REPORTER'S RECORD
DAILY COPY VOLUME 3
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 11th day of January, 2012, the following proceedings came on to be heard in the above-entitled and numbered cause before the Honorable John K. Dietz, Judge presiding, held in Austin, Travis County, Texas:

Proceedings reported by machine shorthand.

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I N D E X

DAILY COPY VOLUME 3

JANUARY 11, 2012

PLAINTIFFS' WITNESSES

EXHIBITS OFFERED BY PLAINTIFFS

EXHIBITS OFFERED BY DEFENDANTS

EXHIBITS OFFERED BY DEFENDANTS (Continued)

PROCEEDINGS

JANUARY 11, 2012

(Jury present)

THE COURT: Who are these people and where did they come from? They keep coming back. McConnico and Jacks reminded me of like two old cop lawyers. It was like having Tibby Wright and Broadus Spivey in here. Let me mention a couple of things. Y'all be seated. I know you've got something that I'll look at.

I just went back and I talked to the jury, and I said, "How are y'all doing?" And they said, "It's hot in here." And so then I said, "Everything going -- is there anything we can do for y'all?" And the guy says, "Well, I want to talk about exhibits," and I went, "Whoop, can't do that." And he said, "Well, we couldn't see some of the ones yesterday. They were too small type." And so when y'all do your magnification and you draw your box and stuff, some of us senior citizens are needing larger type, like 16, 20 point stuff. And then they said, "Also speak up when back is turned, can't hear." Is that from them?

MR. JACKS: Got it.

THE COURT: It was you, Jacks.

MR. JACKS: It was me. Della pointed it out to me.

THE COURT: Because McConnico faces them when he's begging them. So the other thing is, somebody piped up -- and I will try to have these conversations out here, and I told them I would. They piped up and they said, "Are we going to have all this stuff available to us?" And I said, "I'm going to talk to y'all when you get out here."

But one of the things that I want y'all to consider, when I tried the mold case ten years ago, there were only 1500 exhibits admitted, but they were all done electronically. And so when the jury went out, somebody said, "Well, how are we going to give the jury the documents?" So we greed to put together 500 of the key documents. And -- now, I don't know how many documents are here, but I keep hearing 8,000 pages, 11,000 pages, something -- am I close?

MR. McCONNICO: You're close, Your Honor.

THE COURT: Okay. Well, psychologically, what happens when you hand 11,000 pages to somebody and you say "Here's something you cannot read and get through." And so I really think that, as y'all have on so many other issues, you might think about what are the key documents; they would have everything available to them, but there's some easy way to get to the key documents. And I don't know how many key documents, but

good God Almighty, there can't be that many, maybe only 1100 or maybe 110 or something along that thing, but y'all -- if y'all would be so kind as to talk about it and see about approaching it. But I mean, I can tell you that I'm sure, psychologically, when you hand somebody that, it -- it just makes it impossible for them to think about doing it, and so then they do this (indicating).

MR. JACKS: Understood.

THE COURT: Okay.

MR. JACKS: Thanks.

THE COURT: And let me look at this before I get tied up into it. Are these with the first witness?

MR. McCONNICO: Your Honor, I'm not certain what you're looking at, so I guess --

THE COURT: I'm looking at defendants' objections to plaintiffs' January 11, 2012 exhibits.

MR. McCONNICO: I don't think it is, because all the exhibits -- the ones that we have are the ones that you and I went over this morning.

Am I correct, Natalie?

MS. ARBAUGH: (Nods head affirmatively).

MR. McCONNICO: So it's not, Your Honor.

THE COURT: So here's what would be --

here's what would be really helpful to me.

MR. McCONNICO: Okay.

THE COURT: What would be really helpful is if I had a hard copy of these exhibits in this order and I could look at them. Now, the proviso is, you hand me this much -- and I'm not going to go through it all.

MR. McCONNICO: Right.

THE COURT: I'm not going through it. I can't. But if you could give me the hard copy, then what I can do is, while y'all are talking, I can multi-task and kind of look at these as I did yesterday on some stuff.

MR. McCONNICO: Right. And I think we can pull out really the relevant pages.

THE COURT: Okay.

MR. McCONNICO: Because they're going to be -- some of these are going to be multiple pages, but we're really only having a problem with particular pages.

THE COURT: Right.

MR. JACKS: May I ask a question, because I haven't looked at that? But in which -- do these fall in the category of we need a ruling but we aren't going to be arguing this objection to the Court.

MS. APPLEBERRY: There are many of

these -- Steve has the ones that we plan to argue.

THE COURT: Yeah. I'm going to tell y'all that I'm -- you're going to -- the more stuff you put in writing, great, because I'm going to just put it in, because my plan is -- my discussions is going to be here are my rulings, respectfully.

MR. McCONNICO: We understand.

THE COURT: Okay. Because there's going to be so much of it that y'all, respectfully, are going to object to, and so the more I can -- you've just got to pretend that I've got some semblance of notion of the rules of evidence and that I'm going to be looking at the World Wide Web on Lexis and doing my research. And so on evidence, I don't find it that -- respectfully, I don't find it that helpful.

MR. McCONNICO: Right.

MS. APPLEBERRY: Tommy, are you going to play it this morning?

MR. JACKS: No, this afternoon. Would it help the Court if you had a list like this if there were some highlight on the ones that they want you to really look at?

MR. McCONNICO: What I was going to --

THE COURT: Actually -- actually, if you want to know the way I would ideally like it --

MR. JACKS: Yes, we would, Your Honor.

THE COURT: -- okay, is how I would like -- I would like it in bite-size chunks like that where I deal with it, because once we get one of these omnibus things, then they become -- then I've got to look through a bunch of pages. And so my preference is, if I can take it in bite-size chunks --

MR. JACKS: Right.

THE COURT: -- I want it that way.

MR. JACKS: And here's the -- there are going to be some objections where the offering party already knows you're going to overall it, and they don't want to waste your time with asking you to look at those. There are some that they'd like for you to really look at because they think maybe they've got a chance that you won't overrule it. And we're trying to give you only the latter group to attend to and let you know which ones we think fall into which category. That's kind of at least the way we've been approaching it.

THE COURT: I need to have a conversation with y'all over here.

MR. JACKS: Understood.

(Discussion off the record)

MR. McCONNICO: Your Honor, can we

pre-admit some records real quick?

THE COURT: Yes, you can.

MS. APPLEBERRY: Your Honor, defendants are going to admit Defendants' Exhibit 7, 43 --

THE REPORTER: Wait, wait. I'm sorry.

THE COURT: I need this part so she can get the record.

MS. APPLEBERRY: Defendants' 7, Defendants' 43, Defendants' 50, Defendants' 73, Defendants' 74, Defendants' 417 and Defendants' 1387. These will be used with witnesses today. It's my understanding the plaintiffs have no objection to the admission of these exhibits.

THE COURT: They're admitted.

(Defendants' Exhibits 7, 43, 50, 73, 74, 417 and 1387 admitted)

MS. ARBAUGH: Yes.

MR. JACKS: Your Honor, actually, we have one exhibit that was not on the list of 300 that will be introduced with the first witness this morning, and it is Plaintiffs' Exhibit 1646, and we understand there's no objection to that.

MR. McCONNICO: No objection.

THE COURT: It's admitted.

(Plaintiffs' Exhibit 1646 admitted)

(Jury present)

THE COURT: Let me visit with y'all for just a second. We've called building maintenance to see -- because it is hot, and it's -- at least it's hot when you're wearing polyester.

Number two, I talked to them about the size of the print, and we're going to kill all of the lights, and hopefully that will make it better. But if there is a problem, let's just use the sophisticated thing of shouting out, "Can't see," and then that will alert us that we need to do something. And likewise, I thought it was a particular attorney who shall go unnamed, but I said, "Mr. Jacks, when you turn your back to the jury, they can't hear you when you're talking," and so I think this unnamed lawyer will do something different.

Third, there was a -- for -- it was a slow news day yesterday and there was a story about this case in this morning's paper, so I'm anticipating that there's going to be from time to time a story. So generally, what we ask of juries in this situation is if you just happen to see something, put it aside and don't read it. With all due respect to the newspaper, you can read in the paper and go to court and it's like two different events. And again, it's this outside

influence that we're trying to guard against. And so you're free to read the rest of the paper, do whatever, but just don't read these articles. Does that sound all right?

(Jury responded affirmatively)

THE COURT: And finally, with the bulk of the documents that will come in, I have asked them to try to work together to pick out the ones that are most important so that -- rather than getting a *Doomsday* book, you'll get something more manageable.

With that, Mr. Jacks.

MR. JACKS: Yes, Your Honor. May I approach about one matter before we get underway.

(Discussion at the bench as follows:)

MR. JACKS: Both sides have greed to supply this list of acronyms and a note page for each witness with the witnesses' picture, and we would ask whether these could be distributed to the jury. And we're all in agreement about both doing that and about how they look.

THE COURT: And may I see it?

MR. JACKS: Yes, you may, Your Honor. And they'll get supplemental pages daily as witnesses are being presented.

THE COURT: If you'll give them to Stacey,

and Stacey does the distribution.

MR. JACKS: Yes.

(End of bench discussion)

THE COURT: Your cup runneth over. What they're saying is that they're -- we're going to distribute a notebook that both sides have greed to. It'll have a page of acronyms that will be used throughout this trial, and there's a brief description as to the acronym. And then there is a page of each witness who testifies, and you'll see it with a picture and a space to make notes if you're inclined to make notes. You're not required to make notes, but you're free to make notes. And the only thing that we ask is that when we go home at night, that these notebooks be given to Stacey or our substitute bailiff who will be here for three or four days.

Mr. Jacks.

MR. JACKS: Your Honor, at this time, plaintiffs call, by deposition, Dr. Alexander Miller. And we are calling him as a witness identified with an adverse party.

(Video played as follows:)

ALEXANDER MILLER, M.D.

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

DIRECT EXAMINATION

Q. Could you state your full name, please?

A. Alexander Lewis, L-e-w-i-s, Miller.

Q. Okay. Can you kind of walk us through, starting in spring of 1996, your involvement --

A. Yeah.

Q. -- with TMAP?

A. I have to say to the best of my recollection --

Q. Sure.

A. -- because this was a while back. But the first event, formal event that I recall was the -- it's the consensus conference on the treatment of depression. And that, I believe, was in the summer of '96.

Perhaps in September of '96 we had a -- a conference on treatment of schizophrenia and bipolar disorder in -- I think it was in Dallas. The other conference, the depression conference -- I didn't go to the depression conference. I think it was in Galveston.

Then in Dallas we had a meeting at which already there were identified sites, meaning both inpatient and outpatient mental health treatment sites identified and presentations by some people from the Expert Consensus Guideline serious about the Expert Consensus Guideline treatments for schizophrenia and bipolar disorder.

Q. And when you say "expert consensus guidelines," what -- what are you talking about?

A. So the expert consensus guidelines was -- were guidelines for treatment of schizophrenia, bipolar disorder and major depression that were based on sort of a questionnaire process with experts and giving experts various clinical situations and asking them to rate different treatment options under those conditions. You know, if -- if a patient presents with symptom X and something else, which of the following options would you select, that -- that kind of process.

Q. And going back to the expert consensus guidelines, that's something that you-all reviewed in the summer of 1996 as part of the schizophrenia consensus conference?

A. Yeah. Yeah, I mean, that was a -- as I say, it was in Dallas. My recollection is September.

Q. September. I'm sorry.

A. Yeah. And -- and we actually had presenters from the Expert Consensus Guideline serious. I think Dr. Allen Frances and Peter Weiden were there.

Q. I think that's right. I think the expert consensus guidelines were published before you-all met in September of 1996; is that correct?

