Ms. Moake to close for specific patients for greater commitment?

A. Asking the physician to use Risperdal, yes.

Q. And you follow up with an example specifically with -- regarding what you witness with Dr. Samaniego and you said, "the advantages of using Ris MTAB for

adolescent patients vs. Seroquel/Zyprexa was demonstrated with faster onset of" action "to control depressive/manic symptoms," right?

A. Yeah, that's what it says.

Q. Well, what does that statement strike you as; a doctor statement or as something that you or Ms. Moake did with respect to the advantages of RIS M-Tab for adolescent patients?

A. I specifically can't decipher exactly if it was delivered by Tiffany or a discussion with the doctor.

Q. If you had witnessed her demonstrating the advantages of using M-Tab for adolescent patients specifically with this particular doctor at this time in 2004, that would concern you, correct?

A. That would be concerning, yes.

Q. And it would concern you because it would be illegal to do so, right?

A. It would be out of indication.

Q. All right. So do you understand that to mean it would be illegal to promote it because it would be out of indication?

A. Yeah. I mean, you cannot promote for that patient.

Q. Did you ever write Ms. Moake up after these sales calls, and specifically this sales call of

Dr. Samaniego, or discipline her in any way for this?

A. I don't have any recollection, no.

Q. Did Mr. Kraner ever come to you after you wrote up this field conference report and criticize you or Ms. Moake for allowing this specific sales call to occur in this fashion?

A. I don't remember that.

Q. And you follow it up after this example we've talked about with "This resulted in dosing for increase use of Mtab in place of" Seroquel/Zyprexa and he committed to use more.

Did I read that correctly?

A. You read that correctly, yeah.

Q. Okay. Do you assume that was a truthful statement when you wrote it?

A. Yes.

Q. Okay. Exhibit 2170 is an e-mail chain in the May 2004 time frame, correct?

A. End of May, yes.

Q. Okay. And at this time Risperdal did not have an FDA-approved indication for use in the child and adolescent population, right?

A. For patients, yes.

Q. And Mr. Meek appears to be sending an e-mail to Robert Kraner who's your supervisor, right, among other

individuals?

A. Correct.

Q. In May of 2004 and he says: "RBD Team, Here are some good tips regarding selling Risperdal vs. Abilify from the Advanced Selling Skills class. Abilify is gaining ground primarily with C&A psychs and we need to make sure Risperdal is growing with this customer segment. Let's make it happen!"

Did I read that correctly?

A. You did.

Q. And did you understand at this time in May of 2004 that your charge was to make sure Risperdal was growing with this particular customer segment?

A. It was part of our focus, yeah.

Q. I'm going to hand you what's been previously marked as Exhibit 1965. And I'm only going to ask you a quick question about on Page 2 of that under "Development." And this is a field conference report that you did of Tiffany Moake in the August 2004 time frame, correct?

A. Yes.

Q. Okay. Do you recall working with Ms. Moake at all on any kind of a back to school initiative as it relates to Risperdal and/or Concerta?

A. Specifically -- you know, I do remember having

some type of focus in that fall time frame.

Q. All right.

A. But I don't know specifically.

Q. Do you recall calling that focus a back to school initiative or back to school effort?

A. I believe so, yeah.

Q. Okay. And as you state here, this particular effort was to maximize on back to school with both Risperdal and Concerta, correct?

A. That's what it says, yeah.

Q. Does that sound at all familiar to you?

A. Generally, kids when they're in school would take, you know, their ADHD meds more.

Q. And is that why you-all decided to have the back to school effort to maximize with Risperdal and Concerta at that time in the fall?

A. I don't remember specifically why we did that. It would -- but it was just to increase our efforts and focus with those types of customers.

Q. And specifically, child and adolescent customers focusing on increasing efforts in the fall to maximize on back to school with Risperdal and Concerta, right?

A. Again, I don't remember all the specifics, but yes.

Q. That's what you wrote?
A. Correct.
Q. Do you recognize Exhibit 1966 as an e-mail you received from Tiffany Moake in August 2004 attaching a PowerPoint for the Risperdal back to school bashing effort?
A. Yes.
Q. Okay. Who created this presentation?
A. I don't remember who created this specifically, Tiffany or me together. I don't remember specifically who created this document.
Q. Do you recall reviewing it?
A. Yes, I remember this.
Q. What's the first item listed as a goal of this back to school bashing program?
A. To accelerate presence with child and adolescent customers that focuses on increasing Risperdal and M-Tab sales.
Q. And did this back to school bashing program occur?
A. Like I mentioned before, we had initiatives all year -- you know, throughout the year on different things. I don't remember specifically, but, I mean, the child/adolescent segment, the customers, we did focus growing our business with Risperdal and Concerta in

those segments.

Q. Okay. When you received this information from Ms. Moake, did you criticize her in any way or tell her that this back to school program was something that should not occur?

A. No, I don't believe I did. I don't remember specifically. But like I mentioned before, we had, you know, initiatives throughout the year to -- you know, to sell our products.

Q. I'm going to hand you what I've marked as Exhibit 1970. And I'll just represent to you this is a compilation of call notes of Tiffany Moake. And do you see the call note that's dated May 13, 2003? I'm going to read her notes on that. Are you with me?

A. I am.

Q. Okay. "Introduced M-TAB with demo and was well received. She said to speak with Dr. Ferruzzi to start using immediately. Will be very helpful to the unit and for the kids."

Did I read that correctly?

A. That's what it says, yeah.

Q. Turning to the very next page ending 685. This is a May 30th, 2003 call note of Ms. Moake in which she writes, "Core M&A with m-tab intro. Really need to push utilization in his population of kids and on inpatient.

Use Joel to help here."

Did I read that correctly?

A. That is what it says here, yeah.

Q. This is a June 6, 2003 call note of Ms. Moake. She writes: "Dr enjoyed Pliszka program and will consider his dosing of Concerta more carefully. Discussed M-Tab for ease of care with children and closed here over" Seroquel.

Did I read that correctly?

A. That's what it says here, yes.

Q. Okay. And again, there's not an M-Tab for Concerta. The M-Tab is only a Risperdal product, right?

A. That's right.

Q. Ms. Moake writes: "Discussed benefit of" Risperdal "in spec" -- I assume that means special population versus Seroquel/Zyprexa. "Got agreement on safety/efficacy in children and closed here."

Did I read that correctly?

A. That's what it says, yes.

Q. So your testimony to the jury, first of all, is that you're not concerned looking at these call notes globally, correct?

A. No, I am concerned looking at these call notes.

Q. So tell me why you're concerned.

A. Because there's references of -- of patient

populations that were different in this time period than what we were approved for.

Q. And I just want to look at overall performance, how you ranked Tiffany for this time period on the last page of Exhibit 2214. What ranking did you give Ms. Moake?

A. A seven.

Q. And you stated, "Overall performance for 2004 consistently exceeds job standards. Skill sets has consistently been developed, which has resulted in positively impacting territory and district business. You contributed to the district's overall performance with focusing on child and adolescent customers and elevated the overall proficiency in selling assertively against Seroquel. Thanks! You are a valued employee to this district and company."

Okay. Was that all truthful information at the time you wrote it in 2004 concerning what you thought about Ms. Moake's overall performance?

A. Yeah. From what I can remember, yes.

Q. Let me hand you what's previously been marked as Exhibit 1967. And following up to that conference call, she writes to you and the others on your team, "We have a great opportunity moving forward for the next 60 days to remain #1 in CNS. In order to capitalize on

our target audience, let's revisit some critical success factors in order to obtain our goal in child/adolescent psychiatry." And then she sets forth four bullet points to facilitate that goal. Did I read that correctly?

A. You did.

Q. And she lists "Efficacy message," "Partnering with McNeil," "Call plan - extra calls on child psychs," "Information - flood the clinics with Risperdal stuff."

Did I read that correctly?

A. Yes, you did.

Q. "The team who shows growth in the CHP market will receive 2 AwardPerQs each." Can you tell the jury what the CHP market is?

A. Child and adolescent psychiatry.

Q. And what does it mean to receive two AwardPerQs each?

A. AwardPerQs are just points that district managers had the ability to give out for recognizing people for various different things.

Q. Okay.

A. But they can use those points to go onto an online website to -- to purchase things.

Q. So the team who showed growth in the child and adolescent market would receive two AwardPerQs each. Am I reading that correctly?

A. Yes, you are.

Q. Okay. And this contest that she's referencing would run from August 23rd to October 1st. And at this time that we're talking about here in 2004 is the same time that back to school bashing program was occurring; is that correct?

A. Seems to be correct, yes.

Q. And then she writes "We have a strong presence with these physicians, so good luck and good selling," right?

A. That's what it says.

Q. Did you approve of Ms. Moake's efforts on this program?

A. Of?

Q. What she's writing about in this e-mail.

A. Yes.

(Video stopped)

MR. JACKS: Your Honor, that concludes plaintiffs' offer from the deposition of Mr. Shane Scott.

MR. McCONNICO: Your Honor, the defendants have a short offer.

(Video played as follows:)

CROSS-EXAMINATION

Q. Did you monitor the -- the call notes of your

sales representatives periodically?

A. Not really. Not really. Like I mentioned earlier, we got reports that would say if they were entering calls, if they were syncing up and things like that. So, you know, so many different -- district -- district members and so much things on, that wasn't something I would frequently do.

Q. Did you look at call notes in doing your reviews?

A. No.

Q. Did you ever witness Ms. Moake promoting Risperdal in a manner that was contrary to company policy?

A. No, I did not.

Q. Did you ever witness Ms. Moake promoting Risperdal in a manner that was contrary to the FDA-approved indication?

A. No, I did not.

Q. Did any doctor or nurse practitioner or anybody ever tell you that Ms. Moake had promoted Risperdal to him or her in a manner that was contrary to the FDA-approved indication?

A. No, I did not.

(Video stopped)

MR. McCONNICO: Your Honor, that concludes

the defendants' tender.

MR. JACKS: Your Honor, if we may move the screen out of the way, we'll call our next witness.

THE COURT: While they're doing that, if y'all want to stand and take a wiggle break, that would be good.

May I get you to raise your right hand for me, please?

(The witness was sworn)

THE COURT: Thank you. There's a front door there.

THE WITNESS: Oh.

THE COURT: And if everybody would be quiet while Della works with the microphone.

Mr. Jacks.

MR. JACKS: Thank you, Your Honor.

BRUCE PERRY, M.D.

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. JACKS:

Q. I should have said at this time plaintiffs are calling Dr. Bruce Perry, but you're Dr. Bruce Perry, right?

A. Yes, I am.

Q. All right. Dr. Perry, where do you live?

A. I live in Houston, Texas.
Q. You're a medical doctor?
A. That's correct.
Q. What's your area or areas of medical specialty, please?
A. I'm a child and adolescent psychiatrist.
Q. What -- where do you work at the present time?
A. I'm a -- an adjunct professor of psychiatry at Northwestern University in Chicago, and I am the senior fellow of the ChildTrauma Academy, which is a not-for-profit organization based in Houston.
Q. All right. I'm going to ask you some questions about the ChildTrauma Academy a bit later on, but first let me ask you, if you would, please, tell the jury what your educational background is that led up to your getting your medical degree.
A. Sure. Grew up in Bismarck, North Dakota, went to Bismarck High School, went to college at Stanford University and then Amherst College, went to medical school at Northwestern and also got my Ph.D. in neuropharmacology at Northwestern.
Q. All right. Let's pause there.
A. Okay.
Q. Neuropharmacology, what's that?
A. It's basically the study of how drugs work in

the brain.

Q. And you got your Ph.D. at that time at about the time you were getting your medical degree as well?

A. That's correct.

Q. After medical school, did you pursue your speciality training?

A. I did. I went to Yale to do a medical internship, and then after that I did my residency in general psychiatry, and after that I did a child and adolescent psychiatry fellowship at the University of Chicago.

Q. And you finished your child and adolescent postdoctoral training when?

A. I think it was like 1988, something like that. I don't know.

Q. All right.

A. It was back then. I think it was 1988, I think.

Q. Plaintiffs' Exhibit 2284 sets forth your background, your qualifications and your publications and some other stuff; is that right?

A. Yes, sir.

Q. All right.

MR. JACKS: And I believe this is admitted. If it's not, Your Honor, we offer Plaintiffs'

Exhibit 2284.

(Conference between Mr. Jacks and Mr. McConnico)

MR. McCONNICO: No objection.

THE COURT: Admitted.

(Plaintiffs' Exhibit 2284 admitted)

Q. (BY MR. JACKS) At any rate, Dr. Perry, upon completion of your speciality training in child and adolescent psychiatry, what did you do next?

A. I joined the faculty at -- well, I stayed on the faculty of pharmacology and then joined the faculty of psychiatry at the University of Chicago. And after two years there, I came down to Baylor College of Medicine to become the associate chairman for research at the -- in the Department of Psychiatry at Baylor College of Medicine and chief of psychiatry at Texas Children's Hospital.

Q. All right. And what is Texas Children's Hospital?

A. It's a big pediatric hospital. In fact, I think it's probably the biggest pediatric hospital in the country.

Q. And what sorts of programs and what kinds of patients did you work with at Texas Children's Hospital?

A. While I was there, I started two big clinics.

One clinic was a pediatric psychopharmacology clinic, which is basically trying to help figure out what medications you should give kids that have serious mental health problems. And we also started a child trauma clinic, which is for kids who have been impacted by trauma, neglect, abuse, other kinds of maltreatment.

Q. When -- in the years, both at the University of Chicago and then during the years you spent at Baylor College of Medicine and Texas Children's Hospital, were you actively seeing patients throughout that time?

A. Yes, sir.

Q. I've asked you to give me an estimate of how many psychiatric patients you've treated over those years from completing your speciality training up until the time you eventually left Baylor College of Medicine to pursue your present work. What's your best estimate?

A. At least several thousand.

Q. All right. And what portion of those were kids, children and adolescents?

A. 90 percent.

Q. In -- in some of those cases, did you prescribe antipsychotic medications?

A. Yes, I did.

Q. We've heard about first generation and second generation. During what years -- I think we've

established you finished your speciality training in the late '80s. And then in what -- how many years were -- when did you leave Baylor?

A. It was 2001, about ten years ago.

Q. Okay. During those, call it 13, 14 years, did you have experience prescribing both first generation and second generation antipsychotics?

A. Yes, sir.

Q. And did you do that?

A. Yes, I did.

Q. And did you have experience with most of the drugs on the market, at least in both categories?

A. You mean first and second generation?

Q. I do.

A. I either inherited patients that were on any number of first generation or second generation medications and in many cases I was the one to start a new client on antipsychotic medication, both first and second generation.

Q. The jury has heard about the drug Haldol or haloperidol. Is that one of the drugs you've used in your practice?

A. Yes, sir.

Q. They've also heard about the drug perphenazine. Did you use that drug in your practice?

A. I did, perphenazine and a related medication that -- Stelazine, which is similar to that. People that train at Yale, that's one of the more commonly used antipsychotics when I was training. So that's where I learned to use that and continued to use that in child and adolescent populations when I moved to Chicago.

Q. Did you also become familiar with and prescribe from time to time second generation antipsychotics?

A. I did.

Q. Including Risperdal?

A. Yes, mostly Risperdal.

Q. All right. In -- and let's just clear the air on this. Are you here to tell this jury that Risperdal is a bad drug?

A. No. I mean, I don't really think about drugs as bad or good. I think about a drug as being effective and appropriate.

Q. Are you here to tell the jury that the FDA never should have approved Risperdal?

A. No.

Q. Or that Risperdal should be taken off the markets?

A. No.

Q. Now, you've said that you worked and practiced at Texas Children's and Baylor College of Medicine up

into 2001. What has been your primary work since then?

A. Primarily since then, I've been working with a group of colleagues to try and understand and help children who have been impacted by abuse and neglect, kids that are in foster care, the juvenile justice system. Many of them are in the public mental health system, mostly kids that have had really, really tough starts.

Q. Does that work include consulting with physicians who are treating those kids and trying to help those kids?

A. Yes.

Q. And would you describe the nature of your medical practice in connection with consulting with those physicians?

A. We get probably 10, 15 requests a month to do a consultation for a colleague, a physician who is any -- anywhere in the world. We actually have done consultations in Australia, South Africa, United Kingdom, Scotland, but most of it is from Canada and the United States. And what I'll do is talk with the physician, look through the medical records, talk to -- try to convene a meeting with the parents and the teachers and the other people that know the child and on occasion meet with the child and then work with them to

see if we can improve the treatment plan.

Q. Do you see some of these patients, the kids, yourself?

A. Yes, I do.

Q. And -- in the year since you left your practice at Texas Children's and at Baylor, how much prescription writing do you do yourself nowadays?

A. I have a handful of patients that I've been treating for a long period of time that I still continue to write prescriptions for, but the majority of new patients I meet and do clinical work with are brought to us by another physician. So we rec -- we frequently make recommendations about medication changes or additions and so forth, but the actual prescribing is done by the patient's physician.

Q. Have you been called to help when there have been events that inflict trauma on large groups of children?

A. We unfortunately -- and I guess it -- our group, and me in particular, over the years have developed an expertise and experience with large scale trauma, so frequently I get called to try and help either individuals who have been impacted by that or systems that are trying to respond to that. For example, the Branch Davidian siege, I led the clinical

team that worked with all those children. I was part of a small mental health group that was convened by the surgeon general following 9/11 to create a mental health plan for the kids that were impacted by 9/11. I was involved in the response to Columbine and the Oklahoma City bombings and Katrina and the earthquakes in Haiti and so forth.

Q. You mentioned you're on the faculty at Northwestern University School of Medicine; is that right?

A. That's correct.

Q. And the Department of Psychiatry?

A. Yes, sir.

Q. And generally, do you teach?

A. I do. I teach -- we use a lot of distance teaching. Once a month -- or I'm sorry -- once a week we have a 90-minute case conference that involves the residents and the child psychiatry fellows at Northwestern. And I go -- I travel up to Chicago probably quarterly to meet with my colleagues up there, some of whom are research and clinical research partners.

Q. All right. Has the State of Texas asked you to consult on this case?

A. Yes, sir.

Q. And in connection with your consultation on this case, have you been provided information, evidence, materials to review?

A. Yes, I have.

Q. All right. A little or a lot?

A. An ungodly amount.

Q. I'm not going to ask you to detail that, but can you tell us generally the kinds of information that you've reviewed in connection with your work on this case?

A. I've reviewed business plans by J&J over -- for multiple years, marketing plans, training packets, dozens upon dozens of research articles, preliminary research reports. I've reviewed depositions from many of the people who are internal and external to J&J who have been involved in this. And I'm sure there's a lot of stuff I'm leaving out, but I've reviewed a lot of stuff.

Q. And have you billed for the time you've spent?

A. I have.

Q. At what rate?

A. $250 an hour.

Q. Now, Dr. Perry, I want to first -- we speak of child and adolescent psychiatry, and can you tell us where the breakdowns are between children and

adolescents in your field?

A. Well, a lot of people -- you know, there's -- people talk about different cutting -- you know, cutoff points. There's a whole area called infant mental health that works with kids that are younger than three. Typically children are up to about 12, then after 12 you start to think about preadolescent, then adolescent. So we -- I don't actually use that distinction as much in the way I think about these kids.

Q. Next question: Is -- we're here to talk about people, and in this case children, with mental illness of one kind or another or emotional illness. Is treating kids with those kinds of conditions the same as or different from treating adults?

A. It's -- it's more challenging and it is different in large part because the organ that you're dealing with with adults and with kids is the brain, but the brain of a young child is very, very different than the brain of an adult, and the rate of change in the developing brain is very, very rapid as you grow up. And this is a particular challenge with medications or drugs. Many of the systems, these neuro networks that are involved in how the brain develops, are the very same systems where these drugs work. So one of the problems that you have with child and adolescent

psychopharmacology is the unknown effects of influencing development from taking these drugs. So it's -- it's an area where you really want to be confident that you understand the benefits versus the potential adverse effects of prescribing a medication.

Q. And as someone who has special expertise both in treating children and in psychopharmacology or mental health drugs, are you familiar with the side effects of, in particular, the antipsychotic drugs, both the older and the newer?

A. Yes.

Q. Are children in any way less susceptible, more susceptible, as susceptible as compared with adults to the side effects of these drugs?

A. Well, to the degree that it's been studied, evidence suggests that children are more vulnerable to the adverse effects of psychotropic or antipsychotic medications.

MR. JACKS: Let me ask that Plaintiffs' Exhibit 2297 be displayed.

Q. (BY MR. JACKS) And let me ask if among the materials and the literature with which you're familiar is the article being displayed by a Dr. Christoph Correll entitled "Antipsychotic Use in Children and Adolescents: Minimizing Adverse Effects to Maximize

Outcomes"?

A. I'm familiar with that, yes.

Q. All right. And for the subject it treats in this article, do you regard this as being reasonably good authority?

A. Yes.

Q. And I'm not going to go through this in great detail.

MR. JACKS: But let me ask that the summary statement on I believe it's Page 9 be displayed, Mr. Barnes.

Q. (BY MR. JACKS) The summary, at the end of this article states that "Although more data are needed, children and adolescents seem generally more susceptible to develop sedation, acute EPSs, withdrawal dyskinesia, hyperprolactinemia and age-inappropriate weight gain with related metabolic abnormalities."

Now, one, is this statement supported by the article itself in your opinion?

A. Yes, I think it is.

Q. All right. And do you agree with this or disagree with it?

A. It sounds very similar to what I said earlier. I agree with it, yes.

Q. Now, I think we know what sedation is, but as a

doctor, what is meant you talk about a drug sedating a patient?

A. Well, basically it means that it makes somebody more drowsy and groggy, somnial.

Q. We've heard about EPS. I won't go into that anymore. What's withdrawal dyskinesia?

A. That's essentially similar to the extrapyramidal symptoms that you'll get these motor symptoms that occur when you withdraw the medication.

Q. Hyperprolactinemia, I think we've heard about prolactin and its effects. And we know about weight gain. What are related metabolic abnormal -- related --

A. Metabolic.

Q. -- metabolic abnormalities to weight gain?

A. Well, there appear to be some changes in certain lipids and other fatty acids that occur when there's weight gain with antipsychotic medication.

Q. Dr. Perry, the jury has already heard information about when Risperdal first received any approval from the FDA for use in children for any condition. And I don't want to replow all that ground, but I do want to talk with you about the indications for which Risperdal has been approved. When did they get their first FDA approval?

A. First FDA approval was in 2006, and that was

for the irritability of autism.

Q. Irritability in children with autism?

A. Correct.

Q. And then have they -- did they later get any other indications that received FDA approval?

A. A year later there was an indication for the manic phase of bipolar disorder and for the psychotic symptoms of schizophrenia.

Q. All right. Manic phase of bipolar, what's that?

A. Well, folks may be familiar that bipolar sort of has a cyclical, if you will, phasic structure. There's periods where you can get very high and sort of lose touch with reality, and then there are phases when you can get very, very depressed. So Risperdal has been shown to be effective during that period of time when you're in this extreme manic phase where you are also very frequently psychotic.

Q. Okay. And then the last is symptoms associated with schizophrenia.

A. Correct, the psychotic symptoms that are associated with schizophrenia.

Q. Now, looking at kids as a whole, how common or not are these particular conditions?

A. Well, autism is not very common. It's --

you know, different people have different estimates, between .5 and 1 percent of the population. Bipolar disorders may be a little bit more common. There's a lot controversy about that diagnosis. But it's -- again, earlier conservative estimates of it are, again, around about 1 percent of the population. And schizophrenia is probably even less than 1 percent of the population. All these are relatively rare neuropsychiatric conditions.

Q. Now, we've heard in this courtroom about off-label promotion by pharmaceutical companies and discussions of the illegality versus legality of that. I don't want to go into that with you, but I do want to ask you: First of all, I think we've established, it's not illegal for a physician to write a prescription that's off label; is that true?

A. That's correct.

Q. And is that a common thing in pediatric practice and in the practice of child and adolescent psychiatry?

A. Yeah, it is quite common.

Q. Okay. And the reason it's common?

A. The reason it's common is that there really has not been very many medications that have FDA approval.

Q. Now, there's also been testimony, even this

morning, about the ways in which these companies promoted Risperdal to child and adolescent psychiatrists for use in children. I'm not going to go into that testimony with you, but I do want to ask you whether, in the course of your research, you've come across any studies that look at whether that kind of promotion works.

A. Yes. Advertising works and promotion works, not only with the general population, but also with physicians.

MR. McCONNICO: Objection. Excuse me. Can we approach?

(Discussion off the record between the Court and counsel)

THE COURT: I feel like a fitness instructor. I want y'all to go in there and vigorously march around the jury table for two minutes. Go.

MR. McCONNICO: Your Honor, the defendants object to any testimony by Dr. Perry going into any type of marketing or sales representations made by Johnson & Johnson and their effect on anyone in the medical community because this witness has not been designated as an expert in those fields. Allowing such testimony would violate the ruling in the *Gammill v. Jack Williams Chevrolet* case, 973 SW 2d 713 Tex 1998. Trial courts

must ensure that those who purport to be experts truly have expertise concerning the actual subject about which they are offering an opinion. He has not been qualified, has not been designated as an expert --

THE COURT: You've got 15 left.

MR. McCONNICO: -- in that area. He is also in violation of *K-Mart vs. Honeycutt* Texas 2000 in that he is trying to interpret documents for which he has absolutely no expertise. Anything that goes to this journal which they're offering is Plaintiffs' Exhibit 2002 is testimony about hearsay within hearsay, and it violates the hearsay rules of the Texas Rules of Evidence.

THE COURT: My understanding is that he's not testifying about the marketing efforts of Johnson & Johnson and that this is an article upon which he has reasonably relied.

MR. JACKS: Correct, Your Honor.

THE COURT: Okay. Bring the jury back in.

MR. McCONNICO: Can I have a ruling, Your Honor?

THE COURT: No, it's -- oh, that was a -- let's see. How did Judge Haller in *My Cousin Vinny* do it? That was a lucid, well-thought-out objection, Mr. McConnico. It's overruled.

(Jury present)

THE COURT: Everybody be seated. Mr. Jacks.

MR. JACKS: Thank you, Your Honor.

Q. (BY MR. JACKS) Dr. Perry, I believe we were looking at Plaintiffs' Exhibit 2002. And is this an article that was published in one of the journals in your field, the field of psychiatry?

A. Yes, sir.

Q. And specifically, the journal of *Psychiatric Services*?

A. That's correct.

Q. And written by, among others, researchers from the Department of Psychiatry at Columbia University?

A. That's correct.

Q. And I'm not going to go into this in detail, but I do want to ask you, what were these researchers investigating?

A. They were looking at the -- what appeared to be related to a prescribing physician's opinions about whether or not a second generation medication would be effective, and it was essentially looking at what influences prescribing practices.

Q. And what did they conclude about what influences prescribing practices based upon the study

they did?

A. They found that prescribing physicians would be more optimistic about the efficacy of a drug if they had been visited on a frequent basis by a representative presenting them information about that drug and if they were familiar with treatment practice guidelines.

Q. Treatment practice guidelines sometimes called algorithms?

A. That's correct.

Q. And in connection with your work on this case, did you also investigate issues of conflicts of interest created by the activities of pharmaceutical companies and specifically of these companies in this case?

A. Yes.

Q. Is one of the sources you relied upon a publication about conflicts of interest?

A. Yes, sir.

Q. And it was published by whom?

A. It was published by the National Academy of Science and specifically The Institute of Medicine within the National Academy of Science.

Q. In the course of that report from The Institute of Medicine of the National Academy of Science, did they address the issue of pharmaceutical sales representatives, contacts from pharmaceutical companies,

contacts with physicians and with the medical community?

A. Yes.

MR. JACKS: Let me ask that Plaintiffs' Exhibit 1884 be brought up, please.

Q. (BY MR. JACKS) Is this the publication you're referring to?

A. Yes, sir.

Q. All right. And let me ask next that we reference -- I believe it's Page 194 of this exhibit. And actually, in the course of your -- you prepared a report as a result of the initial work you did in this case; is that true, Dr. Perry?

A. Yes, sir.

Q. I'm not going to burden the jury with reading all of it. It's over 100 pages; is that correct?

A. That's correct.

Q. Did you, in the course of your report, in fact rely upon a number of the findings of the National Academy of Science in this report on conflicts of interest?

A. Yes, sir. They addressed detail visits, conflict of interest around research studies, ghost writing, seeding the literature with -- seeding the academic literature with nonacademic publications. They addressed a whole range of potential conflicts of

interest in this area.

Q. And among them, the -- what was the most common contact with pharmaceutical companies in the workplace?

A. Typically with a representative, a detail man or woman visiting the physician.

Q. Bearing food?

MR. McCONNICO: Objection. This is leading. He can certainly testify, but he doesn't need to be led by Mr. Jacks, Your Honor.

Q. (BY MR. JACKS) All right. Did they make findings of that in that regard?

A. Yes, sir, providing lunches and so forth.

Q. And you mentioned seeding the literature. Is that a term with which you've become familiar during your work on this case?

A. Yeah. I was familiar with the concept prior to this, but certainly learned a lot more about it in the course of reviewing the documents for this case.

Q. Did you find and did you review any of the internal documents from Janssen relating to what they call publication planning?

A. Yes, sir.

MR. JACKS: Let me ask that Exhibit 2286 be brought up, please.

Q. (BY MR. JACKS) Now, the title of this document

that's Plaintiffs' Exhibit 2286 is "Risperidone Publications 2003," and it says "Project/Writer Planning Report" with a date of July 2003; is that correct?

A. That's correct.

Q. Now, we're showing just one page from this document. Did -- in reviewing this document and others like it, did you find that -- what did you find? What did you learn?

A. Well, I found that the publication plans for each year tended to be very, very, very thick. They included plans for creating abstracts and materials to be presented at academic meetings, the preparation of documents that were reviews of the use of medications and other treatments in target populations. They had a variety of methods in which they would track their progress. One was using this kind of spreadsheet model where they had essentially columns that identified, you know, what -- who were the target audience, what was the target message, what was sort of the putative key or target journal, and then who was assigned to do the writing by the -- the contracted medical writing company, which -- and then frequently who would be the academic face or the academic author that would be used in the presentation of the article.

Q. Let me ask that -- did you find any publication

planning relating specifically to your area, child and adolescent psychiatry?

A. Yes, sir.

MR. JACKS: May we bring up first Page 9 of the exhibit, please. Actually, I want to see Page 9 first.

Q. (BY MR. JACKS) Does Page 9 contain a heading for child and adolescent psychiatry?

A. Yes, it does.

Q. And in the left-hand column it shows the audience, then the major topics, the objectives, the message?

A. Yes.

Q. Suggested journals, suggested authors?

A. Correct.

Q. When work was begun and so forth. Now, is this -- based on your review of the materials in this case, where did these kinds of spreadsheets originate? Is it in the science department?

A. Well, I actually think that these were the work product of the contracted medical writing people that -- that -- that they used to write many of the articles.

Q. So they would hire some company to write the articles?

A. Correct.

Q. Now if we can go to Page 11, please. In this top row here, we have a publication "Review of Treatment Options for Pediatric Psychiatric Disorders." Is -- in the topics column; is that correct?

A. Correct.

Q. And then in the suggested journal column they've got a journal picked out; is that right?

A. That's correct.

Q. Now, who do they have listed for the author?

A. To be determined, TBD. They had the -- apparently they wrote it and they passed it around internally within the company prior to identifying an academic author.

Q. All right. And is the writer identified?

A. Yes.

Q. Now, I want to talk with you -- this -- by the way, we saw the date was July 2003. At about the same time, based on your review of the case, in 2003 was there any interaction going on between the FDA on the one hand and these companies on the other hand relating to Risperdal?

A. That was the time period when the FDA was trying to get pharmaceutical companies that used atypical antipsychotics to include increased level of warning about the potential for diabetes in their label.

Q. All right. So at the same time they're planning these publications about child and adolescent psychiatry, the FDA is expressing these concerns about diabetes?

A. That's correct.

Q. Let me ask you, during this same time in 2003, was Janssen doing its own reviews of what the state of the science and the literature was for the use of products like Risperdal in children and adolescents?

A. Yes, they were.

MR. JACKS: Let me ask that we bring up, please, Plaintiffs' Exhibit 952.

Q. (BY MR. JACKS) What's Exhibit 952?

A. This is a review, and I believe it's prepared by their research department. And it's a review of the literature about the use and safety of Risperdal that is in published literature all the way up to July of 2003.

MR. JACKS: And if we may look at Page 21, please, Mr. Barnes, of this exhibit.

Q. (BY MR. JACKS) In their summary, do they describe the types of articles that comprise the body of literature as of July 2003 concerning the use of Risperdal in children and adolescents?

A. Yes, they did. And --

Q. Now, they say there are 163 articles. What was

the largest group of articles?

A. They actually -- in their search they got 626 or something articles that talked about or reported on the use of Risperdal in the child and adolescent population, but only 163 of them mentioned or had any data. The other articles were case reports, case series, reviews, republication of previously published data. And so when they actually sort of filtered through all of this preliminary reporting and looked at how many independent actually well-controlled studies there were in the literature, it boiled down to two reference controlled studies and three double blind placebo controlled studies.