A. I think so, yeah.

Q. Okay. Did you-all adopt those whole cloth?
A. Yeah, initially.
Q. So any work that you performed for TMAP was on behalf of whom?
A. I was an employee of the UT Health Science Center in San Antonio and all the salary funding came from them.
Q. When the meeting was held, how were the medications that were going to be listed in the algorithm -- how were those decided upon?
A. The Expert -- we just adopted the Expert Consensus Guideline.
Q. So the Expert Consensus Guideline was adopted --
A. Correct.
Q. -- wholesale?
A. Right.
Q. And as far as what was listed in the algorithm on Stage 1 was conventionals and risperidone.
A. Correct.
Q. And Doctor, I'm going to hand you a copy which has been marked previously as Exhibit 559. And I'm going to ask you, does Exhibit 559 -- does this contain the Expert Consensus Guideline serious for schizophrenia?

A. I think so.

Q. So Page 13 contains the algorithm that was adopted by the TMAP group?

A. Yeah, simplified. I mean, it -- the -- first it put conventional antipsychotics and risperidone on equal footing and -- and then it basically said if one fails, you use the other.

Q. Okay. Doctor, who provided the funding for this Tri-University schizophrenia guideline?

A. It says Janssen Pharmaceutica.

Q. Pharmaceutical companies shouldn't try to guide or design a research study to favor their product when it's not supported by sound medical science; is that a fair statement?

A. I would agree.

Q. That pharmaceutical companies should not use honoraria or other forms of monetary payment to influence medical professionals or administrators to make decisions favorable to a pharmaceutical company's product; is that proper or improper?

A. I think that's a reasonable statement, that it shouldn't be used for that purpose.

Q. That the pharmaceutical companies shouldn't use money to influence medical decision-making; fair statement?

A. I agree.
Q. Well, we certainly know that you were involved with efforts to promulgate TMAP in Texas and elsewhere, right?
A. Yes.
Q. No doubt about that.
A. Right.
Q. You took trips all over the country to do that, right?
A. I did.
Q. Did anyone from Janssen ever tell you during that time period when they were flying you all over the country -- did they ever tell you that they were, in their own internal documents, speaking of the leverage they were attempting to gain from the influence of people like you?
A. No, sir.
Q. If they had told you that, do you think you would have continued to participate in efforts they funded to promulgate TMAP?
A. If they basically said "We're using you," I would have probably not -- not continued to participate.
Q. Well, now, there -- no one's -- no drug company is going to be dumb enough to tell somebody that they're actually being used, right?

A. Yeah.

Q. Are you aware that -- or did anyone from Janssen tell you during your involvement with -- with TMAP and Risperdal that they saw programs like TMAP as a way to drive or increase the sales of Risperdal?

A. No.

Q. I've handed you what we've marked for identification as Exhibit 645. Can you tell me what this is?

A. Sure. This is from my home accounting program, Quicken, and I went back to 1995 looking for any honoraria that I had received from then until present.

Q. This document reflects -- I haven't counted them. It's -- it's certainly in excess of 20 entries between 1995 and 2005 for a total of almost $70,000?

A. Right. There -- I noticed there was one -- the one that's crossed out --

Q. What did you do with all this money?

A. You mean how did I spend it?

Q. Yeah. Did you have any special allocation for it or did it just go into your general funding?

A. Yeah. Now, this is my home funds and the -- the particular account that it went into is just a savings account that I keep.

Q. So you didn't -- you didn't donate this to

charity or turn it back to anyone else; this is just money that you kept?

A. Yeah. Well, yeah, correct.

Q. Now, as I understand it, the original algorithm in September of 1996, before Janssen had committed any funding, had the -- the older atypicals and the newer atypicals at the same level in the algorithm; is that a fair statement?

A. In 1996?

Q. Yes.

A. Yeah, right.

Q. To put it another way, the first generation and the second generation were at the same level.

A. Right.

Q. Let me draw your attention to Exhibit 521, moving ahead a few months to March 6th, 1997. And again, at this juncture, if you look on Page 2 of Exhibit 521, Janssen has, in fact, provided the $75,000 in funding, correct?

A. Right. I wasn't at this meeting.

Q. You're not disputing the accuracy of the facts on Exhibit 521, are you?

A. It says "received" and then it lists the companies and Janssen for $75,000, so that's what it says.

Q. In the summer of '97, in the Galveston meeting, the first generation antipsychotics moved to Level 3.

A. Right.

Q. The second generation remained at Level 1 --

A. Correct.

Q. -- correct? Such as Risperdal, right?

A. Right.

Q. And later the first generation antipsychotics ultimately moved to Level 4.

A. Correct.

(Video stopped)

MR. McCONNICO: Your Honor, the defendants call their deposition testimony of Dr. Miller.

(Video played as follows:)

CROSS-EXAMINATION

Q. Could you describe your educational background for us, please, Doctor?

MR. JACKS: May we stop for a minute.

(Video stopped)

MR. JACKS: May we approach, Your Honor?

(Discussion at the bench as follows:)

MR. JACKS: Would you mind informing the jury that the deposition exhibit that the witness says or attorney says is a different number, but when the first page it showed -- if you look at the PX number,

that will be the trial exhibit number. And so in their note taking, if they're taking notes, that's the number that applies to the trial. It might help and be less confusing. Or we can provide a concordance for the jury at a later time, but while they're watching it, if they can know that the PX numbers are --

MR. McCONNICO: But you're not talking about giving the deposition testimony to the jury?

MR. JACKS: Oh, no.

THE COURT: He's just saying --

MR. JACKS: As you watch it.

THE COURT: -- as you watch it, there's a number on the deposition. And what he's wanting me to say is, "Ladies and gentlemen, instead of the number that you see on the TV screen --"

MR. JACKS: That you hear.

THE COURT: "-- that you hear, I need to tell you that it's plaintiffs' exhibit whatever it is.

MR. McCONNICO: Oh.

MR. JACKS: If they'll look for the PX number which is shown -- you'll see it on the screen.

MR. McCONNICO: We -- we're fine with that.

THE COURT: Okay. The PX number that's shown on the screen?

MR. JACKS: Right. That's the trial number.

MR. McDONALD: Or the DX number.

MR. JACKS: Or the DX number, yeah.

THE COURT: Is it the DX or the PX?

MR. JACKS: There will be some of both.

MR. McDONALD: There's going to be some of both.

(End of bench discussion)

THE COURT: Okay. From time to time in this video deposition -- so some of these depositions were taken several years ago. And generally, when you're taking a deposition, you hand them paper and it's marked at the time, and it's just marked like Deposition Exhibit 297 or 298, "Yes, I see this and that." But what we've done -- or not what we have done. What they have done is a lot of times in this video, we are going to be using PX for plaintiff's exhibit, DX for defense exhibit, and it's -- it'll be synced to the actual exhibit that's admitted in this case. So they may be talking about one number which occurred at the time they were taking the deposition, but there should be on the screen a PX or DX number that relates to the document that's introduced in this trial. Does that make sense? Thanks.

(Video played as follows:)

Q. Could you describe your educational background for us, please, Doctor?

A. I went to college at Yale University, graduated in 1965. I went to medical school at Washington University in St. Louis, graduated in 1970. Do you want post training? After -- from Washington University I went to the National Institute of Mental Health -- well, sorry. I did an internship for one year in internal medicine at Jewish Hospital of St. Louis. And then I went to the National Institute of Mental Health for two years as part of the public health service and did research there. And then I went to Massachusetts General Hospital for my psychiatry residency from 1973 to 1976. And then I joined the Harvard faculty.

Q. And when you moved to San Antonio, what positions did -- did you hold?

A. I came in as an associate professor, so that was a promotion, and stayed as an associate professor until 1986 when I was promoted to professor.

Q. And what's the difference between being an associate professor and being a professor?

A. Well, a professor is the highest rank you can get. In terms of our particular standards, associate professor would be characterized as somebody who has an

emerging national reputation in their field, and a professor would be somebody who has clear evidence of a national and even international reputation in their field.

Q. And what do you mean when you say developing a national reputation? How does one go about doing that?

A. Well, it would be in terms of publications and refereed journals that -- that are cited in the literature, obtaining grants and -- from peer-reviewed sources and -- so evidence that one's peers value one's work. And a significant component of sort of the -- the package of materials for promotion is letters from outside people at other universities who can speak to your impact on the field and their -- their assessment of your work and the quality of the work.

Q. I would like to ask you if you've got an idea as to how many times you've been published, and it might help you if I --

A. Yeah.

Q. -- give you what I've marked as Exhibit 630, which was produced to us by your lawyer. It appears to be a copy of your CV.

A. There's 115 journal articles listed here and most of them are peer-reviewed, as indicated by a star in the document. The ones that aren't peer-reviewed

don't have a star.

Q. And have you also had any involvement in writing or publishing chapters to textbooks?

A. Yes. And there's 13 book chapter articles listed here.

Q. And what kind of books are these, Doctor? Are these educational textbooks or are they other -- other types of books?

A. Most of them are books intended for psychiatrists or mental health practitioners. There's a couple that aren't in that category, but I would say that's the most -- the majority are in the category of sort of text intended for either psychiatrists as a group or subspecialists interested in schizophrenia.

Q. And going back to your work at the San Antonio Texas Health Science Center, it lists here that you're currently chief of the division of schizophrenia and related disorders in the Department of Psychiatry. Do you see that?

A. Right.

Q. Is that something that -- a position that you still currently hold?

A. Yes. I have a co-chief.

Q. And you're a distinguished life fellow of the American Psychiatric Association, correct?

A. Correct, yeah.
Q. What does that mean to be a distinguished fellow or a distinguished life fellow in the APA?
A. Well, it means that you -- that a group at the APA has looked at your curriculum vitae and accomplishments and views that you're worthy of distinction.
Q. And what is your understanding as to what this lawsuit is about?
A. Well, I guess to put in maybe simple terms, that the development of TMAP was influenced by Janssen in ways that were favorable to Janssen products.
Q. In your experience on TMAP, do you believe that to be true?
A. No.
Q. I would like to turn our attention and start talking about medication algorithms generally. You're obviously familiar with what a medication algorithm is?
A. Yes.
Q. Can you explain to us what your understanding is of a medication algorithm guideline?
A. Okay. Well, in -- I want to distinguish somewhat between an algorithm and a treatment program because in -- in some ways it's not accurate to characterize TMAP as just an algorithm. The -- an

algorithm narrowly defined is a series of steps in which the results of each step determine the next step. So in -- in the actual algorithms in TMAP, be it schizophrenia or bipolar disorder or depression, there's actually a number of options at each step, or almost every step, where it's a clinical decision as to which option is selected. So it's -- it's not a -- an algorithm in which there's only one choice and then only one choice beyond that, and so on. The one exception in the schizophrenia algorithm is that -- for people who don't respond to other antipsychotics. Clozapine is the single -- or Clozaril, the former brand name, is the single recommended choice.

Q. What -- what do you mean when you say that it wouldn't be fair to categorize it as just an algorithm?

A. Well, because it's a -- it's a -- it's a program of treatments. It -- it involves really four elements. One is the medication sequence that's recommended, but attached to that with -- with regard to the medications, there's guidance as to dosing and strategies for starting and stopping the medications. There's very explicit guidance about assessment of effects of medications, and so the symptom scales that we were talking about before are intended to guide clinicians in making the decision whether a medication

is effective or not. And there's also very explicit guidelines about documentation and how -- what documentation is needed in terms of what medications have been used, response to medications, target symptoms, side effects and that kind of thing. And then patient and family education program.