Q. All the rest were case reports or open studies, chart reviews, that sort of thing?

A. That's correct.

Q. Now, I want to talk about good science and not good science. In terms of good science, case reports, strong support or not?

A. Well, can I -- can I qualify -- I mean, not that I -- it's -- case reports have a value, but your ability to take any data or information from them and conclude and generalize is very, very limited. So there's a sequence by which you can actually give weight to evidence. And the sequence is a case report and then

a case series and then an open label trial, and the more children and the more conditions and the longer you treat, the more you know. And one of the key issues actually is that, you know, the people that are doing this research are decent good people, but there is a very -- there's an unconscious bias when you do research, and there's an unconscious bias when you write prescriptions. It just is part of the reality of the way human beings are influenced. And so what -- in order to really see whether or not the effects are going to be truly reliable, in other words, scientifically valid, they do what's called blind. The study is blind. The investigator doesn't know who's getting placebo and who's getting the drug. And the more sites that you involve in this, multi-site studies that are not funded by a pharmaceutical company actually end up having more -- less bias. The inclusion of comparators so you can compare this new treatment with other available treatments, the more you add in controlling elements to your research, the more you can say with confidence this is the efficacy, this is the -- these are the side effects.

Q. So in their review, they started out with 600-odd articles but narrowed that down to 163 of which 111 of them were case reports and 30 were open. Is that

the opposite of blinding?

A. Well, that's when the investigator knows who's getting the drug.

Q. All right. Sixteen were chart reviews where they were looking at records of times past?

A. That's correct.

Q. And then three were double blind placebo controlled studies; is that correct?

A. Correct.

Q. Now, during this same period of time, 2003, 2004, did you review documents showing what Janssen's assessment of the strength or not of their science was with respect to using Risperdal in kids?

A. Yes.

MR. JACKS: Let me ask you to bring up Plaintiffs' Exhibit 1006, please.

Q. (BY MR. JACKS) All right. And this is an e-mail from a person named Gahan Pandina in Janssen; is that correct?

A. That's correct.

Q. And what he -- his subject is "first draft pediatric positioning paper for review." Is this one of these papers that was being produced by their publication planning operation?

A. Yes, sir.

Q. And does he describe the state of the science from his perspective in May 2004, a year later than the review Janssen had done --

A. That's correct.

Q. -- in 2003? And in what conditions does he claim that Janssen has any scientifically-proven efficacy at that time?

A. It's DBD, which is the studies on disruptive behavioral disorder in individuals who have low IQ, and the PDD/Autism studies.

Q. And just pilot data in some other areas?

A. Correct.

Q. And we know that Janssen eventually applied for and received an approval for use in autism --

A. Correct.

Q. -- for the irritability symptoms in autism. Did you review any of their records, internal records, showing the business reasons for their pursuing that indication from the FDA?

A. Yes.

MR. JACKS: And let me bring up, please, Plaintiffs' 883.

MR. McCONNICO: Your Honor, may we have a running bill of objection to his testifying as to business reasons?

THE COURT: I'm giving this some thought. Let me speak cryptically to the record, if I may. Except for a brief exception regarding autism, we have restricted this witness' testimony to the research that he has reasonably relied upon in his practice and in his expertise, and that does not include editorially commenting upon Johnson & Johnson's marketing practice during this decade.

MR. JACKS: Thank you, Your Honor.

Q. (BY MR. JACKS) Did you review a document called "Autism Indication Rationale" with a date of May 29, 2003?

A. Yes, sir.

Q. I want to first turn to Page 15 of this document, Dr. Perry. And this is a part of the Autism Indication Business Rationale portion of this presentation; is that correct?

A. That's correct.

Q. And you see four items listed on that page; is that right?

A. Yes, sir.

MR. JACKS: Let me ask that we bring up Page 31 from this same document, please.

Q. (BY MR. JACKS) The -- is the heading here the same as the fourth heading in the previous slide,

"Limiting Exposure to Negative Media & Resulting Barriers to Access"?

A. I'll take your word for it.

Q. Well, we can go back and check.

A. Yes.

Q. "Limited Exposure to Negative Media" --

A. Yes, it is.

Q. -- "& Resulting Barriers to Access"?

A. It is.

Q. All right. And is there data presented showing the -- really, and based on your review of this document, can you tell which of these represents Risperdal growth?

A. I believe it's the blue part of the bar.

Q. All right. And does it show -- what does it show with respect to growth over the years from 1998 up through 2002?

A. Growth appeared to be quite robust from year to year until 2001 when there was a decrease in growth, and then in 2002 there was a return to growth.

Q. All right. And is there a notation of 2001 media controversy pointing to the year 2001 when they lost sales?

A. That's correct.

Q. And from your review of the materials, what --

was there media controversy in 2001?

A. From reviewing materials, it appears that that's coincident or coincides with a series of media reports in Florida about the overuse of psychotropic medications in the foster care population.

Q. In foster care kids?

A. That's correct.

THE COURT: This might be a good time to break.

MR. JACKS: All right. Thank you, Your Honor.

THE COURT: I'll see y'all back around 1:30. Thank y'all. We're in recess.

(Lunch recess taken)

(Jury not present)

THE COURT: Thank you. Be seated. What's up on the evidence?

MR. McCONNICO: Judge, the last answer I think violated what you said they could go into about the marketing and what effect it had on the market. They were --

THE COURT: Let me look.

MR. McCONNICO: Yeah.

THE COURT: I've got it up here. At 11:53:28, "And from your review of the materials, was

there a media controversy in 2001?" Answer, "From reviewing the materials, it appears that there's a" -- a co -- what is that?

MR. McCONNICO: Coincident.

THE COURT: -- "coincident with a" -- it's not "serious" -- "a series of media reports in Florida about the overuse of psycho" -- I guess that "tropic medications in the foster care of" medication.

Okay. So what do you want me to do about it?

MR. McCONNICO: I'd like for the jury to be instructed to disregard the final --

THE COURT: You want me to reread that and instruct them --

MR. McCONNICO: No, I do not, Your Honor, just to disregard.

THE COURT: Okay. So you want me to make just kind of this cryptic comment, "I want you to disregard the last answer of this witness"?

MR. McCONNICO: Yes, sir.

THE COURT: Yeah. Yeah, that's pretty effective. We're taking up time with -- I mean, I'm either going to reread it and instruct them that it's not -- to not pay any -- yeah, that's what I'm going to do. I'm going to reread it and tell them to disregard

it and it should not play any part in their deliberations.

MR. McCONNICO: Judge, then I will withdraw the motion. But I would like the witness and counsel instructed to not go any further into any of these business plans or what moves the market, because that was what was said this morning.

THE COURT: Mr. Jacks.

MR. JACKS: I'm not going to do that.

THE COURT: I will stomp Tokyo flat.

MR. JACKS: Understood, Your Honor.

THE COURT: Okay. All righty. Well, let's bring in the jury and see what happens.

Doctor, is there such a thing as group psychoses?

THE WITNESS: Yeah, there are actually.

THE COURT: Widespread delusions and mania.

THE WITNESS: It's been known to happen.

(Jury present)

THE COURT: Okay, everyone be seated.

You had a few questions with this witness; is that correct?

MR. JACKS: I do, Your Honor.

Q. (BY MR. JACKS) Dr. Perry, before the lunch

break, you had given testimony about the 2003 literature review Janssen had done, a statement from Mr. Pandina in 2004 about his assessment of the state of the literature. I'd like to fast-forward and ask you some questions about the literature as it exists today concerning the science underlying the use of Risperdal and drugs like it in treating children with some of the conditions you've talked about.

Let me ask, first of all -- and I'd like to focus your attention to literature that deals particularly with studies done in children and adolescents. Are you with me?

A. Yes, sir.

Q. What, Dr. Perry, in your estimation is the best literature available currently relating to the efficacy and safety of using Risperdal to treat children?

A. Well, there are several studies that are in the controlled -- placebo controlled multi-center study category. Probably the best study that I'm aware of that compares Risperdal with a first generation antipsychotic and another second generation antipsychotic is the -- what's referred to as the TEOSS study. TEOSS is treatment for early onset schizophrenia spectrum disorder.

Q. All right. Hang on one second. TEOSS, spell

it, please.

A. T-E-O-S-S.

Q. All right. And that stands for?

A. I think the T -- I'm pretty sure the T is for treatment. Treatment of early onset schizophrenia spectrum disorder.

Q. Okay. And is it the case that one of the indications which you've mentioned that -- for which Janssen received FDA approval related to symptoms of schizophrenia in use of a certain age?

A. That's correct.

MR. JACKS: Now, let me ask that Exhibit 2287 be brought up, please.

Q. (BY MR. JACKS) Is this one of the reports of the results of the TEOSS study?

A. Yes.

Q. And about when was this published?

A. I believe this is the first report in 2008, I believe.

Q. All right. And this was a double blinded study, I believe you said; is that correct?

A. Correct.

Q. And you've explained the significance of that. What --

MR. JACKS: If we can refer to Page 9,

please, Mr. Barnes.

Q. (BY MR. JACKS) I'm not going to go into this study or ask you to in great detail, but I would like you to discuss its conclusions, please, Dr. Perry.

The -- let me read this and I'll ask you a question about it. "The results of this study do not support the widely-held assumption that risperidone and olanzapine, two of the most widely-used second generation antipsychotics, are superior to an advantageous first generation antipsychotic for the treatment of early onset schizophrenia and schizoaffective disorder. The safety data underscore the risks of weight gain and metabolic side effects with some second generation antipsychotics, particularly olanzapine, and the importance of closely monitoring weight, glucose and lipid levels and liver functioning."

Now, what in your mind, Dr. Perry, is significant about the -- this first phase or the first report of the TEOSS study?

A. Well, I think the significance is this is a study that actually had several comparative medicines. And when they were compared with each other, there was no advantage of the second generation medications -- or antipsychotics or first generation antipsychotics, which is very much in contrast to both widely-held beliefs and

prescribing practices, that the -- by this time, by 2008, I think in most states, somewhere up well over 90 percent of the antipsychotics that were being prescribed were second generation antipsychotics.

Q. Now, this was a study in children; is that correct?

A. That's correct.

Q. I trust that you're familiar with the CATIE and CUTLASS studies.

A. Yes.

Q. Were those in children or adults?

A. Those were in adults.

Q. How would you compare the findings of the TEOSS study with -- in kids with the findings in CATIE and CUTLASS and adults, speaking generally?

A. Well, generally speaking, both the TEOSS study in children and the CATIE study are -- they're well controlled. They have comparisons between second generation and first generation antipsychotics, and the results show that there really is no increase in efficacy or necessarily in side effect profile when you compare first and second generation antipsychotics.

Q. Let me ask you whether there was follow-up work done in the TEOSS study.

A. There was. The participants in this study were

given the option of continuing in a 44-week study so that the total length of the combined study would be approximately a year.

Q. All right. And so this study reported the early part of that and then the -- there's another study that reports what happened afterward?

A. Yes, sir.

MR. JACKS: May we bring up Plaintiffs' Exhibit 2292, please.

Q. (BY MR. JACKS) And is Plaintiffs' Exhibit 2292 a report of the follow-up findings of the TEOSS study group?

A. Yes, sir.

Q. And let me ask you with respect to both Plaintiffs' Exhibit 2287 and 2292 whether you would regard them as providing good authority with respect to the subjects they say?

A. Yes, sir.

Q. And what -- and again, we're not going to delve into this study in great detail.

MR. JACKS: But I would ask if we could show on Page 2, please, Mr. Barnes, the summary of the results here.

Q. (BY MR. JACKS) And again, I'll read this into evidence and then ask you a question about it,

Dr. Perry. "Conclusions: Only 12 percent of youth with early onset spectrum" --

A. Schizophrenia.

Q. -- "schizophrenia" -- thank you -- "with early onset schizophrenia continued on their originally randomized treatment at 52 weeks. No agent demonstrated superior efficacy, and all were associated with side effects, including weight gain. Improved treatments are needed for early onset schizophrenia."

Now, what, to someone in your field of child and adolescent psychiatry and as one who has special training and expertise in psychopharmacology, is significant about these findings?

A. The most really stunning finding is that so few children were able to stay on the medication for even a year. The dropout rates were astounding both for lack of effectiveness and for adverse effects. And so of the, for example, 41 kids that started on the Risperdal wing of this study, at the end of the study, only four kids were still on Risperdal. And, you know, this is -- really indicates in large part that when you do a short study and you get some initial impressions, you're really not getting the whole picture and that we really need to do more studies like this to really understand the true effects -- effectiveness and side effect

consequences of these medications.

Q. I'm going to shift gears with you. I need to ask you about something called compendia, pharmaceutical compendia.

A. Yes, sir.

Q. Are you familiar with those?

A. I am.

Q. Have you in your own career served in any way in connection with drug compendia?

A. I was on the USP, Pharmacopeia advisory committee for a number of years, yes --

Q. All right.

A. -- which is one of the multiple compendia.

Q. All right. And what are drug compendia?

A. Essentially, they're -- there are different versions of these, but they are collections of the reports for various drugs that have been published over the -- a certain time period that they're published. And again, they're a little bit like that review that we talked about earlier where they -- you know, they don't distinguish between a case report and a case series. They just sort of generally report what it -- what has come out in the literature. And some of the compendia actually make some recommendations about whether or not the drug is -- appears to have effectiveness, and so

they'll make sort of a global recommendation that this doesn't appear to be effective or there is potential effectiveness or there appears to be evidence that it is effective.

Q. All right. And have you reviewed some of the drug compendia respecting Risperdal for purposes of your work on this case?

A. Yes, sir.

Q. Now, last couple of things I need to ask you about. Did I ask you to provide at least an estimate of the percentage of kids -- Medicaid kids in Texas who have received Risperdal where the condition for which they are being treated is a condition for which the FDA has approved the use of Risperdal?

MR. McCONNICO: Objection, Your Honor. He has not been listed as an expert with this --

MR. JACKS: May we approach?

THE COURT: Before y'all come, with these eyes, I need to see the request for disclosure.

MR. JACKS: Your Honor, if I'm not mistaken, the last one --

THE COURT: That's your price of admission to over there.

MR. JACKS: I believe it incorporated his report and this is in his report.

THE COURT: I need to see it.

MR. JACKS: All right. There are the report pages there.

THE COURT: Ladies and gentlemen, this is one of those short recesses to the jury room.

(Jury not present)

THE COURT: Have y'all found the request for disclosure yet? Who has it?

MR. JACKS: I have it.

THE COURT: Well, there are two claims of having it, but I'm undecided which is the better claim.

MR. JACKS: Well, I need to confess error in that the cut and paste function of Word in the first sentence addressing Dr. Perry appears Dr. Rothman's name where the same sentence had appeared on the previous page. And so the first sentence reads under Dr. Bruce Perry, "A detailed summary of the expert opinions that Dr. Rothman intends to express at trial can be found in his expert report, a copy of which is attached hereto in Folder 5 of the attached CD including incorporated by reference herein."

Our intention was obvious, to incorporate the report of Dr. Perry, and in fact, it was the report of Dr. Perry that was attached as --

THE COURT: Okay. It's kind of like that

gorilla in the ad. When he does that (indicating), that means shhh.

Okay. I have a second question.

MR. JACKS: Yes.

THE COURT: Assuming that I boogered up the cut and paste function is good cause -- are you listening over there, McConnico?

MR. McCONNICO: I am, Your Honor.

THE COURT: Okay. Assuming that's good cause, how would this not unfairly surprise or unfairly prejudice the other party? And so the evidence that I'm looking for is, look, here we're -- in the inexhaustible deposition of the good doctor, we discussed this for 10, 15, 20, 30, 40 pages.

MR. JACKS: I'll be right back to you.

THE COURT: Here, you might want to take your cut and paste with you.

MR. JACKS: Thank you. And I take full responsibility for that error, Your Honor.

THE COURT: What does that mean?

MR. JACKS: Just the kind of guy I am.

MR. McCONNICO: You notice I have not used that terminology with my wife in the courtroom.

THE COURT: What, that you take full responsibility?

MR. McCONNICO: That I took full responsibility.

THE COURT: You're a male. You can only do one thing at a time. You're genetically programmed that way.

MR. McCONNICO: That's true.

THE COURT: McDonald, here.

MR. JACKS: Judge --

THE COURT: Okay.

MR. JACKS: I --

THE COURT: I don't need to talk to, Ray, but --

MR. JACKS: I'll represent to the Court that I haven't gone back through his deposition, but I did review my notes to his deposition this morning, and I don't think I saw a reference to questioning by Mr. Schwartz on that subject.

THE COURT: So McConnico, you say the magic words.

MR. McCONNICO: Your Honor, we move that this would be surprise. It was not provided in request to our -- discovery request at the beginning, and we object to any testimony on these points.

THE COURT: Granted.

Whoops, I have a -- Mr. Jacks, take full

responsibility over this paper.

MR. JACKS: Thank you, Your Honor.

THE COURT: You're welcome.

MR. JACKS: I shall.

(Jury present)

THE COURT: Okay. Everyone be seated. Did I mention to the jury that when I started here 34 years ago, that that room was a jail holding cell? Did I mention that? Oh, well, I must have forgot.

Mr. Jacks.

MR. JACKS: Thank you, Your Honor.

Q. (BY MR. JACKS) Dr. Perry, earlier in your testimony, you testified about the three indications the FDA approved for use of Risperdal in children; is that correct?

A. Yes, sir.

Q. And I'm not going to ask you to repeat all that testimony, but would it be a fair summary to say that each of those is a rare condition found only in the very small proportion of kids?

A. That's correct.

Q. Now, same question about the compendia. If you consider from your review of the compendia the indications, in addition to the FDA-approved indications, that -- where one or more of the compendia

has reported effectiveness of Risperdal in treating that condition, how would the frequency or the incidence of those conditions compare with the ones that are FDA approved?

MR. McCONNICO: Objection, Your Honor. I don't think this witness has been -- we were never given any notice he was going to testify on this, of these percentages.

THE COURT: Give me one second. (Pause) A brief conversation over here.

(Discussion off the record between the Court and counsel)

Q. (BY MR. JACKS) Dr. Perry, when you were testifying earlier about how common or uncommon the FDA-approved indications are in children, you said they were --

A. Relatively rare.

Q. Without mentioning any numbers or percentages, I need to ask you a similar question about the indications where one or more of the compendia have found effectiveness of Risperdal in an indication, but not one the FDA approved. Common, uncommon, rare? Where does it lie along the spectrum?

A. It's equally rare.

MR. JACKS: Thank you. I'll pass the

witness.

CROSS-EXAMINATION

BY MR. McCONNICO:

Q. Good afternoon, Dr. Perry.

A. Good afternoon.

Q. We met this morning briefly.

A. Yes, sir.

Q. First, what you really are an expert at and y'all went through at the first of your testimony is children that have been abused, children that have been abandoned, children that have health issues because of trauma. Is that fair to say?

A. I think that's a little narrow. I --

Q. Let me rephrase it. That's where you give most of your efforts in treating people today?

A. That's where most of our clinical research is, is with that population, correct.

Q. With your group?

A. Correct.

Q. And I'm sure, like everyone in here, I appreciate very much your working with that group. But it has been over ten years since you've prescribed any type of the antipsychotics that we're talking about here today for children; is that a fair statement?

A. No. I have prescribed antipsychotics for

several patients in the last ten years.

Q. Ten years. Not much?

A. Not much, that's correct.

Q. And the reason not much is because you're not treating day to day children that are suffering from bipolar, that have a bipolar problem, that have a schizophrenia problem, that have an autism problem. Those aren't the kind of kids that are coming into your office day in and day out to see you, are they?

A. That's incorrect. In fact, we see dozens and dozens of kids with autism. I have a patient who has schizophrenia in Canada right now.

Q. How many?

A. Oh, gosh, in terms -- if you want to put -- if you want to look at the diagnoses of bipolar, schizophrenia and autism --

Q. No. I'm just saying how many schizophrenia kids are you treating right here today?

A. That personally I'm the direct --

Q. Yes, you personally.

A. -- primary care provider? Two.

Q. Two. So today you're treating two children as their personal doctor who have schizophrenia, am I correct?

A. That's correct.

Q. And you don't typically see patients in your office day to day. I'm not saying you don't see them, but that's not what you do most of the time, is it?

A. Correct, I don't do clinical work in isolation.

Q. Now, you work with a group and you consult with a group and you might see 10 or 15 patients a month?

A. Correct.

Q. Okay. Now, back when you were seeing more patients back in the '90s, as Mr. Jacks and you discussed, you gave some of these antipsychotic drugs, both the first and the second generation?

A. That's correct.

Q. And you gave it, as we've heard, off label because they had not been approved by the FDA at that point in time?

A. Correct.

Q. And that was the right thing to do for your patients?

A. I believed it was at the time, yes.

Q. Yeah. And it helped some of your patients?

A. Yes.

Q. Yeah. You gave some of your patients back then Risperdal when it was off label?

A. That's correct.

Q. And that helped that patient?

A. In some cases it did. In some cases --
Q. It didn't.
A. -- it wasn't clear.
Q. That's true of a lot of drugs. A lot of drugs, sometimes it helps certain patients; sometimes it might not help other patients as much. That's just the way drugs work, correct?
A. I wouldn't use that last phrase, but that's a common observation when you use medications, yes.
Q. Because everyone is biologically different, and a drug that might work in one person might not work, the same drug, as well in someone else that has the same symptoms?
A. That's correct.
Q. Now, y'all were talking about percentages at the end, and earlier I heard you say that 1 percent maybe of the population is bipolar.
A. That's what some people estimate, yes.
Q. In Texas we have right at 25 million people. That would mean 250,000 people in our state are bipolar, correct?
A. Correct.
Q. Some people estimate that -- you've seen it, and you said it earlier. Schizophrenia might be, what, 5 percent; other people say it might be 1 percent.

Correct?

A. Correct.

Q. And if it's 1 percent, we have 250,000 schizophrenics here in the state of Texas?

A. That would be correct.

Q. And then in Austin, say we have approximately a million people. Use those same statistics. In Austin we'd have 10,000 schizophrenics, roughly?

A. Roughly, correct, yes.

Q. Same with bipolar?

A. Correct.

Q. Now, schizophrenia develops late, usually in someone's teens or early in their 20s, am I correct?

A. That's typical, yes.

Q. Yeah. And when it does develop, it is a devastating illness?

A. Absolutely.

Q. And the people that come, they become isolated from their families, they become isolated from their friends, and like a lot of the lawyers in this case have had to read a lot about it, and a lot of what I've read said it's the most devastating mental illness someone can have.

A. It's very devastating, yes.

Q. Yeah. So in that situation, people are going

to search for the drug they think that can best treat the person suffering that devastating illness?

A. Yes, sir.

Q. And Risperdal has been given now for almost 17 years, correct?

A. That's correct, yeah.

Q. Texas doctors have had now 17 years to treat people with it to see how it works, correct?

A. Well, they've been prescribing it for 17 years, yes.

Q. And they've been able to see how it's worked in their patient population?

A. They form -- yeah, I'm sure all the clinicians have impressions about how it works, yes.

Q. Because they're the ones seeing and watching the patient and see how a patient responds to a drug, aren't they?

A. Typically, yes.

Q. And 17 years later, after it's first been used, Texas doctors are still prescribing it and still using it with patients?

A. Correct.

Q. So it's had a history of use?

A. Yes, sir.

Q. It hadn't just been determined by a bunch of

studies. We've had it now 17 years where it's had a history of use. Do you agree with that?

A. Yes, sir.

Q. Now, you were sent and testified about a lot of documents that were sent to you by -- concerning Janssen.

A. Yes, sir.

Q. You in your practice don't sit around normally day to day and look at documents, internal marketing plans, plans of what drug companies plan to do. That's not something that you do day to day in your practice, is it?

A. No, sir.

Q. The only reason you did that was for this lawsuit?

A. Correct.

Q. Yeah. And then today, if we divide up your time, you spend about 35 percent of your time teaching?

A. That's correct.

Q. About -- developing programs and writing about 30 percent of your time?

A. Correct.

Q. And then you spend about 20 percent of your time on working on cases like this or things such as this?

A. No, that's not correct.
Q. No. Well --
A. I spend a very small percentage of my time doing forensic work.
Q. Well, this case, you spent quite a bit of time on?
A. Over the last three years, yes.
Q. And you've testified in court over -- or close to approximately 15 times?
A. Not on this case, but in --
Q. Other cases?
A. -- total career, yes, sir, that's correct.
Q. Now -- and I'm just going to get over this fairly quickly, but we were sometimes about -- there were some questions asked of you about Janssen marketing and what they were doing in marketing. You have no training in marketing?
A. No, sir.
Q. You have no training in finance?
A. No, sir.
Q. Nor do I. You don't draft business and marketing plans?
A. No, I don't.
Q. That's not your expertise?
A. No.

Q. Now, you understand with the documents that Mr. Jacks went through with you that in 1994 Janssen did intend to perform clinical trials to generate data for the FDA about the efficacy of Risperdal to try to get approval for certain types of use with young people, children and adolescents. That started way back in 1994?

A. I believe that's so, yes.

Q. And that was a multi-year process. I mean, that didn't happen overnight.

A. No, sir.

Q. And they were very deliberate in how they ran through that, getting these tests done for the FDA, running the tests, am I correct?

A. Yes, sir.

Q. And you're not telling this jury that Janssen had any type of improper influence over the Food and Drug Administration?

A. No, sir.

Q. Okay. But based upon the tests that Janssen did -- and you talked with Mr. Jacks about double blind studies. Janssen provided the FDA with double blind studies?

A. Yes, sir.

Q. They provided them with studies, when you say

double blind, like you were saying against placebo, correct?

A. That's correct.

Q. It was after that that the FDA approved the drug to be used for certain uses with children?

A. Correct.

MR. McCONNICO: Let's bring up, if we can, Exhibit 598. Now, we'll blow this up.

Q. (BY MR. McCONNICO) This is a little hazy, but this is a usage that the FDA approved. We heard this, but after going through this process, the FDA did approve, atypical agent indicated for treatment of schizophrenia in adults and adolescents age 13 to 17 years. Then it goes on, alone in combination with the lithium, and it also says -- I'll skip down -- or manic or mixed episodes associated with bipolar I disorder in adults and alone in children and adolescents 10 to 17 years. 1.2, that's the dosage, correct?

A. No, I think that that's some other reference --

Q. Okay.

A. -- number.

Q. And then it says treatment of irritability associated with autistic disorder in children and adolescents aged five to 16 years, right?

A. Correct.

Q. Now, the FDA approved every one of those uses for Risperdal based upon hard, good scientific studies?

A. Correct.

Q. Okay. Now, do you know of any other antipsychotic -- second generation antipsychotic that has as many approvals for use in children and adolescents as Risperdal?

A. No, I don't.

Q. Now, let's talk about the Texas Health and Human Services Commission. They're the commission that administers Texas Medicaid, correct, if you know?

A. I don't really know that much about it, but I trust you, yes.

Q. Okay. Did you learn in this case they're the group that decides through its Vendor Drug Program and its Drug Use Review, which is called DUR, which is an acronym that's used often -- they decide what drug should be on the Texas formulary?

THE COURT: Excuse me. It's going to be necessary in light of the answer to the previous question, "I don't really know that much about it," that he's got the requisite 602 knowledge in order to answer your question.

MR. McCONNICO: Yes, sir.

THE COURT: Thanks.

Q. (BY MR. McCONNICO) In reading about this case, did you find out anything about the Texas Vendor Drug Program and the Drug Utilization Review Board?

A. A bit, yes.

Q. Do you realize they're the ones that administered the Texas Medicaid formulary?

A. Yes, sir.

Q. And you realize, as the people that administer the Texas Medicaid formulary, they've never removed Risperdal from that formulary. You know that?

A. I did -- I assume they didn't. I haven't thought they did.

Q. Had -- did you see in any of the information that was provided to you by the plaintiffs' counsel where that commission of the State of Texas ever recommended that Risperdal be limited in how it is used with children and adolescents? Did you ever see that?

A. Not that I recall, no.

Q. Did you ever see any letter that the drug utilization board or anybody at the Texas Health and Human Services Commission ever wrote to Texas doctors regarding being careful or limiting how Risperdal was given to children and adolescents?

A. I don't -- I don't recall that, no.

Q. Now, how many years has it been since the CATIE

study?

A. I think their first one was published -- or the first part of it was six, seven years ago, something like that.

Q. That was published in a well-known medical journal?

A. Correct.

Q. Doctors are very familiar with the CATIE study?

A. Correct -- well, I -- I think many are.

Q. Many are.

A. I don't know --

Q. How much.

A. -- how much. I --

Q. Yeah. You're not a doctor that day in and day out prescribes antipsychotics for children?

A. Correct.

Q. Okay. So it might be better to ask one of them than you that question. We'll reserve --

A. Well, I don't know how -- you know, I think it's hard for any physician to know how all other physicians are aware of a study or not.

Q. That's right. And it's very hard for any one physician to know what influences other physicians, correct, just like you said?

A. Without data, without research studies, that's

correct.

Q. That's really hard, isn't it?

A. It can be.

Q. Yeah.

A. That's why the studies are helpful.

Q. Because you're taught as a doctor to treat every patient individually, aren't you?

A. Well, yeah, I think you're -- the ethic is to view each person as an individual, correct, yes.

Q. I think that's a good way -- a better way to put it. The ethic is that every person deserves individual treatment?

A. Correct.

Q. Now, seven years after CATIE and after doctors -- well, CATIE's been in the marketplace, what is the most widely prescribed child and adolescent antipsychotic today, if you know?

A. I don't know.

Q. Would it surprise you if it was Risperdal?

A. Not one bit.

Q. Okay. And that's seven years after CATIE, isn't it?

A. Roughly. I mean, I may have that date wrong, but it's something like that.

Q. And that's seven years after doctors have had a

chance to test the ideas of CATIE in the marketplace on their patients, isn't it?

A. Yes.

Q. Do you believe that Texas doctors would continue to give their patients Risperdal if Risperdal did not help their patients?

A. No, I don't.

Q. Now, were you provided a report that was given to the Texas Legislature by the Texas Health and Human Services Commission entitled "Safety and Appropriateness of Antipsychotic Medications for Medicaid Children Under the Age of 16"?

A. Is -- I think I was. Is this the one for the children in foster care?

Q. No, sir. Let's pull this up, Exhibit 360. It's an exhibit in this case, and this is what the Texas Health and Human Services Commission provided to the Legislature. It says, "Safety and Appropriateness of Antipsychotic Medications for Medicaid Children Under the Age of 16," report to the Texas Legislature as required by this particular act in 2009, and it was done in November of 2010. Did the plaintiffs' lawyers give you a copy of this? Do you remember it?

A. I do have a copy of this, yes.

Q. Okay. Let's go -- this report was issued, say,

in October of -- your report in this case was issued in October of 2010, right?

A. Correct.

Q. This report as we just saw on the board was issued in November of 2010, a month later, correct?

A. Correct.

Q. So they were -- the report that you gave your testimony on and this report were both issued pretty much the same point in time?

A. Roughly.

Q. Let's go to Page 12 of this report, to the Texas Legislature, of Exhibit 360. We'll bring this out. Context. And I'll read this because it's a little...

"HHSC was charged with providing this report due to concerns among certain members of the public and elected officials about inappropriate prescribing of antipsychotic medications to Medicaid children younger than age 16."

Did I read that correctly?

A. Yes, sir.

Q. That seems to also be a concern in this lawsuit. Do you agree with that?

A. I -- well, I think that's an issue --

Q. Yes, sir.

A. -- because it's come up.

Q. Next, let's go to Page 32 of this report. Methods. And they say a search of the peer-reviewed professional literature from June 1st, 2000 through May 31st, 2000 was conducted through the federal public access gateway website. Did I read that correctly?

A. Yes, sir.

Q. What's important when you say peer-reviewed literature?

A. It's a publication that has been submitted to a journal where other professionals will review the submission and essentially make comments to improve it and -- and/or approve it for publication.

Q. And it has a -- really another layer of protection to make sure it's done the correct way. Would that be a proper thing to say?

A. Yeah, that's roughly -- yeah, that's fair.

Q. Let's look at Page 35 of Exhibit 360. And here, "Summary: Risperidone is the most" -- "Risperidone is the most studied antipsychotic in child psychiatry." I read that correctly?

A. Yes, sir.

Q. And this is what they're saying a month after your report and their report to the Texas Legislature. They're saying there has not been a more studied

antipsychotic in child psychiatry, correct?

A. That's what they're saying, yes.

Q. Now let's go to Page 21. "SGAs" -- and again, that's second generation antipsychotics -- "are reported to be better tolerated than first generation antipsychotics." Again, I read that better -- I read that correct?

A. That's what they wrote in this report, yes.

Q. I apologize saying I read it better. I don't think I read it any better than the way it's printed. But the key to this when it says it's better tolerated, it doesn't have as many side effects?

A. That's the implication, yes.

Q. Yeah. And the side effects we're talking about are side effects like we've learned in this trial, things like EPS, things like tardive dyskinesia, which has been called TD. Those are side effects, right?