Q. When you say documentation, why -- why is that important?

A. I'm sorry?

Q. You mentioned documentation.

A. Yeah.

Q. Why is that important?

A. Documentation is critical for at least two reasons, maybe three. Certainly in our system, public health system, and most public mental health systems, there's a lot of turnover of doctors and personnel, and if -- if -- if the history of medication treatment isn't well documented and the response to medication treatment, then the next doctor who comes along and is involved in the case doesn't have adequate information on which to base prescribing decisions. So that's one thing, is that -- sort of a related issue is that patients get seen in multiple different settings, outpatient clinics, hospitals, crisis intervention units, emergency rooms, and so on, to -- to the extent

that documentation of treatment can follow the patient to each of those settings, it gives the person who's acting at that moment in time the information they need to make better informed decisions about treatment. And then a -- a third area is the area of quality assurance. So, you know, every agency has, or should have, some sort of quality assurance program and -- and the documentation makes it possible to see if the items that are specified in the quality assurance program are being followed. And then if I can just -- even when one is seeing the same patient for 40 years, which is pretty rare in the public system, but if you're in private practice, you still need documentation because memory is imperfect, and you need to remember -- you need a way of finding out what you did in the past.

Q. What is your understanding as to whether or not TMAP mandates that doctors prescribe particular medications to their patients?

A. There's no mandate in TMAP to prescribe any particular medication.

Q. How -- how did -- how did schizophrenia become part of the modules included within TMAP?

A. Well, the three so-called priority diagnoses in the public mental health system are schizophrenia, bipolar disorder and major depressive disorder and they

were at that time and they still are. So to undertake a medication algorithm project of the nature of TMAP, they needed to have experts in those three areas, and there really wasn't anyone senior in Dallas at that time who could take on that role, and so John Rush asked me if I would take on that role.

Q. Do you have an understanding as to why Dr. Rush selected you?

A. Well, I think he knew some of my reputation, and he also was working part of the -- one of the people in this project at the Mental Health Mental Retardation Department was a woman called Marsha Toprac, T-o-p-r-a-c, and -- and she also regarded my work highly. I had worked with her a lot through the clinical research unit. So I think, you know, he and she agreed on me as a -- a choice.

Q. Did -- did you view it as a good thing, being asked to be part of the TMAP development team?

A. Yes. I -- I at the outset wasn't exactly sure what my role would be and what I would do, but as I learned more and saw this as an opportunity to really do something that would improve the delivery of psychiatric care, and so that -- that was quite appealing to me.

Q. So you come onboard in the spring of 1996. I believe that there were a series of consensus

conferences. Have you heard that term before?

A. Yeah, yeah.

Q. Can you kind of walk us through, starting in spring of 1996, your involvement --

A. Yeah.

Q. -- with TMAP?

A. I have to say to the best of my recollection --

Q. Sure.

A. -- because this was a while back, but the first event, formal event that I recall was the -- it's the consensus conference on the treatment of depression. And that, I believe, was in the summer of '96. Perhaps in September of '96 we had a -- a conference on treatment of schizophrenia and bipolar disorder in -- I think it was in Dallas. The other conference, the depression conference -- I didn't go to the depression conference. I think it was in Galveston. Then in Dallas, we had a meeting at which already there were identified sites, meaning both inpatient and outpatient mental health treatment sites identified and presentations by some people from the Expert Consensus Guideline series about the Expert Consensus Guideline treatments for schizophrenia and bipolar disorder.

Q. And when you say Expert Consensus Guidelines, what are you talking about?

A. So the Expert Consensus Guidelines was -- were guidelines for treatment of schizophrenia, bipolar disorder and major depression that were based on sort of a questionnaire process with experts and giving experts various clinical situations and asking them to rate different treatment options under those conditions. You know, if -- if a patient presents with symptom X and something else, which of the following options would you select, that -- that kind of process. So --

Q. All right. Your involvement with TMAP, was it specific to working on the schizophrenia module?

A. Well, we all worked together and discussed global issues, but -- and we all looked at one another's work on each module, but my primary responsibility was the schizophrenia module and the materials that went with the schizophrenia module.

Q. I'm handing you what's been marked -- previously marked as Exhibit 519, which is an article published in the *Psychiatric Services* journal in January 1999 entitled "The Texas Medication Algorithm Project: Development and Implementation of the Schizophrenia Algorithm," and you among others is listed as -- as an author. Do you see that?

A. Yes.

Q. And up there in the -- in the synopsis field,

do you see where it says "Input from clinicians"? It's probably about halfway through the paragraph.

A. Yeah.

Q. I'm just going to read from that. "Input from clinicians, consultants and consumers informed development of the algorithm which was based on existing Expert Consensus Guidelines."

A. Uh-huh.

Q. Is that consistent with your understanding as to the development of TMAP?

A. Right, and I think that's what I was describing.

Q. If you would, turn over to Page 71 of the article.

A. Uh-huh.

Q. Do you see Figure 1 --

A. Yes.

Q. -- where it says "Initial version of the algorithm for pharmacological treatment of schizophrenia"?

A. Right.

Q. And you see where it lists conventional antipsychotic or risperidone?

A. Right.

Q. So in this initial version of the algorithm, it

has conventional antipsychotic or risperidone listed as first tier. Do you see that?

A. Right.

Q. Do you have an understanding as to why the -- the -- this schematic was changed to remove conventional antipsychotics as a first line or Stage 1 drug?

A. So -- so this was the -- what we did in the feasibility study. Now, after the feasibility study, we convened -- the clinicians and the -- all the TMAP team and so on, the participants in the feasibility study convened in Galveston, I think. So that would have been sometime in 1997. And at that point, olanzapine had been available for, I don't know, maybe nine months or so. It had been out on the market long enough so that people had had a significant experience with it. Risperidone had been around for a while. And there was a -- evidence that -- there was very clear evidence that these agents didn't cause as much in the way of so-called extrapyramidal symptoms as the older agents. So -- and there was developing evidence, partly based on that, of -- of less likelihood of causing tardive dyskinesia. So at the Galveston meeting, we -- again, talking amongst ourselves, talking with the clinicians who had been involved in the implementation of the feasibility study, we tentatively concluded that given

the available evidence, we really should put the new generation antipsychotics as earlier choices than the old antipsychotics. And there was -- there was also an emerging literature -- aside from the extrapyramidal symptoms and tardive dyskinesia, there was some literature to suggest better effects of the newer antipsychotics on things like negative symptoms, and at that point there wasn't much of any literature on cognitive deficits as I recall.

Q. So is it fair to say that at the time that y'all revised the algorithm to move conventional antipsychotics from being Stage 1 to elsewhere in the algorithm, that you believed that to be supported by the facts of the evidence as it existed at that time?

A. Yeah. We had to make decisions based on the available evidence and so the available evidence we thought supported that, yes.

Q. Is RIS CONSTA listed as a Stage 1 medication?

A. No.

Q. Is it listed in preference or in priority to any of the conventional long-acting injectables?

A. No.

Q. Oh, do you know if pharmaceutical funding was solicited in connection with the development of the TMAP --

A. No.
Q. -- algorithm?
A. No pharmaceutical funding was solicited.
Q. Do you feel like you've dedicated your time and services to best serving the interests of the mentally ill in the state of Texas?
A. I do.
Q. How many years would you say that you have devoted to working and serving the mentally ill population of Texas?
A. I think the real involvement began in 1989, so that would be coming up on 20 years.
Q. Do you know who Dr. Steven Shon is?
A. I do.
Q. And was he involved in or part of the TMAP team?
A. Yes.
Q. What was his -- his role and responsibility on that team?
A. I would regard him as mostly playing an administrative role, working with the Department of Mental Health and Mental Retardation at the time and -- and with -- during the feasibility and actual -- later stage of TMAP as somebody who helped bring sites onboard, evaluate sites and things like that and -- and

he -- we had pretty much monthly meetings once we got rolling. He would come to some of those. And mainly, again, I would say the issues that he dealt with were in the administrative implementation realm.

Q. Do you know whether or not among the goals or purposes of TMAP was to convert patients on first generation antipsychotics to second generation antipsychotics?

A. The rule of thumb in TMAP is if it ain't broke, don't fix it. So there was no goal to switch people who were doing well on their current medication, regardless of what the current medication might be.

Q. I have marked as Exhibit 633 a copy of a "Procedures Manual Schizophrenia Module Physician Manual" dated -- or the revised date of December 1999. Do you see that, Doctor?

A. Yes.

Q. And I'm looking at page overview 7, and it's Bates numbered Miller 11530?

A. You said 11530?

Q. Yes, Doctor. On Exhibit 633, if you turn to page Miller 11530.

A. Yes.

Q. And if you'll turn over to page 11534. And again, this is before TMAP was rolled out as being a

part of TIMA system wide. And up there at the top of the page, do you see the parenthetical?

A. Yes.

Q. And what does it say?

A. It says, "Any stages can be skipped depending on the clinical picture."

Q. And who makes that determination, Doctor?

A. The treating physician.

Q. I'll show you what I've marked as Exhibit 635. And Doctor, 635 appears to be another "TIMA Procedural Manual Schizophrenia Module" listing you as an author dated January 8, 2003; is that correct?

A. Yes.

Q. I would like to turn your attention to Bates number -- or page bearing -- ends with Bates number 267. There's a notice.

A. Okay.

Q. Could you read that for us, please?

A. Yeah. "Notice. These guidelines reflect the state of knowledge, current at the time of publication, on effective and appropriate care, as well as clinical consensus judgment when knowledge is lacking. The inevitable changes in the state of scientific information and technology mandate that periodic review, updating and revisions will be needed. These guidelines

(algorithms) do not apply to all patients and each must be adapted and tailored to each individual patient. Proper use, adaptation, modifications or decisions to disregard these or other guidelines, in whole or in part, are entirely the responsibility of the clinician who uses the guidelines. The authors bear no responsibility for the use of these guidelines by third parties."

Q. I'm going to show you a copy of the lawsuit that's been previously marked as Exhibit 331, and I'll read from that. "Defendants in conjunction with other manufacturers of atypicals provided substantial financial contributions to and improperly influenced the development of these standardized public health protocols." Did I read that correctly, Dr. Miller?

A. You did.

Q. You're not telling Judge Dietz and this jury that you believe Dr. Shon was not unduly influenced. You're saying that he wasn't a mental health program decision-maker?

A. I'm saying that he wasn't the decision-maker about incorporation of Risperdal in the algorithm.

Q. Are you familiar with the CATIE trial?

A. Yes.

Q. Did you have any involvement or participation

in the CATIE trial?

A. Yes.

Q. And what was your involvement?

A. I was involved in two different levels. I was on the CATIE advisory board, external advisory board, and I was on the CATIE -- I was responsible for bringing four sites in Texas into the CATIE study, and I was co-investigator with the people at each of those sites in the CATIE study.

Q. And the CATIE trial along with the CUTLASS study and other research and studies were among the materials and information considered by the TMAP consensus conference in 2006, correct?

A. Right.

Q. And I believe it was your testimony that initially you-all, the TMAP group, adopted the Expert Consensus Guidelines?

A. Correct.

Q. And later you-all revised the Expert Consensus Guidelines, correct? Or I'm sorry, you revised the algorithm that --

A. We revised the --

Q. -- by the Expert --

A. That's right.

Q. -- Consensus Guideline?

A. That's right.
Q. Do you know during the time period from 1996 into 1997 whether or not the expert guidelines had themselves been modified?
A. No. They were next -- the next modification that I'm aware of, I think, came in 1999.
Q. And how -- how were they revised?
A. My recollection is that they had the new generation antipsychotics first and the older antipsychotics second, similar to ours.
Q. You reviewed this lawsuit, correct?
A. Yes.
Q. And you've sat through two full days of deposition questioning correct?
A. Yes.
Q. Based on that, do you feel that your integrity as a clinician, a researcher, and as a professor has been called into question?
A. I do.
Q. How does that make you feel?
A. I'm not happy about it.
Q. What -- what do you have to say in response to that?
A. I think it's grossly inaccurate and unfair and -- and I feel like a pawn in somebody else's game.

Q. Do you feel like you've been co-opted by my clients in connection with your work on TMAP and TIMA?

A. No.

Q. Do you believe that TMAP and TIMA serves the best interests of the mentally ill in Texas that are dependent upon public healthcare?