A. Correct.

Q. The side effects can be very debilitating?

A. That's correct.

Q. Do you know whether these doctors that put this together were compensated for their time in preparing this report?

A. I don't know.

Q. You've been compensated for your time here?

A. Correct.
Q. And all together, earlier I think you told us back in the deposition that you've been paid close to $200,000 for your work, and that was a year ago, correct?
A. Correct.
Q. And you've been continuing to get paid since a year ago for your work in this case?
A. Well, not yet.
Q. Okay. Do you know what that total is going to be?
A. You know, I don't know. I think more.
Q. More than 200,000?
A. Probably, total -- well, not -- not on top of what I've already been paid. I think it'll probably be an additional $40,000.
Q. Now, you and I were talking a little bit earlier about the side effects. It's been known for years that all of the antipsychotics do have some side effects?
A. Yes, sir.
Q. That was true with the first generation antipsychotics?
A. Yes, sir.
Q. And -- but like giving any drug, you have to be

aware of those side effects, and then you have to balance what is the risk of leaving this disease untreated compared to the side effects?

A. Correct.

Q. And leaving schizophrenia untreated can be pretty devastating?

A. If you don't treat it, yes.

Q. Yeah. I mean, it could result -- a lot of the people that we see that are homeless, a large percentage are schizophrenics?

A. Correct.

Q. A large percentage of the people in our prisons or jails are schizophrenics?

A. That's true.

Q. A lot of times when schizophrenics are not treated, they can commit some fairly devastating damage either to themselves or to other people?

A. It's possible, yeah.

Q. It happens?

A. It's not clear whether they were all not treated, however.

Q. Right. But we do know it's frequent -- I shouldn't say frequent. Schizophrenics sometimes do commit fairly violent acts either against themselves or against others?

A. Yes, they have.
Q. Yeah. Now, when you prescribed Risperdal back in the '90s, you knew at that point in time it had certain side effects?
A. Correct.
Q. You knew that there was a possibility of weight gain?
A. Yes.
Q. You knew there was a possibility of TD?
A. Correct.
Q. You knew there was a possibility of EPS, which we've gone into in some detail and we'll go into it in more detail, but you knew that?
A. Correct.
Q. Knew that the weight gain could also be associated with diabetes?
A. Well, I probably didn't know that at that point, but --
Q. Yeah. But you knew at that point in time that if people gain weight, sometimes that is associated with diabetes?
A. It can increase your risk, yes.
Q. But knowing all of that, you still elected to give the Risperdal because you thought to a child that the benefits outweighed the risks?

A. Correct.

Q. As long as we're talking about side effects, we do need to be very cognizant that some side effects are more harmful and devastating than others. Do you agree with that?

A. Yes, I do.

Q. For example, tardive dyskinesia can be permanent?

A. That's correct.

Q. Where -- and I'm not belittling it. Weight gain can be a serious situation, but that can be monitored and you can do certain things about it with diet, exercise or other medication, correct?

A. That is possible, yes.

Q. And tardive dyskinesia and other EPS symptoms can be totally debilitating?

A. They can be very serious, yes.

Q. Now, let's look again back at that report that the Texas Health and Human Services Commission gave to the Legislature. Look at Exhibit -- I mean, Page 27. Now, again, this came out about a month after your report in this lawsuit, correct?

A. Correct.

Q. We'll go down to the bottom and it says -- let's pull this up. First generation antipsychotics

compare -- carry more risk in neurologic EPS and -- could you read that for me? I'm having a hard time from this --

A. Anticholinergic side effects.

Q. And later risk of tardive dyskinesia than second generation antipsychotics. Did I read that correctly?

A. Yes.

Q. And what we're saying is the first generation antipsychotics -- those are drugs like Haldol, Zyprexa, Thorazine, others -- they can have more of these risks that you and I were describing that can be very debilitating of EPS, which are Parkinson-like syndrome, than the second generation. That's what they're saying?

A. That's what they're saying, yes.

Q. That's right. Now, you disagree with that?

A. I do.

Q. But this is what was reported to the Legislature by the Texas Health and Human Services Commission and the group of doctors that they got to investigate this, you know, not involved in this lawsuit, got to investigate it, that's what they're telling our Legislature, right?

A. Yes.

Q. They have absolutely no reason to tell the

Legislature anything except what they think is the truth, do they?

A. Exactly, what they think is the truth.

Q. Right. So what they're saying is, folks, these really serious side effects are less with the second generation like Risperdal than they are with the first like Haldol that's what they're saying?

A. That's what they're saying, yes.

Q. Let's look at Page 27. Okay. And this is discussion in summary. This is the discussion in summary part. First generation antipsychotics carry more risks of neurologic EPS and anticholinergic side effects and a later risk of tardive dyskinesia than SGAs. They're saying it again in their summary?

A. Correct.

Q. Do you realize how long this study was that they did of this study before they came up with these conclusions?

A. You -- you mean their review --

Q. Yes.

A. -- how long their review was? No, I don't know how long it was.

Q. Would it surprise you it was ten years?

A. I guess I would be kind of surprised, yeah.

Q. If they went back and they looked at a ten-year

review of the scientific --

A. Oh, I'm sorry. I'm sorry. I misunderstood your question.

Q. Yeah. They did a ten-year --

A. That would be a surprise if it took them ten years to write this, yes.

Q. And my question was not properly phrased. I apologize. It could have been. But it would not surprise you if they did a review of ten years of a scientific literature, would it?

A. No, no.

Q. In fact, that's what they should do?

A. Exactly.

Q. Now, tardive dyskinesia, as we've learned, can be very serious because it can be permanent?

A. Correct.

Q. And all versions of the Risperdal label over the years included tardive dyskinesia as a potential adverse event, didn't they?

A. I believe in the labeling, it did, yes.

Q. Now, the study -- and we'll put this up -- also found that the second generation antipsychotics could cause weight gain and sedation more than the first generation. Would that surprise you?

A. No.

Q. You would agree with that?
A. I believe that's accurate, yes.
Q. And you would also agree that there could be a difference between the second generation and their propensity to cause weight gain?
A. Correct.
Q. Some of the second generation antipsychotics will cause more weight gain than others?
A. Correct.
Q. And this is what they said: The side effect of increased appetite, weight gain, is common for FGAs and SGAs and can naturally lead to obesity. But they say risperidone and haloperidol, which also sometimes is referred to as Haldol, did not differ in the amount of weight gain. That was their conclusion, correct?
A. That's correct.
Q. Most studies show that of the second generation, olanzapine or Zyprexa have more weight gain than Risperdal, correct?
A. Correct.
Q. Now, Zyprexa and olanzapine and Risperdal are all second generation antipsychotics, correct?
A. Correct.
Q. But of those second generation antipsychotics, Zyprexa and olanzapine are going -- I mean, I'm sorry,

they're the same. Zyprexa is going to have more weight gain than Risperdal?

A. Typically, in the controlled studies, yes.

Q. Let's look at 360. What I will -- and just to speed this up a bit, the Risperdal label has always -- I say always -- but lists the potential for weight gain, doesn't it?

A. Yes, sir.

Q. One thing I want to establish that -- about off-label marketing is the FDA -- I mean, off-label prescription -- is the FDA allows off-label prescription?

A. Yes, sir.

Q. Medical boards allow off-label prescriptions?

A. Yes, sir.

Q. Professional guidelines sometimes recommend it?

A. Correct.

Q. And Medicaid pays for it?

A. They have, yes.

Q. Okay. So I just want to make it clear that when it comes to off-label prescription, whether it's for child -- for children and adolescents, that is just something that happens in medicine because we rely upon the doctor to give the right drug to the right patient. Is that fair to say?

A. Well, I -- it happens. I don't know if it's because we rely on them to give the right medications, but off-label prescribing is very common.

Q. Very common. It's not uncommon at all.

A. No.

Q. The -- it is more difficult to conduct human research on a child and adolescent population than it is an adult population?

A. Correct.

Q. And because it's more difficult and some of the things you said earlier, you're not going to have as many tests to submit to the FDA of how this works with children and adolescents as you can with an adult, meaning a particular drug; is that right?

A. Well, because it's more difficult doesn't mean that these studies can't be done, so I'm not in a position to say why they aren't being done. They just require more resources to do them.

Q. Well, really, we now know that most of the resources to do this have been done in the last -- for children and adolescents, most of the testing has been done in the last 10 or 15 years?

A. Correct.

Q. And Janssen, to get these approvals from the FDA, did a lot of very good testing for the FDA to

submit?

A. They -- they had many short, solid, quality studies.

Q. Yeah. And double --

A. Short-term.

Q. -- blind placebo studies?

A. Correct.

Q. Do you agree that there's been more research on antipsychotics in use in the last ten years than occurred in all the previous years combined?

A. I believe that's probably accurate, yes.

Q. And obviously, the more studies the better, because the doctors need the information?

A. Correct.

Q. And they rely upon the pharmaceutical companies to give them the information?

A. That's not the only source hopefully, but, you know, yes --

Q. In our --

A. -- pharmaceutical companies do provide information to physicians about medications.

Q. I think this is an important point. In our country, who develops new drugs? Pharmaceutical companies or the government?

A. Pharmaceutical companies.

Q. And so by developing new drugs, are they necessarily going to gain a lot of information about the drugs?

A. Yes, they will.

Q. And is it important for them, once they gain that information, to share it with the doctors?

A. Absolutely.

Q. You yourself have not talked with any doctors in the Texas Medicaid Program who told you that Janssen engaged in off-label promotion of Risperdal to them?

A. I haven't done any direct interviews of physicians, no.

Q. And you have no way of knowing what an individual doctor is doing based on what a drug rep tells them?

A. No, I don't.

Q. Okay. And when a drug rep comes into your office -- and probably being in the consulting practice here today, it's rare -- but would you receive what they're saying with a grain of salt?

A. We don't see -- we ask them --

Q. Right.

A. -- politely to go next door.

Q. But --

A. We don't see them.

Q. Yeah. In the past, you did see drug reps?
A. Our clinic received them, yes.
Q. Did you take what they told you with a grain of salt?
A. I did, yes.
Q. Why?
A. Because I've done -- I've actually participated in outcome studies that were funded by drug companies, and I am familiar with the phenomenon of unconscious bias. It's just part of what's --
Q. Okay. Now, let's talk a second about when you participate, most drug reps -- were you here -- you saw one of the depositions of some of the drug people today, correct?
A. Correct.
Q. Who do you think has the most experience in actually giving a drug to a patient? The drug rep or the doctor?
A. I would hope that it's the physician.
Q. I do, too, because how much education does the doctor have? Has a drug rep usually gone to medical school?
A. No.
Q. Have they done an internship?
A. No.

Q. Have they done a residency?
A. No.
Q. Have they been taught how to treat a particular patient?
A. No.
Q. Has a doctor been taught all of that?
A. Hopefully.
Q. Have they gone through that whole education process?
A. Yes.
Q. Do they have a lot more education than a drug rep on how to treat a particular patient?
A. Yes.
Q. And you reviewed some call notes in this case, right?
A. Correct.
Q. And you saw that there were some call notes that were brought up earlier, correct?
A. Yes, sir.
Q. I'm going look at a few more. And let's look at a call note, Plaintiffs' 130. You might have to read this like some other doctors, and I hope your bifocals are better than we've seen.
A. I can see if I get really close.
Q. Okay. This is a -- and if you look up at the

right, the lady that's writing this is Tiffany Moake, and we saw Ms. Moake this morning give a deposition. And you weren't here, but the first time that I ever saw these folks in the jury, I told them that some of these call notes were not defensible, and they're not. But let's go into them in a little bit more detail, okay, you and I?

A. Okay.

Q. Now, this is Ms. Moake. And if you go down there, she's over seeing a doctor Rolando Rodriguez in San Antonio. And you go down and it says -- keep going down.

A. Uh-huh.

Q. And it says doctor has created his own formulary that involves low dose Risperdal augment in kids. Okay. What's his own formulary?

A. Honestly, I would only be guessing.

Q. Okay. I don't want you to guess. He's showing independence. The doctor is getting something together of how he gives the drug, correct, his own formulary? Is that fair to say?

A. Again, I -- it would be a complete guess for me. I don't know whether that means he makes his own preparations or -- I don't know what that means.

Q. Okay. And you go on over there for a way. No

other atypical works like Risperdal does, and therefore, it's his first choice. Did I read that correctly?

A. That's correct.

Q. This doctor is basing the drug he gives upon his own experience. That's fair, isn't it?

A. Well, I mean, if you want to talk about --

Q. Just, first, is that --

A. I would say that it's -- you know, that -- I don't know if you'd call it fair. It's not scientific, but it's certainly his experience.

Q. Right, okay. We'll just stop there. The doctor is giving it because it works for him, right?

A. I'm assuming that he's giving it and he's presuming that there's efficacy.

Q. Well, no other atypical works like Risperdal does, and therefore, it's his first choice. I read that right?

A. That's his impression -- right, I mean, it's -- that's what he's doing.

Q. Now, let's go over to the next one, and this is 86998. And again, this is Tiffany Moake. This is another -- and go down to where the patient in -- that was on Abilify said it was the best medicine ever. Do you see that on the second line?

A. Yes.

Q. That's a second generation, correct? That's not Risperdal, but it's a second generation, right?

A. Correct.

Q. Sometimes patients know what works best for them, right?

A. Exactly. Often they do.

Q. And when they do, doctors should listen to them?

A. Correct.

Q. Okay. Let's go to J288407. And then you look up -- and again, I think this was Tiffany Moake that we heard from this morning. And look over here where it says "Bridge to Concerta." And this is the doctor saying "Bridge to Concerta, and he thinks all our Concerta stuff is propaganda." Did I read that right?

A. Yes.

Q. Just because a detail man is telling a doctor something doesn't mean he just accepts it outright, does it?

A. No.

Q. What's propaganda to you?

A. It's misinformation.

Q. Okay. And that's what that doctor thinks that they're getting about Concerta, right?

A. Correct.

Q. And whose product was Concerta?
A. I believe it's a McNeil product.
Q. Okay. So the doctor doesn't have to believe what the drug rep tells him, does he?
A. No.
Q. And then let's go to 20022. Again, this is Tiffany Moake. And look over to the -- on the top line where she says "She gave me a funny look, got to the point." "She gave me a funny look, got to the point Re M-Tab and she thought of every reason not to use, mainly cost and insurance." Did I read that right?
A. Yes, sir.
Q. So again, doctors can be independent. They can make up their own minds about things concerning cost and insurance, can't they?
A. Yes.
Q. Now, let's go down to 922248. And again, this is Tiffany Moake. Look what she puts in bold print. Doctors concerned with sexual side effects in adult population with Risperdal. He doesn't use here for this reason.
Did I read that right?
A. Yes, sir.
Q. Now, doctors can -- they don't have to just rely upon what a detail person tells them. They can

read the warnings. They can read the medical literature. If it disagrees with it, they can say, look, I'm concerned about this and I'm not going to have anything to do with your drug. They can say that, can't they?

A. Sure.

Q. And that's what this doctor is saying, according to Ms. Moake, correct?

A. Well, about that specific indication --

Q. Yes.

A. -- or that specific use in the adult population.

Q. Right. Now, let's go down to Plaintiffs' 129. This is another doc -- another detail person that you were shown these call notes. And at the very first, this doctor, Dr. Del Campo in Beaumont, and he says right at the first -- says he only uses Seroquel for patients that have sleep issues.

I read that correctly?

A. Yes, sir.

Q. And again, doctors can decide to use another second generation, and they can tell this detail person that, can't they?

A. Of course, yes.

Q. And Seroquel does have more of a sedative

component maybe than Risperdal, right or wrong?

A. It depends on the population, but --

Q. Okay.

A. -- it can, yeah.

Q. And then we go to 3019632. Do you remember being -- these were call notes we were told you were shown. Do you remember being shown these call notes?

A. I've seen these, yes.

Q. Okay. And you didn't see all the call notes. You only saw a few of the 500,000, right?

A. I didn't see 500,000, no.

Q. Okay. But these were a few that the plaintiffs' attorneys did provide to you?

A. These, I saw -- you know, there's 180 of these that actually had text in them that were in the child and adolescent population and then, you know, thousands more that just were blank.

Q. Okay. And they didn't tell you anything if they were blank?

A. No, just that there was a visit.

Q. Yeah. Look over here on this -- way on the side where it says -- this doctor is, again, Dr. Del Campo in Beaumont. And we start on the top, he is concerned about efficacy but wants to do no harm to patients. Efficacy is whether or not it works?

A. Correct.

Q. That's a legitimate concern.

A. Correct.

Q. And then the agent says brings up Risperdal CONSTA data and dosing information, administration. He was interested in it but wasn't convinced of it fitting into his practice.

Did I read that right?

A. Yes, sir.

Q. Okay. So this doctor just didn't think this drug was going to fit into his practice, right?

A. At -- well, at that formulation of Risperdal.

Q. Right.

A. Yeah.

Q. And then let's go down to the next one, which is 4690221. Now, this agent reviewed Hirschfield data and presented new information about using Risperdal in treating kids and adolescents with symptoms of aggression, irritation, tantrums, self-injurious behavior, also presented prolactin levels. He was concerned with prolactin associated with Risperdal. Competition created concern.

Now, these doctors are not being visited just by drug agents or drug representatives from Johnson & Johnson or Janssen, are they, probably?

A. Typically, no.
Q. And they're also being visited by people from Lilly or Avantis, who also makes second generation antipsychotics?
A. That's possible, yeah.
Q. Yeah. And it's also possible that when those other agents come in to see them, whatever critical and negative they have about Risperdal, they're going to tell them?
A. Correct.
Q. Because they tell them that because they want them to prescribe their drug and not Risperdal --
A. Correct.
Q. -- correct? So these doctors are not just getting -- not just hearing from the Janssen sales reps, right?
A. I would expect not.
Q. They're also hearing from sales reps from other manufacturers that are trying to tell them things that will convince the doctor not to give Risperdal?
A. Correct.
Q. For better or worse, this is a competitive marketplace, right?
A. Yes.
Q. And here it says he's concerned about

prolactin. And as the plaintiffs' attorneys have told you, that sometimes Risperdal has been associated with more prolactin than some of the other second generations, and you agree with that?

A. Yes.

Q. And here is the competition making sure the doctor knows about it front and center, right?

A. Yes, sir.

Q. Okay. Let's look at the next one. Look down at the other -- at the very bottom. He --

MR. JACKS: Do you have a number?

MR. McCONNICO: I'm sorry. This one is 4690220.

Q. (BY MR. McCONNICO) At the very bottom, it says he was concerned with TD rates associated with Risperdal. The doctor is telling the salesperson this, right?

A. Yes, sir.

Q. Competition created a concern, right?

A. Correct.

Q. So again, they're not going out there into the marketplace without the competition pointing out if they might have any defect, right?

A. Correct.

THE COURT: Mr. McConnico, we're going to

take a break.

Ladies and gentlemen, I'll see y'all back in about ten minutes.

(Jury not present)

THE COURT: Thank y'all. We're in recess.

(Recess taken)

(Jury not present)

THE COURT: Bring them in.

(Jury present)

THE COURT: Thank y'all. Be seated.

Q. (BY MR. McCONNICO) Dr. Perry, before we took a break, we were talking about the call notes. And I don't want to leave any type of false impression. There's some bad information in these call notes, even the ones you and I went over about what agents did and didn't do. Am I correct?

A. I assume -- are you referring to the off-label promotion?

Q. Yes.

A. Yeah.

Q. With that said, we need to look at what a doctor actually does in real life; do you agree with me, not just hypothetically?

A. I guess I'm not -- I don't --

Q. Let me rephrase it another way. Can you point

to one call note where a doctor said I'm prescribing Risperdal because of what the agent told me?

A. No.

Q. Okay. And you were only given a few of these call notes -- well, I'm not saying there were a few; there were quite a few, but in the relative scheme of things -- by the plaintiffs' counsel. You haven't looked at all of them?

A. I was given all of the child and adolescent call notes, and, you know, the -- as I said, the ones that had text, I looked at.

Q. But most of them had no text?

A. Correct.

Q. And those you can't comment on at all?

A. No.

Q. Let's talk about you -- this morning you were talking about TEOSS. And you explained to us -- and what does TEOSS stand for again? It's T-E-O-S-S.

A. Correct. It's treatment of early onset schizophrenia spectrum disorder.

Q. And this was first reported, as you told us, in the *American Journal of Psychiatry* in 2008?

A. Correct.

Q. And the findings were presented at multiple academic meetings in 2007 prior to the publication?

A. I believe that's accurate, yes.
Q. So psychiatrists who prescribe antipsychotics to children and adolescents, they've had the opportunity to be exposed to TEOSS and its findings?
A. Yes.
Q. And since the publication of TEOSS and its findings, there has been no significant change in the way Texas physicians prescribe second generation antipsychotics?
A. Not that I'm aware of.
Q. And the TEOSS study was referred to in that Texas Health and Human Services Commission report that you and I went over earlier this afternoon, right?
A. I believe it was cited, yes.
Q. And that was something that they assessed and they were aware of before they wrote their conclusions to the Texas Legislature?
A. I assume, because they cited it, yes.
Q. And after -- as you and I saw, after even looking at the TEOSS study, they still said the SGAs, which are the second generation antipsychotics, are better tolerated than the first generation antipsychotics. That was one of their conclusions?
A. That's what they concluded, yes.
Q. Now, let's drill down into TEOSS a little bit

more. What they did is they compared two of the second generation antipsychotics, Risperdal and Zyprexa, to one first generation antipsychotic, which is molindone?

A. Correct.

Q. And that's sometimes referred to -- is it Moben or Moban?

A. Moban.

Q. Moban. And molindone is not commonly used in a clinical practice, is it?

A. No.

Q. Doctors rarely prescribe it for patients?

A. Correct.

Q. In fact, you have never prescribed molindone, which was the first generation antipsychotic that was used in the TEOSS study?

A. Yeah, correct. I've inherited patients on the medication, but I've never prescribed it initially, no.

Q. And there was some mention of CATIE, and CATIE had some of the similar issues because it used a drug of the first generation that's very rarely prescribed?

A. It's currently rarely prescribed. It used to be frequently prescribed.

Q. But it's not today?

A. No.

Q. And it was chosen -- molindone was chosen, even

though it was rarely prescribed, because the authors thought it was the best option among the first generation antipsychotics because they had a perception that it had a low propensity for weight gain and EPS side effects?

A. I think that that's the rationale.

Q. But even though they said molindone has less of a chance of creating EPS or weight gain, they took some precautions because they gave a medication -- some medication with it that is kind of an anecdote to EPS, am I correct?

A. To a certain percentage of the clients on that, yes.

Q. What are those drugs called?

A. Well, the anticholinergic medications, basically.

Q. And why -- we've seen that word. Why are those drugs given sometimes with the first generation antipsychotics?

A. Essentially, what they do is they block, you know, receptors that influence movement in a way so that the drug, the antipsychotic, doesn't result in some of these movement disorders.

Q. And the movement disorders we're talking about are EPS?

A. Correct.

Q. And they're kind of what I said at the first are Parkinson-like syndrome where people kind of get the shakes and can't control them?

A. Some of the symptoms, correct.

Q. Some of the symptoms are like that.

A. Yeah.

Q. And TD, a lot of times the mouth moves in an involuntary way, the jaw and the lips, and you can't control that?

A. Correct.

Q. And then you can get a thing called akathisia where you can just -- you can't control the movements of your limbs at all?

A. And you feel very restless, correct.

Q. Yeah. You can't sit still.

A. Correct.

Q. Then another one is you get dystonia where your eyes roll back in your head, your head locks or you can lock the body in a very bad position?

A. On occasion, yeah.

Q. Yeah. And it's been explained to me, and I understand it. If that happens, it is one scary event.

A. And can be painful.

Q. And people that it happens to do not want to

take the drug ever again that caused it?

A. That's a common response, yes.

Q. Yeah. So you really don't want that to happen, because if you have a schizophrenic, you want them to stay on the drug, but if that happens, there's a high likelihood they're going to get off the drug?

A. Correct.

Q. And so with the first generation, what you did is you gave these drugs -- these other drugs that you hope would block those types of symptoms?

A. Not all of the time, but --

Q. Sometimes.

A. Yeah, if there was a sense that that was going to happen.

Q. And what were those drugs called again?

A. Anticholinergic.

Q. Yeah. And that was given in this particular test you told us about with the TEOSS?

A. It was. It was given to patients taking all the medications.

Q. Benztropine, right?

A. Correct.

Q. And do you think that the participants receiving the Risperdal and Zyprexa also received this?

A. They did.

Q. Okay. Are you certain on that?
A. Well, in the follow-up study they did. I think 46, 47 percent of the people on the maintenance wing for Risperdal took Benztropine.
Q. Did they on the first study?
A. I don't recall that, but they did that on the follow-up.
Q. And in the first study, the molindone group -- and let's look at Exhibit 1256, Page 6. And this is -- when I say Zyprexa, this is another name for Zyprexa. Olanzapine resulted in more weight gain than either of the other two medications as Risperdal, correct?
A. Correct.
Q. And that kind of confirms what you and I said earlier that there are different second generation antipsychotics. Zyprexa is one of them. Risperdal is one of them. Abilify is one of them. Geodon is one of them. But Zyprexa tends to produce more weight gain than Risperdal and the others?
A. Typically.
Q. Yeah. And let's look at -- there is another thing on here in the discussion. We'll get back to it, but they said -- and tell me if you remember this. The molindone group, which is the first generation, reported significantly higher rates of akathisia -- that's the

restless legs you told us about -- and EPS than those receiving Risperdal or olanzapine despite receiving Benztropine. Do you remember that?

A. Yes.

Q. Okay. So what that means is, in the first study, that the molindone group who were getting the first generation antipsychotic, they had higher rates of akathisia, which is the restless legs, which is an EPS, than those receiving Risperdal, correct?

A. Correct, in the short-term, yeah.

Q. And the authors also concluded that the molindone was not associated with more Parkinson or dystonic symptoms likely due to the prophylactic benztropine treatment. Do you remember that?

A. Yes.

Q. Okay. So what you were telling the jury is that the first -- if you give sometimes these first generation antipsychotics, you want to give this drug with it, which I as a lay person call the anecdote for these problems to prevent them?

A. You can, yes.

Q. Yeah. And what the -- what the people did is they said the reason they didn't get more of it was because they got the anecdote?

A. Correct.

Q. The authors also concluded -- and let's see if we can pull this up, Exhibit 1256 at Page 9. The decision to provide -- let's see -- prophylactic benztropine -- here we go -- to all you treated with molindone, which is the first generation antipsychotic, may have minimized differences in -- and I'll just -- EPS symptoms among the medications. In addition -- would you read that to us? You might see it clearer than I do.

A. In addition, anticholinergics like benztropine may have significant adverse neurocognitive effects.

Q. What does that mean?

A. It basically means that in -- your thinking can be influenced, although it didn't measure that in this study. So I'm not sure what -- I think they're just making an add-on comment.

Q. But that does -- that's something that's known in medicine and in science?

A. Yeah. If you take high levels of -- it's like Benadryl. If you take high levels of Benadryl, it can make you kind of groggy, sluggish. That's basically what they're referring to.

Q. And that's like what you and I were saying earlier. All medicines generally have a side effect, and you've just got to balance the risk versus the

benefit, correct?

A. Yes.

Q. And that's one of the risks of these anticholinergics?

A. Correct.

Q. Then let's look at Page 10. The authors -- and pull this out. And this is the reason they chose it. Molindone was chosen as the best option among the first generation antipsychotics based on its low propensity for both weight gain and EPS side effects.

That's what you and I were discussing earlier, right?

A. Yes, sir.

Q. Even though it's rarely given. But the authors, if you remember, also go on to conclude that if they had used something that's more frequently given, such as Haldol, that would have facilitated comparison with certain adult studies. And that would have been a better thing to say how does this compare all together.

A. I think they were basically -- and if you want me to try to interpret what they were saying, I'm happy to do that, but --

Q. Well, we can just start here. There are -- there are first generations they could have compared it to that would have been more real world experience, like

Haldol, correct --

A. Correct.

Q. -- because it's used more frequently? But they didn't use one of these drugs that's used prevalently; they used something that's used very rarely?

A. Correct.

Q. What is the AACAP?

A. That's the American Academy of Child and Adolescent Psychiatry.

Q. Is it a national organization for child and adolescent psychiatrists?

A. Yes.

Q. Are you a member?

A. Yes.

Q. What are -- are you aware that this group attempts to assist its members in child and adolescent psychiatrists by publishing things they call practice parameters?

A. Yes.

Q. What are practice parameters?

A. They're typically broad directives about how to conduct your practice. They try to give recommendations about a variety of things based upon the working group's review of evidence-based studies.

Q. And when you say evidence-based studies, what

are you talking about?

A. Well, the group is basically trying to look at what is the available evidence to influence a specific kind of practice. So it might be, for example, the treatment guidelines about children with posttraumatic stress disorder or treatment guidelines about children who have schizophrenia or so forth.

Q. Right. And in fact, the American Academy of Child and Adolescent Psychiatrists consensus group has been developing practice parameters for the use of atypical antipsychotics in children and adolescents for several years, correct?

A. I believe that's so, yes.

Q. And when I said atypical, that's just another word for second generation antipsychotics?

A. Correct.

Q. In this case, when I -- sometimes you'll hear atypical; sometimes you'll hear second generation. But when we say that, we're talking about the same group of antipsychotics, right?

A. Yes.

Q. And of course, Risperdal is part of that group?

A. Yes.

Q. And the final practice parameter was approved by the American Academy of Child and Adolescent

Psychiatrists in August of 2011, if you know?

A. I do know that, yeah.

Q. And this practice parameters, it tended to offer clinicians, the people that are actually treating the children, quote, a rational approach to the use of antipsychotics in children and adolescents. That's the purpose, right?

A. Yes.

Q. Now, what they did in coming up with this is the committee did a literature search of all the world's medical and scientific articles on antipsychotics and their use in children and adolescents?

A. I believe they did, yeah, a search like some of these other studies have done.

Q. And what they came up as their conclusion in 2011, this past summer, they said, the AAC practice parameter for second generations, quote, risperidone has the most substantive amount of methodology-stringent evidence about its use in children and adolescents. And if we do, we can pull that up out of that guideline. Do you remember that?

A. I do.

Q. So after looking at all this literature, their conclusion was risperidone has the most substantive amount of methodology-stringent evidence about its use

in children and adolescents. So what they're saying is there has been a lot --

THE COURT: Can we interrupt with an answer every now and then?

MR. McCONNICO: Yes, sir.

THE COURT: Okay.

Q. (BY MR. McCONNICO) What are they saying about the evidence that was looked at when they got into risperidone?

A. They're comparing it to the evidence for other second generation antipsychotic and saying that there is more for -- there are more studies done and more reports on Risperdal than other second generation antipsychotics.

Q. When they use -- what does substantive mean?

A. I assume that means that have data.

Q. Yeah. What does stringent mean?

A. I believe that they're referring to the fact that they have a certain level of scientific rigor.

Q. And earlier we were talking -- well, strike that.

This is a very strong endorsement for Risperdal in use in children and adolescents. Do you agree?

A. Not really.

Q. It's an endorsement?
A. No. It's a statement about the availability of research data compared to other antipsychotics.
Q. Yeah. And their conclusion is the research data is very strong in favor of Risperdal?
A. I think that it doesn't -- I think it says there's more for Risperdal. I don't know that it says it's stronger for. It just says that it's been more stringently studied.
Q. Okay. Now, the -- they did not in any way after they did that data say that we think the first generation are better for children than the second generation, did they?
A. No. I don't believe that was the task of that group.
Q. They didn't conclude that, did they?
A. I don't believe they addressed that directly, no.
Q. Okay. Now, as we sit here today, the Texas Vendor Drug Program has not made any changes in how they reimburse Risperdal when it is prescribed for children that are Medicaid patients as far as you know, have they?
A. Not that I'm aware of.
Q. Okay. As we sit here today, this lawsuit has

been going on for several years. You've done this study for many years now. Your report was done a couple of years ago. There has been no change in any type of restrictions saying we want you to give the first generation antipsychotics before you give the second generation antipsychotics by the State of Texas? They haven't directed that to any pharmacist, have they?

A. Not that I'm aware of.

Q. And even though Texas doctors have now been using Risperdal for more than 17 years, has there been any fall-off in the amount of Risperdal they prescribe after that 17-year period history of giving it?

A. I don't think so.

MR. McCONNICO: Right now I have no further questions. Thank you.

REDIRECT EXAMINATION

BY MR. JACKS:

Q. Dr. Perry, one of the first things Mr. McConnico asked you is whether or not it was true that going back to 1994 when Risperdal was first brought onto the market by these companies, that they expressed their intent to conduct clinical trials. Do you remember him asking you about that?

A. Yes.

Q. And so they could get an FDA approval for some

indication of using the drug in children in their label --

A. Correct.

Q. -- is that right?

MR. JACKS: May we bring up Plaintiffs' Exhibit 2, please?

Q. (BY MR. JACKS) Is one of the documents you reviewed in this case one of the first business plans that this company prepared concerning Risperdal?

A. Yes.

Q. Page 983, please. Do you see the discussion under the heading of "Market Expansion"?

A. Yes.

Q. And I know you've seen this document before, but in this document, does it refer to a need to conduct trials? And let me read something to you. I'll ask you about it. "Market Expansion. To establish Risperdal as a broad-use product in several market segments, it becomes necessary to demonstrate safety and efficacy of Risperdal through small scale trials."