A. I think TMAP and TIMA are very worthy programs that help people.

(Video stopped)

MR. McCONNICO: That finishes our presentation, Your Honor.

MR. JACKS: Your Honor, at this time, plaintiffs will enter into evidence some exhibits. Mr. Sweeten is going to be doing that for the plaintiffs. Thank you, Your Honor.

MR. SWEETEN: Your Honor, there are three documents we are publishing to the jury prior to the deposition of Dr. Shon. The first of those is PX 863. This is an internal Janssen e-mail. And as with e-mail chains, we start from the bottom and go up the page to the front.

THE COURT: When you say publish, are you -- are you going to -- do you want to give that to the jury?

MR. SWEETEN: No, Your Honor. I'm going

to read it to the jury.

THE COURT: I see. Okay.

MR. SWEETEN: This is an e-mail from Jeff Newton of Janssen U.S. sent Tuesday, March 11th, 2003 to Paula Neff. Cc'd are Yolanda Roman, Janssen U.S., Lee Blevins, Janssen U.S., Nancy Bursch-Smith, Janssen U.S., Ellen Grasso-Sirface of Janssen U.S., and Ruth Valpreda, Janssen U.S., and then Sharon Hopkins of Janssen U.S. The subject is "Forward: HCC - speaker form update."

"Hello everyone. The changes to the attached speaker form have been approved by Dave Mallegol and legal honorarium has been replaced with 'fee for service.' Thanks to Paula Neff for taking the initiative to make this change. Jeff. Jeff Newton, Manager Public Health Systems and Reimbursement, Janssen Pharmaceutica."

Going up the chain, which starts on the first page, this is an e-mail forward from Yolanda Roman sent Saturday, March 15th, 2003 to Sadie Heller, Janssen U.S., Lee Blevins, Janssen U.S., Nancy Bursch-Smith, Janssen U.S., and Evelyn Grasso-Sirface, Janssen U.S. Subject: HCC - speaker form update."

"Lee, Nancy and Evelyn: As we've discussed and as highlighted in the PHSR HCC audit, all government employees serving as speakers, advisory board

members, must have a signed document (i.e., speaker agreements and advisory panel agreements) which also includes a signature from the individual's supervisor. Please be advised: No work by any state employee if a supervisor approval has not been sought. Any PMEs sent in without this will be denied with a documenting memo. If the state employee then refuses to seek approval, he/she will not be able to be paid for services already rendered. Unfortunately, the manager involved will be in a difficult position."

We're going up the chain. This is a response from Ellen -- Evelyn Grasso-Sirface dated March 18th, 2003, to Aliza Tomlinson, Cheryl Josephson, James Thornton, Jeffrey Newton, Paul Ford. "Attachments: TOP Public Sector & Advocacy List. Subject: Forward: HCC - Speaker Form Update."

"Team, please see Yolanda's memo. This is very important. Let's make sure that if we have a KOL or speaker that resides in our region, we are responsible for getting the signed agreement. Remember, there are two ways to achieve this, a one-time document and an ongoing document. In either case, it requires a signature from the speaker's supervisor. Thanks in advance for 100 percent cooperation. Evelyn. Evelyn Grasso-Sirface, Field Director, Public Health Systems &

Reimbursement."

The second document is Plaintiffs' Exhibit 99, which is also an e-mail chain. This is lengthy. I'll read sections to you. Starting at the end of the e-mail chain -- the beginning of the e-mail chain and going backwards, we start -- this is from Pearsall Coard, Friday -- sent Friday, November 14th, 2003 to Nancy Bursch-Smith, Janssen U.S. Subject: Steve Shon's honoraria payment.

"Nancy, I received a phone call from Israel Garza today that Steve Shon has not been paid his honoraria for his participation in the Janssen sponsored program in New Jersey. I do not know much about the details of the program, but I believe this is the program that Sid asked for our assistance in inviting Steve. Who needs to be contacted at Janssen in order to expedite Steve getting paid? Percy Coard, Manager, Public Health Systems & Reimbursement, Janssen Pharmaceutica."

Going up the chain to the preceding page, it is an e-mail from Nancy Bursch-Smith sent Saturday, November 15th, 2003 to Sid Frank, Janssen U.S., and Robert Del Femine, Janssen U.S. It's a forward regarding Steve Shon's honoraria payment.

"Robert and Sid, who can I contact

regarding Steve Shon's honorarium from the advisory board that you all held in NJ this past September? Apparently, he has not been paid for this program. Thanks, Nancy. Nancy Bursch-Smith, Field Director, Public Health Systems & Reimbursement, Janssen Pharmaceutica."

And then skipping to the preceding page, which was Bates stamped 684 at the bottom. This is continuing on the chain. It's from Nancy Bursch-Smith, Monday, November 17th, 2003, 11:07 a.m., to Robert Del Femine, Janssen U.S., Adrienne Minecci, Janssen U.S., and Gregory Ballish, Janssen U.S., CC: Sid Frank, Janssen U.S. Subject: Regarding Steve Shon's honoraria payment.

"I am not sure where this was held, but I do know it was a strategic marketing ad board in which Dr. Shon from Texas participated. Sid, can you help me out with the location/name of this board? Thanks, Nancy. Nancy Bursch-Smith, Field Director, Public Health Systems & Reimbursement, Janssen."

Going up the chain is a response from Adrienne Minecci, Monday, November 17th, 2003 at 8:02 p.m., to the same individuals, Bursch-Smith, Del Femine, Gregory Ballish -- oh, Page 683.

"Dominic, please see the communication

below. This refers to the sales strategic plan facilitated by Atlantis. Apparently, Dr. Shon has not received payment. Please forward to appropriate individuals to expedite payment to this important customer. Thanks, Sid."

We'll just go on to Page 682. So the e-mail chain starts on the bottom of the preceding page and we'll go back to the -- to the next page. This is from Dominic La Selva, November 18th, 2003 to Sid Frank, Jennifer Wilde, Kathy Beaudoin, regarding Steve Shon honoraria payment, importance high.

"Kathy: Please see this string of e-mails. I'm assuming that payment has been made to Dr. Shon. Please confirm. Thanks. Dominic La Selva, Vice President Primary Care Sales, Janssen Pharmaceutica."

And then I'm going to go up two e-mails, so starting on the bottom of the Page 681. This is an e-mail from Kathy Beaudoin sent Monday, November 24th, 2003 to Sid Frank, Dominic La Selva, Janssen U.S., subject regarding Steve Shon honoraria payment.

"Just wanted to provide you a Steven Shon update. As I said before, we had been waiting to hear back from him regarding clarification for who he wanted the check made out to. About two weeks ago, our admin

spoke directly with Israel (Steven Shon's admin) who specifically instructed us to issue the expense check to Dr. Shon and to make out the honoraria check to the Texas Department of Mental Health and Mental Retardation, which we did, and Fed Ex'd the check to him. I received a call from Paula today saying that Steven was upset because the check was not made out to him. Apparently Israel made a wrong assumption. So we are cancelling the first check and reissuing it and Fed Exing it back out to him. But Dr. Shon is not very happy with us (Atlantis Group) as I think we have caught the blame on this one. Just a heads up in case you hear something from Steven. Kathy, The Atlantis Group Inc., Doylestown, Pennsylvania."

And further up the chain to the very top of Page 681, this is from Nancy Bursch-Smith dated Tuesday, November 25th, 2003, 10:42 a.m. to Sid Frank, Janssen U.S., CC: Yolanda Roman, Janssen U.S., subject regarding Steve Shon honoraria payment.

"Sid, I do think that Steve and Israel (his admin) messed this up, but Paula has handled like a professional and just took care of it. It may be a good idea in the future that if we use Steve Shon in any ad board that PHSR is not involved in, that we are kept in the loop with the vendor. Steve is very high

maintenance. Thanks, Nancy. Best regards, Nancy Bursch-Smith, Field Director, Public Health Systems & Reimbursement, Janssen Pharmaceutica."

The last document is a request to admit sent to the defendants. It is Plaintiffs' Exhibit 2079, and I'll read the title of the document on the first page. It's "Defendant Janssen Pharmaceutica, Inc.'s Objections and Responses to the State of Texas's First Set of Request for Admissions and First Set of Interrogatories."

Going to the second page, "Objections and Responses to the State's Discovery Request." Request for Admission No. 1 sent to Janssen says: "Admit that defendants have never obtained explicit written consent from any authorized representative for the Texas Department of Mental Health and Mental Retardation, the Texas Department of State Health Services or the Texas Health and Human Services Commission for Steve Shon to give speeches, seminars or lectures for defendants or their third-party vendors, to consult with defendants, to serve on an advisory board of defendants, to attend other meetings or events for or on behalf of defendants, or to enter into a fee-for-service arrangement with defendants."

Response from Janssen: "JPI objects to

this request" --

MR. McCONNICO: Your Honor --

THE COURT: Sustained.

MR. SWEETEN: I will go down the page starting at the second paragraph.

MR. McCONNICO: Renew the objection --

MR. SWEETEN: I'm going to start -- okay. Defendants admit that they are not aware of any signed written consent or authorization forms executed by persons employed by the Texas Department of Mental Health and Mental Retardation, the Texas Department of State Health Services, or the Texas Health and Human Services Commission pertaining generally to Dr. Shon that were delivered to defendants."

And that's -- if you could go to Page 5, verification signed by Michael Chester, sworn to 15 day of July, 2009.

THE COURT: Could I see y'all two here real quick?

(Discussion at the bench as follows:)

THE COURT: Who are you moving to now?

MR. JACKS: Dr. Shon's deposition. This is a good time for a break if you want to take a break.

(End of bench discussion)

THE COURT: Let us take a ten-minute

break.

(Jury not present)

THE COURT: Mr. Jacks, how are we on the schedule?

MR. JACKS: We're going to play Dr. Shon's deposition.

THE COURT: No, no. How are we doing? Y'all said y'all had this all scheduled out. How are we doing on schedule? Are we behind?

MR. JACKS: Perhaps a little, not a lot.

THE COURT: Okay. Don't cut too much out.

MR. JACKS: I'll try not to cut too much out, Your Honor.

THE COURT: For instance, cut out McConnico's multi lengthy objections to all of the discovery and the subject to the objections. Cut that stuff out.

MR. JACKS: The instruction was to do that, and I'm sorry it didn't get followed through.

THE COURT: Okay. I'm high maintenance, as I saw in the thing. I'm living the vision.

(Recess taken)

(Jury present)

MR. JACKS: Yes, Your Honor, we -- plaintiffs next call as a person identified with an

adverse party, Dr. Steven Shon. I'm advised that all the exhibits that will be displayed during the plaintiffs' portion of Dr. Shon's deposition already have been admitted into evidence, Your Honor.

THE COURT: Okay.

(Video played as follows:)

STEVEN SHON, M.D.

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

DIRECT EXAMINATION

Q. Dr. Shon, would you state your full name, please.

A. Dr. Steven Paul Shon.

Q. When was the first consensus conference held for TMAP?

A. 1996 and it was in Galveston.

Q. Would it be correct to say that most of your work as a psychiatrist since you finished your residency has been in the medical director field?

A. Yes.

Q. And then what year did you come to work for -- in Texas?

A. The beginning of 1992.

Q. Are you board certified as a psychiatrist?

A. No.

Q. What year were you made medical director?
A. Probably about '95 or '6, somewhere in there.
Q. Dr. Shon, I want to go back to something you told us a few minutes ago about this meeting you had with the Janssen lawyers. Do you recall that?
A. Yes.
Q. That was a meeting that took place a month or two ago; is that right?
A. Yes.
Q. And you testified it was a two to three-hour meeting?
A. Yes.
Q. Whose idea was it to have the meeting with the two Janssen lawyers?
A. Well, I was contacted by the attorneys and they said they were, you know, preparing and did I have time to meet with them.
Q. Who contacted you?
A. I believe it was Scott Jones.
Q. Your full-time work for the State of Texas prior to your departure in October 2006 was in the psychiatric field, right?
A. Yes.
Q. That's how you made your money?
A. Yes.

Q. Tell the jury how you're living now without being a practicing psychiatrist or working in the psychiatric field.

A. I'm retired, and I have a pension income from the state of California and from the State of Texas.

Q. Have you considered yourself retired since you left the employ of the State of Texas in October of 2006?

A. Yes. My plan was to retire within the year.

Q. Now, that was not a voluntary departure in October of 2006, was it?

A. That's correct.

Q. Who was the first person you recall from Janssen contacting you with regard to the work that you had done on TMAP after this Galveston meeting?

A. I don't recall the very first person -- I don't recall, but I think I know who it was.

Q. Okay. Who's your -- what's your -- what's your best guess for who that person was?

A. I think it was Nancy Bursch-Smith.

Q. You mentioned that you -- Nancy Bursch-Smith was -- from Janssen was someone who called on you from time to time?

A. Yes.

Q. Do you know why or do you have an understanding

of why she would have been interested in what you were doing in developing TMAP?

A. Well, I think she, like all of the pharmaceutical people, were interested because they knew that it focused on medications, and I'm sure they were concerned about what kind of impact it might have on their particular medication.

Q. Do you recognize Exhibit 291 as the February 19, 1997 minutes of the Medication Operations Committee?

A. Yes.

Q. So first of all, what is the Medication Operations Committee?

A. It was a committee put together by -- there's an association of all of the community centers, community mental health centers and public community mental health centers in Texas, and this committee was formed to look at medications and -- primarily because of the cost of medications. So some of the things that were focused on were how we could reduce costs.

Q. It says, "Review of current medication policies and TMAP project." I'm just going to read this and ask you some questions about it. "Dr. Shon" -- that's you, right?

A. Yes.

Q. "-- described two emerging clinical issues. It has been shown that the medications being used are effective and that the new medications are being used." What do you mean by new medications?

A. The second generation antidepressants first, because that's what the first study was about, and also second generation antipsychotics were being used.

Q. What was the state of the scientific evidence of those products in February 1997?

A. The efficacy was shown to be as good as the studies that compared it to the older first generation medication. The safety or side effect data at the time showed that they were clearly superior to the older medications when it came to the side effect of tardive dyskinesia.

Q. What studies were you personally aware of in February 1997?

A. Oh, I -- primarily the studies that were -- had been submitted to the FDA.

Q. Now the studies submitted to the FDA, of course, those are studies submitted by the drug companies, right?

A. Yes.

Q. So the study with respect to the efficacy and safety of Risperdal would have been something that would

have been submitted by folks at Janssen, right?

A. Yes.

Q. The scientific evidence that you're referring to in the last sentence of Paragraph 2 of that exhibit, other than the studies submitted by the drug companies themselves to the FDA, were you aware of any other scientific evidence about Risperdal as of February 1997?

A. I was not. Our experts may have been, but I was not.

Q. Now, you say in that -- take your attention back to that -- to that second paragraph in Paragraph 2, you're talking about the three separate algorithms and you say, towards the middle, "Dr. Shon said that the plan is to phase in one of the algorithms (probably for schizophrenia because it is the simplest one) to the state contract by year end." Did I read that correctly?

A. Yes.

Q. What does it mean to phase something into the state contract? What does that mean?

A. It means to have the community centers begin using the algorithm.

Q. Who was Dr. Knox?

A. He was a medical director of one of the community centers.

Q. Smart guy?

A. I think so.
Q. Good doctor?
A. I believe so.
Q. Well intentioned?
A. Yes.
Q. The minutes say there that "Dr. Knox voiced a concern," if you want to read along with me. "Dr. Knox voiced a concern about adding the algorithm to the state contract before all the data is in."
Now, understanding, Dr. Shon, that you didn't write these minutes, someone else did, but what is -- what is your understanding of that statement about Dr. Knox's concern?
A. Let me clarify this. We were doing -- going to embark on a large study that was going to compare treatment as usual, whatever doctors are prescribing and how they're -- versus following the algorithms. And Dr. Knox said should we wait until after that study is done. And so that was his concern.
Q. So let me -- let me stop you there. So his concern was, let's not add the algorithm to the state contract until we've done all the studies, right?
A. Well, he raised the question.
Q. It was a question he raised that the minutes reflect was a concern?

A. Yes.

Q. And you responded, according to the minutes, "that the reason for this is to continue the momentum and set the standard of care as quickly as possible to prevent being compelled to abide by someone else's standards." Did I read that correctly?

A. That's correct.

Q. Now, let me ask you some very focused questions about that, Dr. Shon. First of all, do you agree with that statement in the minutes?

A. Yes.

Q. By continuing the momentum, did you mean getting the algorithms in place and working in the way that you thought was the most effective?

A. Yes.

Q. I'm going to ask you to tell me and the jury, what is Exhibit 292?

A. It was the -- there have been so many iterations. This was an early iteration of the algorithm, and I think it was a document that was used as we did some of the training and things.

Q. Is it -- is it your recollection this is one of the earliest iterations of the TMAP --

A. Yes.

Q. -- program?

A. Yes.
Q. It's dated January 30th, 1997?
A. Yes.
Q. And that certainly is consistent with your recollection that that would have been the earliest period that TMAP would have been rolled out?
A. Yes.
Q. All right. There's -- that's a chart entitled "Why MAs?"
A. Yes.
Q. Does that mean medication algorithms?
A. Yes.
Q. The last point there on that page is, "None have been empirically tested"?
A. Yes.
Q. Does that mean the medication algorithms had not been empirically tested at this point?
A. At that point in time, correct.
Q. Okay. Page 45, is that the schizophrenia algorithm, the earliest iteration of it in the TMAP program?
A. That's -- yes, that appears so to me. As I said, that's several iterations ago, but yes, that's what it looks like to me.
Q. Where is Risperdal in the algorithm?

A. Risperdal is in Stege 1.

Q. What does it mean to be a Stege 1, first-line treatment?

A. That means that the efficacy and safety warrant those being a first choice or option. And again, option.

Q. All right. A person presents themselves with symptoms of schizophrenia and the first line or first treatment recommended is either a conventional antipsychotic or risperidone, right?

A. Yes.

Q. Let me show you what we've marked as -- it's already been used as Deposition Exhibit 67. Under subpoint 4 about two-thirds of the way down, the -- it is reflected "Asked by Nadia Dac about the use of Risperdal versus Lilly's Zyprexa, Dr. Shon said that in Texas, Zyprexa was once used 2:1 over Risperdal, but since cost became an issue, the two are dead even." Do you remember saying that at this advisory board conference?

A. I don't recall that. Where is that? Oh, I see.

Q. And you also said, just above there, at this advisory board meeting in San Antonio -- you said that -- you characterized Janssen's Risperdal as a

preferred first-line treatment, correct?

A. Yes.

Q. Did you ever represent to anyone while you were employed by TDMHMR that atypical antipsychotics were safer than the typical older antipsychotic medications?

A. I said the safety profile was better, particularly -- well, in regards to tardive dyskinesia, yes.

Q. So the presence of Risperdal in the first-line preferred treatment algorithm is a representation that that drug for that patient is either more efficacious, more effective or safer?

A. Yes.

Q. Is it your testimony that you served on a number of Janssen so-called advisory boards?

A. I was -- yes. I was on a few advisory boards, that's correct.

Q. Is it your testimony that you served as a board member of a Janssen publication called *Mental Health Issues Today*?

A. Yes.

Q. Is it your testimony that you served as a continuing medical education speaker in continuing medical education programs sponsored or funded by Janssen?

A. Yes.

Q. Dr. Shon, did you visit other states -- while you were medical director for TDMHMR, did you visit other states to talk about the Texas Medication Algorithm Project?

A. Yes, I did.

Q. Did you take any trips in which you trained folks in other states on the operation of TMAP?

A. Yes.

Q. Did you visit other states while you were medical director for TDMHMR to participate in pilot programs involving medication algorithms similar to TMAP?

A. Yes.

Q. When did you start going to other states to talk about TMAP?

A. Probably in the late '90s.

Q. Okay. Do you think it was as early as 1997?

A. Could have been.

Q. You were not being invited as a scientific expert, were you, sir?

A. No, not as a scientific expert.

Q. And you weren't someone that was being invited to these states or going to these states because you had done extensive research in how these medications worked?

A. No.

Q. You weren't going to these other states because you were someone that had -- had extensive experience prescribing these medications, right?

A. Correct.

Q. And you weren't a day-to-day psychiatrist while you were at TDMHMR, right?

A. No.

Q. Dr. Shon, you know, don't you, and tell the jury this -- you know that at at least one of these advisory board meetings you gave advice to Janssen on strategy for marketing and positioning their products within state formularies? Are you saying you didn't do that?

A. I don't -- don't recall giving them specific strategies about marketing their products. I remember discussing the products. I remember discussing how products -- and there were questions about how do products get on formularies, how are they prescribed within your states.

Q. Would it be wrong to do that, to engage in assisting a drug company? As a state employee, would it be wrong, Dr. Shon, for you to engage in assisting them with their marketing or product strategy?

A. Yes. I don't believe that one should help a

private concern with their marketing of their own specific product.

Q. Would that be wrong?

A. Basically, yes.

Q. So you're telling the jury that it would be improper and wrong for you as medical director for TDMHMR to advise Janssen or any other pharmaceutical company on product marketing or strategy?

A. Specific marketing, that would be wrong.

Q. What's your best recollection while you were medical director of TDMHMR of how many times you went to other states to talk about TMAP?

A. I'd say once or twice a month for a period of several years.

Q. You knew that a lot of the time, Dr. Shon, a substantial amount of the time, it was Janssen that was paying for these trips; isn't that right?

A. That's true. I knew that Janssen paid for a substantial number of those trips.

Q. I believe you were asked by the attorney general this notion of comp time or comp leave. Are those the same things?

A. Yes.

Q. And comp leave was, essentially, in effect compensation for working extra hours for which you were

not otherwise compensated?

A. Yes.

Q. So if you worked eight hours of what we would call overtime, that would translate into eight hours of compensatory time?

A. Yes.

Q. What was your view of how you could use your compensatory time as a state employee?

A. I could take it off when there was a time when it wasn't going to, you know, be busy or affect my work or something like that.

Q. I guess let me ask it a slightly different way. So when you were on compensatory leave, though, you understood that you were still operating under the same ethical rules and -- and regulations and laws that governed you while you were actually working at the State; is that fair?

A. Yeah. Basically, yes.

Q. I mean, just because you were on compensatory leave, that didn't mean that you could do something that would be unethical if you did it while you were actually in the office working?

A. That's correct.

Q. Do you recognize Exhibit 307 as the 2001 -- August 2001 employee handbook for the Texas Department

of Mental Health and Mental Retardation?

A. Yes.

Q. Now, before I ask you that, so this is a handbook that you were familiar with while you were medical director?

A. Yes, more or less.

Q. Do you see there under "Introduction to MHMR" that it says "The mission of the department is to improve the quality and efficiency of services and supports for our citizens with mental illnesses and/or mental retardation. Our goal is to increase their opportunities and abilities to lead lives of dignity and independence"? Do you see that?

A. Yes.

Q. And do you agree that that was the mission of the department when you were medical director?

A. Yes.

Q. And that was a mission that you took seriously?

A. Yes.

Q. That was a mission that you tried in all respects to fulfill?

A. Yes.

Q. Let's talk about your travel. Without the Janssen and the other pharmaceuticals' money, you couldn't have made presentations in as many places as

you did; is that a fair statement?