A. Yes.

Q. Now, did I read that right?

A. Correct, yes.

Q. Now, did they in fact conduct small scale trials?

A. Yes.
Q. If you look down further --
MR. JACKS: And we'll scroll down, please, Mr. Barnes, to the --
Q. (BY MR. JACKS) Do you see, by the way, that children is one of those markets that they're targeting?
A. Yes, sir.
Q. And do you see that they speak of the business purpose for conducting what they call market expansion studies?
A. Yes.
Q. And they refer specifically to support the broad-use strategic objective by seeding the literature and, if appropriate, changing current labeling?
A. Yes, sir.
Q. Now, you reviewed with the jury this publication planning program that these companies instituted where they would have paid outside writers to write articles, the author yet to be determined, in connection specifically with the child and adolescent market; is that right?
A. Yes, sir.
Q. Would that be an example of seeding literature?
A. Very much so.
Q. You said that when you covered the review that

Janssen did of the literature in 2003, that they started out with over 600 articles that were in the literature at that time about Risperdal; is that right?

A. That's correct.

Q. And they threw out almost 500 of them and narrowed it down to 123?

A. I don't know if it was 123, but it was close to that number.

Q. All right. And of that 120 some-odd, how many were double blinded studies?

A. There were really five controlled studies. Three were double blinded placebo. Two were comparison, controlled studies.

Q. All right. And in fact, they did approach the FDA about trying to get a change in their label so they could talk about children in the label for the product. Do you recall that?

A. Yes.

Q. Did you study that in your research in this case?

A. I reviewed that, yes.

Q. And let me bring up Plaintiffs' Exhibit 433, please. And is Exhibit 433 one of the documents you reviewed where the FDA was addressing a supplemental new drug application that the companies submitted dated

August 15th of 1996 concerning Risperdal?

A. Yes, sir.

Q. And did -- in fact, did they try more than once to get the FDA to give them permission to start mentioning Risperdal in their label for children?

A. I believe they did.

Q. All right. Was this the first time?

A. I'll trust you.

Q. Okay.

A. I didn't memorize all those documents.

Q. If you don't know, that's all right.

MR. JACKS: May we go to the second page, please, Mr. Barnes.

Q. (BY MR. JACKS) And if we look at the -- what the FDA concluded, and I'm going to start with the sentence, "To permit the inclusion of the proposed vague references to the safety and effectiveness of Risperdal in pediatric patients and the nonspecific cautionary advice about how to prescribe Risperdal for the unspecified target indications would serve only to promote the use of this drug in pediatric patients without any justification."

Is that what the FDA said with respect to their first effort to get a labeling change that would allow them to promote this drug for use in children?

A. Yes, sir.
Q. Now, there was reference to this HHSC report to the Legislature.
A. Yes.
Q. You're familiar with that report?
A. I am.
Q. Was it a study?
A. No.
Q. Was it a clinical trial?
A. No.
Q. What was it?
A. It was a review and a report that was prepared by, I believe, several people and that had commentary and input from an advisory board.
Q. All right. Was it a review of the literature?
A. In some regards, yeah. Yeah.
Q. In fact, did they in -- I believe it was Appendix B, list the literature that they found significant having to do with the subject of the safety and appropriateness of antipsychotic medication for Medicaid children under the age of 16?
A. Yes.
Q. And in that Appendix B, they listed some 131 references; is that right?
A. Yes.

Q. About the same number that Risperdal -- that Janssen had listed in its review of a few years earlier?
A. Roughly, yeah.
Q. All right. And they said that Risperdal was the most studied drug. Do you remember that phrase?
A. Yes.
Q. Mr. McConnico read it to you.
A. Yes.
Q. The most studied drug of the antipsychotics for use in children, and you didn't disagree with that.
A. It's been the most studied but still is not well -- completely characterized.
Q. Well, now you're talking like -- well, when you say -- when you say --
A. Right.
Q. -- not completely characterized, what do you mean?
A. I basically mean that the body of data is still incomplete. All of these studies are short. The longest study that's -- that's done in a controlled way is a year. And in that study -- we talked about it. It's the TEOSS study. The studies that ended up with FDA approval were eight weeks long. There was one study with autism that was a continuation study that was a little bit longer, but that study had all -- you know,

there are lots of serious side effects in that study. In fact, one of the participants at Yale found that the kids kept gaining on average three pounds per month to the point where the average weight gain by the end of six months of these kids who had autism was 18 pounds.

It's -- it's been studied. It's been -- there's lots of reports out there. You can Google it. There's a zillion things. The problem is it hasn't been studied in a complete way. And it hasn't been studied in a way that compares it to equally effective agents that may have significantly less adverse effects.

So, for example, they talk about the indication of autism in schizophrenia and the -- as if somebody who comes into your office, if you don't get Risperdal, they're going to go untreated. Well, there's a lot of other things you can give them that can help them. There are some things that are even not medication. In fact, there's -- the field is emerging that one of the major factors in long-term outcome and health and recovery with people that have schizophrenia have nothing to do with the medications they're on. So you know, it's not like that's the only thing that you can do, if you don't give Risperdal, you can't give anything.

Risperdal -- the statement that Risperdal

is the most studied is accurate, but it's misleading. It leaves people with the impression that, oh, wow, it's been studied. But the reality is even the investigators who did the TEOSS follow-up, their conclusion in their concluding sentence is short-term studies that are controlled are inadequate to give us information about clinical use of this medication. And --

Q. All right. Question.

THE COURT: Interrupt with a question every now and then.

MR. JACKS: I'm doing that right now, Your Honor.

Q. (BY MR. JACKS) And by the way, you said you can Google it, but I think the Court has given contrary instructions in this case to --

A. Oh, I'm sorry. You don't Google it.

Q. Don't get anything balled up here. Now, you mentioned that there was, in addition to TEOSS, a long-term study having to do with children with autism, correct?

A. Correct.

Q. Is that what's sometimes referred to as the Csernansky study? Is that the one you had reference to?

A. I was thinking more about the study that the author was Dr. Martin.

Q. Okay. Well, tell me about --
A. Dr. Martin is --
Q. That's why we've got you here instead of me. Now, tell us about Dr. Martin, who he was, what he did.
A. He was an investigator as part of a large multi-site group that was -- he's at Yale, and he was the lead investigator at Yale for one of the wings of -- one of these multi-site studies, looking at the effectiveness of Risperdal in kids that have autism, and -- that's it. I'll stop there.
Q. What did he find?
A. Basically found that it's -- it's effective for some of the signs of irritability in kids that have autism, but that there are serious weight gain issues with long-term use -- short-term and long-term use of Risperdal.
Q. All right. Now, you have talked about TEOSS, and I'm not going to go back through all of that, but as to efficacy --
A. Right.
Q. -- effectiveness --
A. Right.
Q. -- what did TEOSS find in comparing Risperdal and olanzapine with one of the older drugs?
A. That they were no more effective.

Q. With respect to side effects -- now, Mr. McConnico read you a statement out of this report written by this -- by the agency HHSC or somebody on their behalf to the Legislature, and he said -- he read a quote that said, well, the first generation antipsychotics carry more risk of side effects, and he said "You disagree?" and you said "I disagree."

A. I do disagree.

Q. Why?

A. Well, I think that when you look at all of these medications, they have generally equivalent rates of adverse effects. It's just that they have different kinds of adverse effects. Some will increase risk for weight gain and cardiometabolic problems like diabetes. Others will increase risk for some of these motor movement activity -- motor things that he was talking about. You know, some of them increase risk for sedation. You know, in one of the studies -- in actually several of the studies with Risperdal and autism, the sedation rate was 78 percent in these kids.

Q. We looked at a study when you were testifying before lunch that talked about the issue of whether children are thought to be more susceptible to these side effects than grown-ups. Do you recall that?

A. Yes, sir.

Q. And it -- again, it concluded -- and you tell me if I've got this right or wrong -- that in fact they are?

A. That's correct.

Q. Is that what you believe?

A. That's what I believe.

Q. Now, if -- with respect to the TEOSS study on this business of it's risk of weight gain and diabetes --

MR. JACKS: May we bring up again, please, defendants -- I believe, it is the first of these TEOSS reports, which is Plaintiffs' Exhibit 2287. And may we bring up the conclusions page that we brought up earlier, please, sir?

Q. (BY MR. JACKS) All right. Now, I want to start with the paragraph that picks up after the highlighting and read it, and I want to ask you about it. "These findings have broad public health implications. In the long-term, the metabolic side effects of olanzapine and risperidone may place many youth at risk for diabetes and cardiovascular problems."

Let me stop there. Is the problem of weight gain and diabetes in children receiving antipsychotics of the second generation strictly an olanzapine problem?

A. No.
Q. Is it also a Risperdal problem?
A. Yes, sir.
Q. A serious one?
A. Yes.
Q. Okay. They go on. And I'm going to start reading this and then we're going to get to the end of the page, so I'm going to trust Mr. Barnes to help me out here.

"The second generation antipsychotics are now widely used to treat nonpsychotic mood and behavioral disorders in youth."

Let me stop right there. Is there an FDA indication for the treatment of mood and behavior disorders in kids for Risperdal?
A. Well, if you lump the active manic phase of a bipolar disorder into that affective class, there is for that, but not for depression, not for ADHD, not for conduct -- you know, conduct disorder, not for oppositional defiant disorder.
Q. All right. Continuing, "The balance between potential therapeutic benefits and risks of adverse events needs to be carefully considered in this age group." Agree or disagree?
A. Agree.

Q. Does this -- some of the statements in this report to the Legislature disturb you?

A. Well, I believe that they are reflections of unintended bias. I mean, I think that -- for example, the comment about second generations showing superiority over first generations, I think that that's essentially what the Institute of Medicine was trying to address when they wrote this entire report about the undue influence on physicians in the way they practice that can come from multiple directions. And I just found that --

MR. McCONNICO: Objection. He is getting outside his field of expertise.

THE COURT: May I see y'all just briefly down here?

(Discussion off the record between the Court and counsel)

Q. (BY MR. JACKS) You referred to the Institute of Medicine report -- Institute of Medicine, National Academy of Sciences report --

THE REPORTER: I'm sorry.

MR. JACKS: I'm sorry. Let me just start over.

THE REPORTER: Thank you.

MR. JACKS: And I'll try to slow down on

this.

Q. (BY MR. JACKS) You referred to the report on conflicts of interest in the medical profession published by the Institute of Medicine, part of the National Academy of Sciences.

A. Yes, sir.

Q. And you've referenced that in connection with what you called unintended bias; is that right?

A. Yes, sir.

Q. And what, according to Institute of Medicine in its report, is the problem with this subtle unintended bias of which you speak?

A. Well, the key problem is that when clinical decision-makers, whether it's around prescribing or other practices, receive their information about clinical practice through clinical practice guidelines that may be subtly influenced by the contributors being consultants to a drug company, when studies that are funded by the drug company appear to have different levels of outcome than studies that are funded by government, when the literature -- the academic literature that's supposed to be independent and biased turns out to not be independent and biased, when articles are ghost written by -- and not actually the product of -- all of those different sources --

MR. McCONNICO: Excuse me. May I have a running bill of all of this testimony?

THE COURT: Yes.

MR. McCONNICO: Thank you.

Q. (BY MR. JACKS) Go ahead, Dr. Perry.

A. All of those -- all of those various --

THE COURT: Time out. I need y'all to walk back, and then I'm going to ask you to come walk back right in.

(Jury not present)

THE COURT: And I want the record to reflect the sidebar discussion that we had, which was that -- that in my opinion this area -- this topic had been opened up during cross-examination, and so -- but in response to Mr. McConnico, you have a running objection to this entire line of testimony. Bring the jury back in.

(Jury present)

THE COURT: Mr. Jacks.

Everybody be seated. Thank you.

MR. JACKS: Thank you, Your Honor.

Q. (BY MR. JACKS) Dr. Perry, you were speaking about unintended biases, and I don't want to ask you to repeat what you said before the -- Mr. McConnico rose. Let me ask you this. We talked about the fact that

there's a list of 131 references in this report to the Legislature by HHSC or people writing it at their request. Did you look through that list of references?

A. I did.

Q. Was the TEOSS study referenced among these 131 references?

A. I think it was. I'm not sure the follow-up was. But it wasn't included in the table about Risperdal studies for some reason.

Q. Do you think that was unintended?

A. I can't say.

Q. Mr. McConnico asked you about call notes, and he went through a number of them with you. Now, you've testified and there's absolutely no dispute in this lawsuit that physicians may and do and sometimes must write a prescription for an off-label use, correct?

A. Correct.

Q. As a doctor, do you think that's a good thing?

A. I do.

Q. There's also no dispute in this court that off-label promotion by pharmaceutical companies is prohibited, is illegal. As a physician, do you think that's good?

A. Yes.

Q. How come?

A. Because I think that physicians, like all other people, like scientists, are influenced by both direct and indirect methods that are trying to persuade them about a practice or a product.

Q. I'm not going to go through these call notes that he read to you, by I'm going to ask you about one. I'm not going to even ask that it be brought up on the screen, but it was from the page ending in 19632 that Mr. McConnico referenced, and the sales representative was Laura Haughn. Is that a name you recognize?

A. Yes.

Q. Did you review other call notes by her?

A. Yes.

Q. Did you review her deposition testimony?

A. Yes.

Q. Did you review a memorandum that she wrote that was sent on up through the ranks to the -- a man named Dave Meek, the field sales director for the whole company?

A. I believe I did. I can't --

Q. Well, let me see if this will ring a bell with you. Do you recall her saying don't use this in a selling situation and then closing by saying let's go beat the everliving, everloving hell out of Abilify?

A. Yeah, I do remember that.

Q. All right. In this call note, she in fact says focus on why Risperdal is best treatment option for kids and adolescents, parentheses, autism indication, history of treatment success, safety, tolerability. Now, at that -- this date is May 27, 2004. Was there any autism indication --

A. No.

Q. -- at that time?

A. No, sir.

Q. I'm not going to read all of it, but this was a doctor who said he didn't want to do any harm to his patients. And here's a part that I think wasn't read before. "Sell hard against Abilify. They're doing a hard core press."

Now, is there any doubt in your mind, as a doctor, that if a sales representative were telling you these things in May of 2004, you would regard that as promotion of Risperdal that was out of bounds?

A. I would.

Q. Last question. There's been discussion -- pardon me, next to the last question. You were asked about the call notes that were blank. Did you notice what the specialty was on all of those thousands of call notes?

A. C&A, child and adolescent.

Q. All right. It said CHP, didn't it?
A. Yeah, CHP.
Q. And for some reason, they didn't write about what they told those CHP doctors?
A. Correct.
Q. Now the last question. As someone who has -- you were at Texas Children's when Risperdal was introduced into the market, were you not?
A. Correct.
Q. In those years, you used both first generation and second generation antipsychotics with your patients as appropriate; is that true?
A. I did.
Q. Did you have some awareness of the relative costs?
A. I'm ashamed to say that I didn't until partway -- several years into the process when I had a patient come back with an unfilled prescription saying I can't afford this. And --
Q. If -- would it surprise you to learn of evidence that the cost disparity between Risperdal and, say, haloperidol was 45 times as much?
A. That's a lot -- I was not aware of that, actually. I mean, I -- if I think back on -- back then, I could probably figure it out, but I hadn't thought

about it in those terms.

Q. Are you aware of any science, any literature, any studies that in your mind would justify the 45 times price differential based on the effectiveness and safety of the drug?

MR. McCONNICO: Objection. That is outside his field of expertise.

THE COURT: I know it was the fifth question after he said the last question. That much I know. But the objection is sustained.

MR. JACKS: I'll pass the witness. Thank you.

RECROSS-EXAMINATION

BY MR. McCONNICO:

Q. Dr. Perry, do you know the doctor that provided most of the information for the Texas Health and Human Services Commission report to the Texas Legislature?

A. The one doctor, no.

Q. Do you know any of the doctors that provided this information?

A. I know the names and several of the physicians that were on the committee or the advisory group.

Q. And you're not telling anybody on this jury that Janssen controlled any of those doctors, are you?

A. No.

Q. Those doctors, from what you know, are independent, well regarded in the field, and they can make up their own minds from what they see?

A. I believe that's accurate.

Q. One of the acknowledgments, the Texas Health and Human Services Commission wishes to acknowledge Dr. Nina Jo Muse, MD, a child adolescent psychiatrist, who provided information on the safety and appropriateness of antipsychotic medications for the pediatric population for this report. Do you know that lady?