A. As many of those, that's correct.

Q. Let me hand you what we've marked as Exhibit 309, sir. Do you recognize Exhibit 309 as an agreement between you, Dr. Steve Shon, and Janssen dated July 11th, 2001 related to the program the Virginia Medication Algorithm Project Stakeholder's Meeting?

A. Yes.

Q. Let's talk about Exhibit 309. You're sure -- looking at Exhibit 309, you're sure in front of this jury that part of the reason for them giving $3,000 to fund your trip to Virginia was because Risperdal was a first-line treatment on the TMAP algorithm --

A. Well --

Q. -- right?

A. I would say -- I can't be sure in terms of reading their minds, but I suspect that that is --

Q. Why do --

A. -- part of --

Q. -- you suspect that?

A. Because companies certainly, you know, promote programs in which they are somehow involved.

Q. Is there anything wrong with them having an economic motivation in your mind?

A. As long as they don't cross certain boundaries

or lines, yes.

Q. What are those boundaries or lines?

A. Directly influencing -- and certainly they have their guidelines, but certainly trying to directly influence their product above other products that -- that's not warranted.

Q. Is it your testimony that you have personally accepted honoraria related to Janssen sponsored programs?

A. For a program that Janssen funded and another agency put the program on, I did accept an honoraria for three years running to do that.

Q. Now, do you recall traveling to Pennsylvania in March of 2001 to address the Pennsylvania Office of Mental Health and Substance Abuse Services regarding TMAP?

A. Yes.

Q. What was the status of medication algorithms in Pennsylvania to your knowledge in March of 2001?

A. They weren't using one.

Q. Do you recall asking for the Janssen reimbursement check to be made out to the Harrisburg State Hospital as opposed to TDMHMR?

A. No, I didn't say that. I was just concerned about our travel reimbursement, essentially, at that

time.

Q. When you spoke on TMAP, Dr. Shon, or at a continuing medical education conference that Janssen sponsored or funded in some way, isn't it true that -- that Janssen required you to submit your PowerPoint presentations to them for their review and comment?

A. No.

Q. That's not true?

A. That's not true.

Q. Let me show you Exhibit 310, Dr. Shon. And do you recognize this as an e-mail from a woman named Ann Swink to you and others dated February 18th, 2002, subject matter slides for the Janssen symposia on treating schizophrenia. Do you see that?

A. Yes.

Q. This was a symposia that you participated in --

A. Yes.

Q. -- in 2002?

A. Yes.

Q. Well, what it says is Ms. Swing asks you -- she says in the third paragraph, "Please have your personal set of slides back to me by March 6th. We will return any feedback CNS might have on your slides to you by March 13th." Do you see that?

A. Yes, I do.

Q. Let's read the next sentence -- sentence after that. "After Janssen has had an opportunity to review and comment on the slides, we will send you those comments to you by March 25th with final revisions due back to me from you by March 28th." Isn't that right?

A. Yes, that's what it says.

Q. So, sir, doesn't this e-mail describe Janssen asking to review and comment on your slides before the Janssen symposia on treating schizophrenia?

A. Yes, it does.

Q. You recognize Exhibit 311 as a PowerPoint presentation --

A. Yes.

Q. -- on TMAP?

A. Yes.

Q. Dr. Shon, is this representative of the kinds of presentations you would give in the trips we've been talking about earlier?

A. Yes.

Q. Isn't it true that part of your algorithm philosophy was that the most efficacious and safest treatments were listed first on the algorithm?

A. Yes.

Q. In fact, you say that in your PowerPoint presentation on Page 851, don't you?

A. That's correct.
Q. Let me ask you to look at what's been previously marked as Exhibit 136.
A. Uh-huh.
Q. Do you recognize this as an agenda for an advisory board conducted at The Mansion on Turtle Creek in Dallas, Texas on Tuesday, June 4th --
A. Yes.
Q. -- 2002?
A. Yes.
Q. Did you attend this?
A. Yes.
Q. Was the subject antipsychotic algorithms?
A. Yes.
Q. Who was the audience for this board?
A. This was the one I referred to earlier where Janssen was coming out with their injectable product, if I remember correctly, and they wanted input from a variety of people as to the usefulness of this product, and a lot of the discussion revolved around how the product might show up in an antipsychotic algorithm, specifically the TMAP algorithm itself.
Q. Now, isn't it true, Dr. Shon, that a couple of weeks later after this meeting at The Mansion hotel in Dallas, that you visited with Nancy Bursch-Smith at

Janssen and gave her some feedback on how Janssen could have done things a little differently at this advisory board meeting?

A. Well, I remember we talked about the meeting. I don't remember exactly what kind of suggestions I --

Q. Well, let me --

A. -- may have given, but --

Q. -- ask you some specific questions to see what you --

A. Sure.

Q. -- do remember. Okay. Did you tell her that Janssen was too focused on the research and clinical piece and that you felt that the meeting should have been more strategically based with Janssen stating what it wants, when it wants it and why CONSTA should be positioned in a certain way?

A. I don't recall saying that specifically. I remember --

Q. Do you recall saying that generally, Dr. Shon?

A. No, I don't.

Q. How did you log your time on your time sheet for the meeting at The Mansion?

A. I think it was just part of my job and -- because this has to do with the TMAP project.

Q. It was State time?

A. Yes, I think so.
Q. Do you recall attending an event sponsored by Janssen called a strategic customer marketing ad board in Princeton, New Jersey in September of 2003?
A. I remember going to Princeton. I don't remember the title or the -- the topic particularly, but...
Q. Do you recall the subject matter of that ad board meeting?
A. I think folks wanted to hear about the algorithm and how the algorithm worked and was used, and that's all I can recall.
Q. Who paid for your attendance at this Princeton, New Jersey meeting?
A. I don't recall, but it was probably one of the pharmaceutical -- if it was with Janssen, it was probably Janssen.
Q. Did you receive an honorarium for participating in this advisory board?
A. I assume so, but I don't --
Q. Why do you assume so?
A. Because if I went and did these speaking engagements, there was an honorarium involved that went to that State.
Q. Do you remember requesting that the honorarium

be paid directly to you?

A. I don't recall.

Q. Do you recall the honorarium being issued by a third-party vendor called Atlantis to TDMHMR instead of directly to you?

A. No, I don't recall.

Q. Let me hand you Exhibit 314, sir. It is -- it is an agreement for -- between -- well, it is a letter between you and Ms. Bursch-Smith describing your potential participation in future event presentations?

A. That's correct.

Q. Now, the third paragraph says that "Janssen Pharmaceutica also requests you provide us with a letter from your governmental agency's supervisor or authorized representative, acknowledging the approval for you to speak at future programs. It is necessary we have a supervisor's or representative's signed letter on file with us. Please note: Each state might have specific requirements or a specific form that must be submitted."

A. Yes.

Q. Did you ever do that?

A. No. I, in fact, called her to let her know that, again, I could not be part of anybody's speakers bureau. If there was an individual program, for example, some of these states would call and request,

and if Janssen was sponsoring that or putting something on and funding it, you know, their request, that could be done, but I was not going to be on their speakers bureau.

Q. Well, does this letter say anything about a speakers bureau? I don't see that word in there. You put that in your answer, but I don't see that in this letter, sir.

A. Well, that's true.

Q. Yeah.

A. I was thinking of it in relation to their speakers bureau because we had had a couple -- all of the pharmaceuticals, and particularly Janssen, on a couple of occasions.

Q. Well, Dr. Shon, the fact of the matter is, you did participate in presentations, right?

A. I did participate in presentations, yes.

Q. So -- so let's just make this clear for everyone's benefit. You didn't call Nancy Bursch-Smith up after you got this letter and say I can't do this, because you had done it, and you did it after June 10th, 2003. You know that.

A. Yes. That's correct. I was thinking of a speakers bureau, but you're right, it doesn't say speakers bureau.

Q. Okay. So answer my other question, which is: Did you provide Janssen with a letter from your supervisor as described in the third paragraph?

A. No, I did not.

Q. Was this the first time you remember Janssen ever requesting written approval from your supervisor for your participation in a -- in an event?

A. Yes. I don't recall --

Q. Did you ever participate in a home office visit at Janssen's headquarters?

A. Yes.

Q. Was that in September of 2002?

A. Probably around that time period.

Q. Let me hand you what's been marked previously as Exhibit 224. I'll represent to you this is an e-mail string, the subject of which is your visit to the Janssen home office.

A. Yes.

Q. The bottom half of the e-mail, the sentence that begins, "Dr. Shon is a very influential KOL in the public sector" psychia -- "psychiatry arena." Have you ever heard the term KOL?

A. No.

Q. It says in the sentence right before that, "It is critical that we support and maintain a strategic

alliance with Dr. Shon for the following reasons." Do you see that?

A. Yes.

Q. And it talks about you being an influential KOL. Did anyone from Janssen tell you that they were interested in supporting and maintaining a strategic alliance with you?

A. That was not discussed, no.

Q. So it says there down there at the bottom, "To provide some flexibility for attendees, Dr. Shon has agreed to make two presentations. The first presentation will run from 10:00 to 12:00 in Alex Gorsky's" -- "Alex Gorsky's conference room," right?

A. Yes.

Q. And Mr. Gorsky was, at the time, either a very senior executive or -- or the chief executive officer at Janssen, was he not?

A. I knew he was an executive. I wasn't sure how high up he was.

Q. "He will conduct the second presentation from 1:00 to 3:00 in a meeting room to be determined. The content of both presentations will be the same." And I believe you told us earlier, Dr. Shon, that the content of the presentations was your overview of -- of both the history and the current developments in TMAP.

A. That's correct.

Q. Did you do this trip on the State of Texas's time or comp time or vacation?

A. I don't recall. I don't recall. It was probably State of Texas time, I think, but I could be wrong.

Q. And Janssen promised to reimburse you for all your costs associated with that?

A. Yes.

Q. And are you familiar that the Texas Penal Code in Section 3607 prohibits a public servant like yourself from soliciting, accepting or agreeing to accept any honorarium in consideration for doing any services that the public servant would not have been requested to provide but for that person's official position or duties?

A. Yes.

Q. If you were being asked to speak because of your title or position, it was prohibited by law and by policy of the TDMHMR to accept honoraria?

A. Yes.

(Video stopped)

MR. MELSHEIMER: Your Honor, might we pause one moment to try to adjust some of the volume issues we're having with the speaker? It'll just take

about a minute.

THE COURT: Okay.

(Video played as follows:)

Q. Dr. Shon, do you recall attending an outcome research advisory board for Janssen in Scottsdale, Arizona from February 27th to March 1st, 2000?

A. I attended a couple of things in Scottsdale. It sounds familiar, but I can't remember the exact name of it.

Q. And Exhibit 317 is a couple of pages from your calendar, plus a check for $3,000 to you at the Texas Department of Mental Health, as well as some receipts and a draft agenda. Do you see that?

A. Yes.

Q. So you personally accepted a 3,000-dollar honorarium for this event?

A. Yes. This includes the honorarium travel.

Q. Why did you think it was proper for you to accept an honorarium for this event?

A. Because it -- and this is one of the ones that I talked to Cathy Campbell about and she -- she said, is this -- does this involve anything with your job? Is your -- in terms of any projects you're working on or anything that would influence your particular roles and functions, and I said no, this is primarily an

educational program and a program where they get input.

Q. Okay. Well, if you look at your calendar on the first page, it looks like you left on Sunday, correct, on the very first page of that exhibit?

A. Oh, yes.

Q. And then when you have Janssen CNS Summit, it goes through February 28th, 29th and March 1st, and that's a Monday, Tuesday and Wednesday; is that correct?

A. That's correct.

Q. But it's your testimony to the jury that this was not job related?

A. That's correct.

Q. Did you -- how did you record your time?

A. I think I took comp time or something along that line.

Q. If you could look at the times entered for those days that you were at the CNS Summit, could you tell the jury how you recorded your time, please? On the 28th and 29th, how do you record hours worked? Is it eight hours on Monday and eight hours on Tuesday under regular hours worked?

A. Yes, it is.

Q. Okay. On the last page, March 2000, how did you record your time for Wednesday, March 1st? It's at the top of that.

A. Oh, yes. Eight.
Q. Okay.
A. Eight hours.
Q. So for this trip to Scottsdale, Arizona in which you accepted a 3,000-dollar honorarium from Janssen from February 27th through March 1st, you not only accepted a 3,000-dollar honorarium from Janssen, but you recorded your time with the State as eight hours of regular time worked; is that correct?
A. That's what it appears.
Q. But your testimony to the jury is also that because this event was not related to your work as a medical director, you could accept the honorarium; is that correct?
A. That's correct. And it appears that things were not recorded correctly.
Q. Did you ever take the position, Dr. Shon, that you could accept honoraria as not being related to your position as a medical director at TDMHMR if it was not during, quote, working hours?
A. Yes.
Q. Okay. So how do you determine what working hours and nonworking hours would be?
A. Basically, nonworking hours would be time away from my regular -- evenings, weekends, things like that.

Q. Would you include nonworking hours as -- as comp time?
A. Yes.
Q. Even if it was comp time you were taking during the week of Monday through Friday?
A. Yes. That's time away from work that was my own time, yes.
Q. And would you include vacation time as time that you would count as nonworking time?
A. Yes.
Q. So it's your position to the jury that all of these times that you included as nonworking hours, if you did something for Janssen, provided any services and received an honorarium, it would be acceptable?
A. Yes.
Q. Because it's nonworking hours; is that correct?
A. Yes.
Q. Dr. Shon, if you'll take a look at what's been marked as Exhibit 318, please. And I'm just going to ask you, do you see how at the top of Exhibit 318 it's dated September 18th, 1992?
A. Yes.
Q. And do you see where it's stamped TDMHMR September 21st, 1992, and it --
A. Yes.

Q. -- says medical director under there, under that stamp?
A. Yes.
Q. That's part of the stamp, it looks like.
A. Yes.
Q. Well, first of all, who is this September 18th, 1992 memo that's Exhibit 318 from?
A. Cathy Campbell.
Q. And it lists Cathy Campbell as the director of legal services, correct?
A. Correct.
Q. And what does this memo purport to be regarding?
A. It's regarding speaking engagements.
Q. Well, in the re line, it says "Acceptance of honorarium," correct?
A. "Acceptance of honorarium." And the underline is in regard to speaking engagements --
Q. That second --
A. -- directly related to the speaker's job.
Q. That second paragraph, Dr. Shon, can you read that for the jury, please?
A. "Under these provisions state employees may no longer accept a speaking fee in situations in which the speaking engagement is directly related to the speaker's

job. Another way that this is put is that a state employee is prohibited from accepting or soliciting a fee for speaking if the employee would not have been requested to speak but for his official position or duties. Accepting a fee is prohibited even if the speech is ... during nonworking hours."

Q. It's still your position that the honoraria you accepted from Janssen, the three honoraria you've testified to, one of which is the Scottsdale, Arizona event, was acceptable because it was, quote, during nonworking hours; is that correct?

A. If it was -- yes, during nonworking hours and I wasn't giving a speech. I wasn't giving a talk.

Q. We've already gone over one of the honoraria, which is the Scottsdale, Arizona event. I'd like to ask you about the other two you mentioned yesterday.

A. Yes.

Q. First of all, when did those other two occur?

A. I believe they were three years in a row. So if this is 2000, it was probably 2001 or 2002. It might have been '99, 2000, 2001.

Q. And did you enter into agreements with Janssen for those events?

A. Yes. It was the same process.

Q. A consulting-type agreement?

A. Yes, same process.

Q. Did Janssen pay you directly those honoraria or were they paid through a third-party vendor such as Excerpta Medica?

A. I believe it was a third-party vendor.

Q. Dr. Shon, if you'll take a look at Exhibit 320. This is your calendar pages and it also has a time sheet, and it's for February 23rd through 25th, 2003.

A. Yes.

Q. Does this refresh your recollection that from February 23rd through 25th, 2003, you attended an event in Scottsdale, Arizona?

A. Yes.

Q. And does it refresh your memory that that was another Janssen CNS Summit?

A. Yes.

Q. And is this the third event you recall receiving an honorarium for?

A. Yes.

Q. Did you ever accumulate comp time or did you ever account toward comp time any of the trips that you took outside of Texas to talk about TMAP to other states?

A. I think there were occasions, if it went into

the weekend or something like that.

Q. So the answer to my question is yes?

A. Yes.

Q. Did you ever ask for funding from Janssen for the Korean-American psychiatrists annual business meeting to be held during the APA meeting in San Francisco?

A. Yes. Yes.

Q. How much funding did you request from Janssen?

A. I don't recall. It was several thousand dollars.

Q. And how much did you receive?

A. I don't recall. It was several thousand dollars. And that's part of the responsibility of the president, is to obtain funding for the events.

Q. Dr. Shon, do you remember yesterday when we talked about the mission statement of TDMHMR, and you read with Mr. Melsheimer from the TDMHMR handbook? Do you remember that?

A. Yes.

Q. And you testified that you took that seriously, and you tried in all respects to fulfill that mission?

A. Yes.

Q. And the mission is -- the mission of the department is to improve the quality and efficiency of

services and supports for our citizens with mental illnesses and/or mental retardation. Our goal is to increase their opportunities and abilities to lead lives of dignity and independence, correct?

A. Yes.

Q. How do you interpret the words "our citizens" with respect to that mission statement?

A. Essentially the citizens of Texas.

Q. It is your testimony to the jury that by traveling to other states to talk about TMAP, you were being consistent with the mission statement of TDMHMR in improving the efficiency of services and supports for Texas citizens, correct?

A. Yes.

Q. Is it also your testimony to the jury that when you were serving on Janssen's advisory boards, you were fulfilling the mission of TDMHMR by improving the quality and efficiency of services and supports for Texas citizens with mental illness and mental retardation?

A. Yes.

Q. Did you see traveling to other states to talk about TMAP in those states, which would initiate and possibly lead to the implementation of algorithms in those states, as being related to your job as a Texas

medical director?
A. Yes.
Q. You testified yesterday that you felt it would be improper for you to engage in marketing product strategy for Janssen, correct?
A. Yes.
Q. So is it a fair statement that you -- if you engaged in marketing product strategy for Janssen, that would also not be consistent with the mission of TDMHMR?
A. Well, I -- yes, I think that the -- developing a marketing strategy for someone was not a role.
Q. Do you agree that when you were the medical director for TDMHMR, you had an obligation to the State of Texas to make sure that the State was not unduly influenced by the pharmaceutical industry?
A. Yes.
Q. You did not have access to Janssen's internal e-mails when you were the medical director of TDMHMR?
A. No, I did not at all.
Q. So is it fair to say that you didn't at all times know Janssen's intentions with respect to you?
A. That's correct.
Q. So I'm asking you, do you think it would be proper for Janssen to use you, use you --
A. Uh-huh.

Q. -- as a key opinion leader to advance algorithms in other states with the intention of using you for that purpose to drive the sales of Risperdal -- do you think that would be proper?

A. I would say this. I think it's improper for a pharmaceutical to use somebody to -- purely to advance their product under the guise of something else. Does that answer your question?

Q. Do you recognize Exhibit 322 as an agreement for an advisory board that you signed on March 3rd, 2002?

A. Yes.

Q. Does this refresh your memory that this was a CNS advisory summit in 2002 you have ended up -- attended at the Ritz-Carlton?

A. Yes.

Q. And you signed this agreement?

A. Yes.

Q. And did you read this agreement before you signed it?

A. I'm sure -- probably did.

Q. Well, did you -- was it your regular practice to review agreements before you signed them with Janssen?

A. Yes.

Q. Did you accept an honorarium for your participation in this advisory board with Janssen?

A. I may have. I don't recall.

Q. Do you see in Paragraph 4 on the first page of this Exhibit 322 -- can you read for the jury what that states?

A. "You represent that" under -- "you are under no obligation, contractual or otherwise, to any other person, institution or entity that would interfere with the rendering of services called for in this agreement or that would prohibit the payments for professional services."

Q. And you agreed to that by signing this agreement, correct?

A. Yes.

Q. And do you recall yesterday when you discussed the agreement related to the home office visit at Janssen and the agreement related to treatment guidelines that those agreements contained the same language in them?

A. Similar language, yes.

Q. So when you attended these events and signed these agreements, these events that were funded by Janssen, you signed these agreements, you understood that when you were participating in these events, or

pursuant to these agreements, that you were under no obligation otherwise -- contractual or otherwise to any other person, institution or entity that would, quote, interfere with the rendering of services called for in this agreement; is that correct?

A. Yes, uh-huh.

Q. Did it ever occur to you when you were signing these agreements with Janssen where you represented that you would not interfere with the rendering of services called for in this agreement with Janssen -- did it ever occur to you what you would do if you were participating in one of these events and an interest or a duty you oh to the State of Texas conflicted with the Janssen interest?

A. Yes, uh-huh.

Q. It did occur to you?

A. Yes.

Q. And you signed the agreements anyway?

A. I didn't believe that that would occur, given the description of the event, but yes, I signed the agreement because the way the event was described, I saw no conflict with that.

Q. Okay. But if a conflict did arise under these agreements, you were obligated to Janssen and not the State of Texas, correct?

A. Well, I would have withdrawn from the program then.

Q. Did you ever withdraw from a program where you signed an agreement saying that you were obligated to Janssen?

A. No, because I -- we would discuss what the program was. If I felt that -- and I actually turned down several programs, going to several programs, but if I felt that there was going to be a conflict, I would not participate.

Q. At some point, and I'm going to suggest to you it was around the year 2000, the Legislature mandated -- the Texas Legislature mandated that TMAP be followed in the Texas community health centers, correct?

A. That's correct.

Q. You don't hold yourself out as a clinician with respect to TMAP, right?

A. No.

Q. In fact, all throughout this deposition, both today and earlier in the year, you've made it clear that you weren't applying your own medical judgment to the clinical analysis of TMAP, right?

A. That's correct.

Q. You are representing, though, in Exhibit 669 that the algorithm philosophy is to put the most

efficacious and safest treatments first, right?

A. That's correct.

Q. That was not something that you had independent knowledge of, right?

A. That's correct.

Q. But you were representing that as being something that was consistent with what you understood to be the TMAP philosophy, right?

A. That's correct.

Q. And so if risperidone is a Level I or Risperdal is a Level I treatment, you're representing that that was the most efficacious and safest treatment, correct?

A. More efficacious and safer than other medications that were not Level I, yes.

Q. You talked with Mr. McDonald about this Exhibit 667, which was a document that you created after the *New York Times* article came out.

A. Yes.

Q. A couple of the staff actually did it at your direction?

A. Yes.

Q. But you gave them the facts?

A. Or they gathered the facts and we all went over the facts together.

Q. Well, I want to look at Page 4, sir, the last

full bullet point on Page 4. You said that "Dr. Shon did not accept compensation for his time in such cases because Texas state employees are prohibited from accepting compensation for presentations." Do you see that?

A. Yes.

Q. Now, that's not true, is it, sir?

A. Well, it was true as far as I -- as I recall.

Q. Well, Dr. Shon, you did accept money from Janssen in the form of honorarium. We're going to go over some of them, but --

A. Yes. That was for -- but not in relation to this project.

Q. Well, sir, you say here -- Doctor, it's stated here on Exhibit 667 -- I take it you reviewed this --

A. Yes.

Q. -- before it was finalized --

A. Yes.

Q. -- to make sure it was right?

A. Yes.

Q. Okay. Correct?

A. Yes.

Q. It says, "Dr. Shon did not accept compensation for his time in such cases because Texas state employees are prohibited from accepting compensation for

presentations, consultation and other work related to their employment with the state."