A. No.

Q. You're certainly not saying Janssen controlled her in any way?

A. No.

Q. You're not saying that Janssen controlled the report that was sent to the Texas Legislature?

A. I think they influenced the opinions of the people who participated. I think that many of the contributors were -- certainly would be in a conflict of interest position based upon their relationship with J&J in the present and the past, and -- but I don't think that J&J controlled them.

Q. Yeah. And this gets back to your theory of unintended bias, doesn't it?

A. It's not really my theory. It's -- it's --
Q. It's a theory of unintended bias, isn't it?
A. No. There's very well-documented literature about unintended bias in this area --
Q. Doctor --
A. -- and it's articulated in the Institute of Medicine report.
Q. Have you done a study for your testimony today?
A. A study?
Q. Yes, sir.
A. No.
Q. Have you done a study of unintended bias that you've talked to this jury about? Have you?
A. Have I done it?
Q. Yes, sir.
A. No.
Q. Okay. You said this was a report. You haven't gone out and done any study to see if these people were influenced by unintended bias, have you?
A. Have I done an investigation of that --
Q. Yes.
A. -- or a study?
Q. Either one.
A. Well, I'm aware of the relationships that several of them have.

Q. Listen to the question. Have you done a study that these people were influenced by unintended bias?
A. I wouldn't call it a study, no.
Q. Okay. Now, you're being paid for your testimony, aren't you?
A. I am.
Q. You have a relationship with these people, don't you?
A. I do.
Q. You've spent a lot of time with these folks, haven't you?
A. Absolutely.
Q. You've developed a close relationship with some of them?
A. Some of them, yeah.
Q. Yeah. Those are the things that sometimes unintended bias kind of creeps in and has an effect on?
A. Absolutely.
Q. Now, you're not saying that Janssen in any way influenced the FDA?
A. Other than providing their reports.
Q. Well, and the reports that the Janssen reported to the FDA were good clinical studies and evidence, weren't they?
A. The ones that were used, yes.

Q. Yeah. And so based upon those good reports and those studies, those double blind placebo studies, the FDA approved Risperdal for certain uses in child and adolescents, didn't they?

A. Correct.

Q. You said several times that Zyprexa generally causes more weight gain than Risperdal, right?

A. Correct.

Q. That's information a doctor should know?

A. Yes.

Q. You know Dr. Alice Mao?

A. I do.

Q. Does she treat more children and adolescents today than you?

A. Probably in any given week currently, sure.

Q. Is she well respected in your speciality of child and adolescent psychiatry?

A. I think she generally is, yeah.

Q. Yeah. Now, you said earlier when you were asked by Mr. Jacks that doctors in treating people can do a lot of things in the treatment?

A. Correct.

Q. It's real important for doctors to have a lot of alternatives in treating people?

A. It's helpful, yes.

Q. And sometimes it's important that they have alternative drugs that they can give to patients?

A. Correct.

Q. That's real important for doctors?

A. Yes.

Q. Because at the end of the day, they're the ones that decide what drug is best for what patient?

A. They make that decision, yes.

Q. Thank you.

THE COURT: Thank you for your testimony. You may step down.

And may I see y'all just briefly at the bench?

(Discussion off the record between the Court and counsel)

THE COURT: Ladies and gentlemen, let's take a five-minute break as we get set up for the next witness.

(Recess taken)

(Jury present)

THE COURT: Were y'all going to do another deposition?

MR. MELSHEIMER: I'm sorry, Your Honor. At this time the plaintiffs call Mr. Tone Jones, who is a Janssen -- a party associated with an adverse party.

Mr. Jones is on the organizational chart here as a district manager for Janssen.

THE COURT: If you have any problems seeing the screen, let me know.

(Video played as follows:)

TONE JONES,

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

DIRECT EXAMINATION

Q. Would you state your name for the record, please, sir.

A. Absolutely. My name is Tone Jones.

Q. Mr. Jones, where do you live?

A. I live here in Houston, Texas.

Q. Would you describe, please, sir, your educational background?

A. Sure. I went to Oklahoma State University, and I majored in speech communications.

Q. Can you tell us about when anybody on either side of this lawsuit first got in touch with you about this lawsuit?

A. It was in the summer, I think, if I recall, of 2009, June time frame, I think.

Q. And who first communicated with you in any way about this lawsuit?

A. My former employer, through Johnson & Johnson legal.

Q. Did anyone on behalf of Janssen ever speak with you about the possibility of signing up as a consultant with regard to this case?

A. Yes. I received a package in the mail, FedEx package, you know, stating, you know, will give me the opportunity to be represented by J&J. And, again, I was no longer with the company, so I wasn't -- I made some phone calls and, you know, thought that it would be in my best interest to not pursue that matter.

Q. All right. Are you here today without any lawyer representing you as a witness today?

A. Yeah. I have no legal -- no one's here representing me.

Q. All right.

A. Representing myself.

Q. Now, sometime after you were contacted by Janssen about this case, did you receive any contact from anybody else about the case?

A. Yes. I received a call -- it was sometime after. Let's see. I was contacted in June of 2009. So then probably -- I can't remember specifically when I was contacted, you know, by, you know, Patrick. And then just -- you know, again, just sharing about the

opportunity to share what occurred, you know, would I be willing to visit about the situation and so forth.

Q. All right. And when you say Patrick, do you mean Mr. Patrick Sweeten with the Texas Attorney General's Office?

A. Yeah, Patrick Sweeten.

Q. All right. Now, when you were contacted by Janssen, I believe I understood you to say, and correct me if I'm wrong, that among the things you understood was that you could sign some sort of a consulting agreement with Janssen if you chose to do so; is that right?

A. Yes, that's correct.

Q. Did you have any understanding about whether Janssen would, if you did that, compensate you in some fashion for time you spent working in connection with this case?

A. Yes. That was part of -- within the -- within the document that was sent.

Q. And then let me ask a similar set of questions with regard to the Texas Attorney General's Office. Did the Texas Attorney General's Office ask you to sign any kind of consulting agreement with them?

A. No.

Q. Did the Texas Attorney General's Office speak

with you about compensating you for any work you might do or time you might spend in connection with this case?

A. No, not at all. That actually made it more comfortable for me to, you know, be here today and share what knowledge I have just to represent myself.

Q. All right. Now, have you had any meetings with Mr. Sweeten?

A. Yes.

Q. All right. And have I attended some of those meetings?

A. Yes.

Q. All right. Let me ask the same question about me and my client and my law firm. Has -- have I or Allen Jones or the Fish & Richardson law firm ever asked you to sign any kind of consulting agreement?

A. Nothing.

Q. Or spoken with you about any compensation for any time you spent in connection with this case?

A. Nothing, no.

Q. I want to go into a little more detail about your history of employment with Johnson & Johnson or Janssen. Was that the first employer you had out of college?

A. Right out of college. I wasn't drafted by the NFL or picked for the major league baseball team, so J&J

drafted me out of college.

Q. When -- and I -- was it -- I believe you said it was 1998; is that right?

A. Yes, I started in April of 1998.

Q. And -- and your first job with Janssen involved doing what?

A. As a primary care sales representative in the Oklahoma City, Oklahoma area.

Q. You said that after serving in Oklahoma for some period of time you were, I believe you said, promoted to Houston. Did I hear that right?

A. That is correct, in 2000.

Q. Okay. And in 2000, you stated in an earlier answer that you assumed some capacity with the CNS part of Janssen. Is that -- did I understand that correctly?

A. That is correct.

Q. And if I've understood you correctly, when you came to Houston, you began promoting the drug Risperdal; is that correct?

A. Risperdal, antipsychotic.

Q. Were there any other drugs that you promoted once you came to Houston and were working in the sales force here?

A. No. The only product in our bag at that time was Risperdal because that was, you know, J&J's premier

product for sales and marketing efforts, and so we had no other distractions but Risperdal.

Q. All right. After doing that for a period of time, I believe you said you got a promotion; is that correct?

A. Correct.

Q. To district manager?

A. To district manager.

Q. What was your district?

A. My district at that time, I had pretty much all of Houston, and then I had reps over in Beaumont at that time and -- because that was before the expansion. So pretty much it was very compact, all of Houston, and then obviously, you know, went over to Beaumont, and then I had North Houston up to the Huntsville area.

Q. And first of all, can you take a look at Exhibit 2394 and tell me -- and tell the jury in general what it is?

A. Sure. This is a Janssen organizational chart from the national sales director down to the district manager level. It illustrates field sales director roles, regional business director roles and also the district managers across the country.

Q. All right. Now, does your name appear on that organizational chart?

A. Yes, it does.
Q. And what was Mr. Kraner's position at that time?
A. He was the regional business director.
Q. In that sense, was he your boss?
A. He was my boss.
Q. Would you highlight the box in which his name appears?
A. Absolutely.
Q. And then working your way up the ladder, what would have been the next level of hierarchy, if you will --
A. Sure.
Q. -- going up above Mr. Kraner?
A. Rob Kraner's boss was Dave Meek. He was the field sales director.
Q. And then would you take it on up to the top of the ladder. Who was above Dave Meek in the Janssen psychiatry sales organization?
A. Dave reported to Mike Walsman, who was the national sales director.
Q. If you would, please, so the camera can hopefully pick it up, would you hold that organizational chart up and hold it still. You're doing a good job of that. And so you're shown as the district manager near

the bottom right-hand side of the organization chart. Your immediate boss was Rob Kraner, the regional business director. And then working the way up the ladder above Mr. Kraner was Mr. Dave Meek, the field sales director, and then in the top box Mike Walsman who's national sales director along with Jeff Bailey; is that -- is that right?

A. Yep, that's correct.

Q. All right. Now, are there other district managers shown in the state of Texas on this organization chart?

A. Yes.

Q. How many others?

A. There were myself -- three of us.

Q. And for about how long was it the case that you were district manager and Rob Kraner was your immediate boss?

A. Until I was separated from the company, so from 2002 to 2009.

Q. All right. And that would include the entire time you were a district manager?

A. Correct.

Q. When you came to the CNS sales force in Houston, did you receive any training in -- in sales as it related to their -- their work?

A. Well, absolutely. CNS training you go to New Jersey, the home office in Titusville. No, I'm sorry. It was in Princeton. They were in Princeton because it was at the hotel there in the Princeton area.

Q. And then did -- once you had completed that training, did you receive any other guidance in learning how to operate as a salesperson in the CNS sales force?

A. Sure. The -- the training consisted of field training, which you had a -- a field trainer that worked with you for a couple of weeks. And then you're at that time ready to move into -- you know, you're working in, you know, silo, if you will. And I was able to go a couple of weeks by myself and then Lisa Little would circle back to check up on me to provide further direction.

Q. All right. Did other salespeople in the organization receive the same kind of training or did they have some different kind of program?

A. No, that was pretty much the road map of everyone's training coming into that franchise.

Q. Were sales messages ever discussed at these sessions?

A. The sales messages was a bread and butter, if you will, skill development that we focused on very consistently at almost every meeting, either as a sales

rep or even as a, you know, district manager.

Q. Where would you as a sales rep or as a district manager get the sales messages?

A. We would obtain the sales messages from the sales and marketing team that was rolled down to the sales trainers and then, you know, down to the -- the RBDs and then to the district managers.

Q. All right. RBD would be regional business director?

A. Regional business director.

Q. Throughout the time that you worked either as a sales representative or later as a district manager in the CNS sales force, did you personally ever deliver sales messages that you made up yourself as opposed to the sales messages that you were given guidance and instruction about from the company?

A. No, I didn't make up any sales messages.

Q. During the time you worked as a district manager, you, as I understand it, supervised other sales representatives; is that true?

A. Correct.

Q. About how many?

A. I would always have between -- the most I had was 11, but typically around nine, nine or ten reps.

Q. Would you have occasion as district manager to

observe them doing their job?

A. Correct, yes.

Q. On what occasions?

A. Typically I try to get with -- be in the field with those representatives, you know -- my goal was once a quarter.

Q. During those seven years as you observed the sales representatives who worked in -- in your team, did, in your experience, those sales representatives create their own sales messages or did they use sales messages that had been handed down to them by the company?

A. Yeah. The messages that were delivered was always on -- you know, focused on what the company message would provide, you know, through the workshops, through the training that -- that was received from home office, so nothing that, you know, the representatives will make up on their own.

Q. When you first went to work in the CNS sales force promoting the drug Risperdal, did you receive any education or instruction about the Risperdal label, what was included in the FDA-approved labeling for Risperdal?

A. The training was very in depth in terms of product knowledge and also through the labeling, which at that time was labeled just for schizophrenia for

patients that were of age, of 18 and above.

Q. Well, during the time when the only indication was for schizophrenia, was it limited to adults with schizophrenia?

A. Correct.

Q. When the first bipolar indication came along, was that an indication that included only adults or did it also include children?

A. It was also for adult patients.

Q. When was the first time that Risperdal received any indication that was approved by the FDA for use in children?

A. Risperdal autism was the first indication, and the date had to be very close to 2006, I believe, time frame.

Q. When you were a salesperson before you became a district representative, did you call on physicians who primarily treated children as opposed to adults?

A. I did have some targets that were primarily child and adolescent prescribers or physicians.

Q. Were your sales activities in that regard -- was your district manager, Lisa Little, aware of your calls on child and adolescent psychiatrists when you were a salesperson?

A. Yes.

Q. When you became a district manager, did sales representatives who worked under your supervision also call on physicians who primarily took care of kids?

A. Yes.

Q. And was it known even above your level as district manager, say at the regional business director, manager or above, that Janssen sales representatives who were promoting the drug Risperdal were calling on physicians who primarily treated children, not adults?

A. Yes.

Q. What was Concerta?

A. It was for ADHD.

Q. And what age patients were the -- was Concerta mainly intended for?

A. For kids. Any patient that was south of 18.

Q. Was there ever a time during the time you worked with Janssen, either as a sales representative or as a district manager, when there was a co-promotion of Risperdal and Concerta?

A. Yes.

Q. Did you develop an understanding through the information you got from the Janssen sales force management about what the strategy was that was behind this idea of co-promoting Concerta along with Risperdal?

A. Yeah. You know, Concerta is -- was not a

Janssen product, if you will, under the J&J umbrella. It was with Ortho-McNeil. Obviously when that product was -- when the decision was made for that product to be in our sales bag, too, a couple things. One, it diverted our focus on Risperdal which at the time was being -- the competition was beginning to increase and we, you know, had a tough time just keeping to make sure we had a market share for Risperdal. Number two, we had to promote with our sister company, Ortho-McNeil, which was a challenge in itself from a partnering perspective. So that raised a lot of questions from the field on the whys behind it, and thus, you know, some of the responses was because it would help justify being in some of our targeted customers' areas, for example, the -- the child and adolescent doctors.

Q. Could you explain why being able to co-promote Concerta and Risperdal might help you get into offices that you might not otherwise get in?

A. Well, again, because, you know, Risperdal was -- the indication was above 18 and we only had schizophrenia indication and then Concerta was south of 18, and so the two products allowed you to talk about two different patient types that that prescriber would see throughout the course of a day.

Q. And when they did that, did those sales

representatives who worked under your supervision call upon child and adolescent psychiatrists in order to promote Risperdal to them along with Concerta?

A. Yes, they had a responsibility for both products.

Q. In terms of their compensation, do you recall whether there was any difference in how much credit they got for Concerta sales as opposed to Risperdal sales?

A. The sales weighting was 70 percent Risperdal, 30 percent Concerta.

Q. If I'm understanding you correctly, and tell me if I'm not, if in a given sales call there was -- you know, if -- if the overall results of the efforts over a period of time resulted in both Concerta and Risperdal sales, the sales representative would receive more compensation for the Risperdal sales than for the Concerta sales; is that how it worked?

A. Yeah. Yeah, you know, because of the weightings, product weightings.

(Video stopped)

MR. MELSHEIMER: Your Honor, we're transitioning to another subject with Mr. Jones. Would this be a good time for the break?

THE COURT: It would. I'll see y'all in the morning. Have a safe trip home.

(Jury not present)

THE COURT: Let me see if I can ask a leading question. There's nothing to take up, is there? No, there's nothing to take up, is there?

MR. MELSHEIMER: I don't think so, Your Honor.

MR. McCONNICO: Judge, an agreed order. For God's sake, don't start this.

MR. MELSHEIMER: I think this is on the Glenmullen.

MS. TIMMS: It's on Glenmullen. And they've looked it over and they had a small change and we made it.

MR. MELSHEIMER: Yeah.

MS. TIMMS: Is it good?

MR. MELSHEIMER: It's good.

MS. TIMMS: Okay.

THE COURT: You leave it in my hands, I'll lose it.

MR. MELSHEIMER: Thank you, Judge.

(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 17th day of January, 2012.

/s/: Della M. Koehlmoos
DELLA M. KOEHLMOOS, TX CSR 4377
Expiration Date: 12/31/13
Official Court Reporter
250th District Court
Travis County, Texas
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