A. Yes.

Q. Did I read that right?

A. Yes.

Q. Okay. You know it's a felony to do that, isn't it, sir, to accept money as described in -- on Page 4?

A. Well, I don't know what level of -- it is, but yes, I know that that is not --

Q. Well, it's against the law.

A. -- appropriate, yes.

Q. All right. And, in fact, you did accept time and again money from Janssen for going out and speaking as a result of work related to your employment with the State of Texas?

A. No, I don't see it that way. This was not -- the -- the things that I went to related to my experience as an administrator across the board.

Q. Are you saying that you believe Janssen flew you all around the country and paid you thousands of dollars in honorarium because of your work in the state of California?

A. My work as an administrator for over 20 years, yes.

Q. Let me hand you what we'll mark as Exhibit 671

to see if I can refresh your recollection about this. Do you see a check dated 1/24/2003 made out to you --

A. Yes.

Q. -- in the amount --

A. Yes.

Q. -- of $3,000?

A. Yes.

Q. And you received that check --

A. Yes.

Q. -- didn't you, sir? No doubt in your mind about that, right?

A. Yes. Yes.

Q. I'm going to hand you what we've marked as Exhibit 672. Now, Dr. Shon, you were participating, according to this document, in the strategic sales planning process. Do you see that?

A. Yes, I see that.

Q. And do you see that you're -- you're listed on there as the medical director, State of Texas, Office of Mental Health and Mental Retardation?

A. Yes.

Q. All right. No -- no mention there of your previous titles, is there, sir?

A. No.

Q. No mention there of any work you've done for

the state of California?

A. No.

Q. You're there because you're the medical director for the State of Texas, isn't that right, sir?

A. I don't know that that's the sole reason, but that was my title and that's what was listed, yes.

Q. Well, certainly a reason that you're there, you would agree with me on that?

A. Probably, yeah. Probably.

Q. I want to go back to your statement earlier on Exhibit -- Exhibit 667 where you -- we talked about on Page 4 where you said that -- or the exhibit said that you did not accept compensation because Texas state employees are prohibited from accepting compensation. But, in fact, sir, you accepted $3,000 in September of 2003.

A. Okay. That's what it appears.

Q. Well, sir, here's the thing. I mean, you answered all these questions from Janssen's lawyer about how various statements in Exhibit 667 were right and accurate and you were trying to correct the record, but when it came down to the money, Exhibit 667 is just flat wrong about that, because you did take money from Janssen while you were and on -- and on account of your position as a state employee. Isn't that right, sir?

A. Yes, actually, I did. And I did that with those other consultations, which we've talked about.

Q. But you -- you agree that part of it, part of the reason you were being asked -- even under your testimony, part of the reason you were being asked was because of your position as medical director of the State of Texas; isn't that correct?

A. That I was an administrator in the state of Texas as part of my career and that's part of what I was asked -- why I was asked, I'm sure.

Q. Exhibit 674 is some information related to the very summit we were just discussing for which you received $3,000, right?

A. Yes.

Q. It's the meeting in Amelia Island, Florida, correct?

A. Yes.

Q. Now, one of the things that was discussed at this summit was Risperdal CONSTA, right?

A. I believe so.

Q. Isn't it true that as a matter of chronology, Dr. Shon, that after you attended the Amelia Island presentation and received $3,000 from the folks at Janssen, a presentation at which CONSTA was discussed, that subsequent to that, the folks from Janssen came to

you and talked to you about the idea of putting Risperdal CONSTA on the TMAP algorithm? Is that true or not true?

A. The chronology is correct.

Q. Let me ask you this, Doctor. How many times did Janssen pay for you to go anywhere in the world before TMAP was implemented?

A. I don't think they did.

Q. How much -- how many -- how much cash money did Janssen pay you in the form of honoraria or otherwise at any time prior to the implementation of TMAP in Texas?

A. Probably nothing. I don't recall any.

Q. From last time and from this time, I count six different CNS conferences that you attended for which you received $3,000. Let me run them over with you.

A. Yes.

Q. So three Arizona that you recall 3,000 a pop, one in Florida that's 3,000. That's -- that's four. We've established there's one in Princeton, New Jersey where you got 3,000. That's --

A. Yes.

Q. That's five.

A. Yes.

Q. Dr. Shon, with respect to the -- the thousands of dollars that you received from Janssen in connection

with these meetings and conferences, what did you do with the money?

A. Deposited them in my personal account.

Q. You didn't take those honoraria checks and -- and give them to TDMHMR, correct?

A. Correct.

Q. Kept that money for your own personal use, correct?

A. Correct.

(Video stopped)

MR. MELSHEIMER: That concludes the plaintiffs' presentation from Dr. Shon.

MR. McCONNICO: This will be another 45-minute clip. Do you want to start it now?

THE COURT: Is there a break in there?

MR. McCONNICO: There is not, but we can make one.

THE COURT: Give me 15 minutes.

MR. McCONNICO: Okay. Your Honor, we will start playing the tape.

(Video played as follows:)

CROSS-EXAMINATION

Q. When were you licensed to practice medicine first, what year?

A. In 1973 or -- '3 or '4.

Q. When you started with the State of Texas, what was your first position?

A. Deputy commissioner for mental health.

Q. Okay. And then how long were you doing that and what was your next title?

A. I was in that position for about three years, and then when the commissioner, who basically recruited me and brought me in, left and the next commissioner came in, I was moved over into another position. The department was reorganized and that position no longer existed. So for, oh, maybe a year I had a different position that involved managed care and he had wanted -- this was Don Gilbert wanted me to, you know, begin to reshape how the community system worked. And then about a year after that, the medical director left, and I moved into that position.

Q. Okay. What year were you made medical director?

A. Probably about '95 or '6, somewhere in there.

Q. Where did the meeting take place?

A. At the room that they were -- in the hotel they were staying at.

Q. Where were they staying?

A. The Mirage.

Q. Okay. So they invited you to their conference

room they had in the Mirage or was it the actual hotel room?

A. I believe it was a hotel room.

Q. Okay. Who was present?

A. The two attorneys that are here.

Q. Okay. Can you tell the jury to the best of your recollection what you recall them asking you?

A. A lot of it was about my background, my work with the State of Texas and then questions about the TMAP project.

Q. Why did you think it was a good idea to meet with them for a couple hours at the Mirage hotel?

A. I just basically saw no problem with that. I think if anybody had asked to meet with me, I would have, whether it was any of the groups in this room.

Q. They told you that -- the lawyers for Janssen told you that the TMAP was going to be the subject of your deposition; is that a fair statement?

A. I don't know if they said it, but I knew that was going to be the -- having read this.

Q. You knew that from looking at the notice of deposition?

A. Yes.

Q. Have you considered yourself retired since you left the employ of the State of Texas in October of

2006?

A. Yes. My plan was to retire within the year.

Q. Now, that was not a voluntary departure in October of 2006, was it?

A. That's correct.

Q. So you -- you weren't planning on retiring in October of 2006; is that a fair statement?

A. Not in October. I was planning to retire by the summer of 2007.

Q. Whether it's Dr. Bell or anyone else, did anyone communicate to you in the fall of 2006 that the allegations made in this lawsuit were in some way related to your departure?

A. Nobody ever said anything directly to me about it, although I suspected that it may have had something to do with it.

Q. Why do you say that?

A. Only because it was a -- somewhat abrupt and the election was coming up very shortly, and I know that anything that could be looked at as maybe even remotely negative was not something that the administration wanted to have hanging over them. I mean, that was something that was very well known.

Q. All right. So the commissioner of the Department of Mental Health and Mental Retardation came

to you in '95 or '96 and raised with you an issue about creating TMAP?

A. No. This is why I want to kind of walk through how this occurred.

Q. Okay. So this -- this notion of the -- the cooperation and working together --

A. Right.

Q. -- between the research universities and the public sector?

A. That's correct.

Q. What did that lead to?

A. And that had been going on, but this was my first kind of injection into dealing with that part of the department. So I went up to the Department of Psychiatry in Dallas, UT Southwestern, and met with Ken Altschuler and John Rush, who were the two people who -- Ken Altschuler was the chair of the department at the time and John Rush a researcher there. And we met one afternoon and talked about what kind of projects we might focus on, because one cycle of the projects had come to an end and we were ready to start another cycle. So we kind of narrowed it down to a couple of areas. One was psychosocial interventions and the other was medication interventions. And it was out of that meeting that the decision was made to focus on improving

the quality of medication prescribing. And that was one of the things that we had talked about because one of the things that I had seen as medical director in reviewing prescribing in our state, and it was really not different in California, was that prescribing could be fairly erratic. It was not consistent at all. One of the examples I would give as I gave talks is that if you had six people who had the same symptoms, everything was the same, perhaps they were clones and had the same psychiatric disorder, and they walked into six psychiatrists' offices all lined up, chances were fairly high that they would walk out with six different medication programs.

Q. So this -- this issue of the erratic or inconsistent prescribing of medications for mental illness, that's -- that's the -- that's one of the topics that you discussed at this meeting at UT Southwestern?

A. Yes.

Q. And that was in what year?

A. At that meeting in '95, '96.

Q. '95. With respect to this early period of the research that you were conducting about -- for what became TMAP, did Janssen play any role in those early meetings?

A. No.
Q. They didn't play any role?
A. No.
Q. How did you know her?
A. She had come by periodically, similar to what basically all the pharmaceutical companies would do. They drop in every couple three months and just want to know what was going on in the department. So basically they all knew that we were having this -- this conference and meeting and that we were going to produce a product. And she, you know, sometime after this meeting, came by and, you know, we said, well, we finally have a product and et cetera that we are ready to submit for publication. We didn't allow anybody to see it, but we told her -- or I told her at that point in time that we had a product.
Q. You told Nancy Bursch-Smith of Janssen that you had a product related to medication algorithms?
A. Yes, for depression. It wasn't -- it was a meeting of all the advocate groups and professional groups to lay out a possibility of doing this, in fact, also other possibilities, but the medication focus was clearly the consensus of the group, that this is the area to move forward in.
Q. And that was in Austin?

A. That was in Austin, Texas.
Q. In 1995, '96?
A. I believe it was the end of '95.
Q. Were there any pharmaceutical companies invited to this stakeholders' meeting?
A. No.
Q. You mentioned that you -- Nancy Bursch-Smith was -- from Janssen was someone who called on you from time to time.
A. Yes.
Q. Do you know why or do you have an understanding of why she would have been interested in what you were doing in developing TMAP?
A. Well, I think she, like all of the pharmaceutical people, were interested, because they knew that it focused on medications, and I'm sure they were concerned about what kind of impact it might have on their particular medication.
Q. Can you tell the jury anything you remember her saying with respect to this first -- these conversations you had with her about the TMAP project you were working on?
A. I think that the -- the stakeholders were very interested in it and so the pharmaceutical companies were also very interested in it for some of the same and

probably some different reasons. Of course, Janssen had no depression product. So it was more of interest to see how this was going.

Q. Did she suggest in any of these conversations with you about the depression algorithm that you might want to consider developing other algorithms?

A. No.

(Video stopped)

THE COURT: Ladies and gentlemen, time for our lunch break. I'll see y'all back shortly before 1:30. Thank you.

(Lunch recess taken)

(Jury not present)

THE COURT: Anything to take up?

MR. JACKS: Not really except that we've got some labels that the members of the jury can use to put their name on their notebook and then the next few pages for each of them, and that can be done -- it doesn't need to be done between now and the next break.

THE COURT: Let's just do it at the end of the evening.

MR. JACKS: That's fine. I just wanted to have these in Stacey's hands, not ours.

MR. McCONNICO: Tommy, are y'all going to call Campbell by deposition right after Shon?

MR. JACKS: Yes.

MR. McCONNICO: We're going to have some objections to that deposition that we can take up now or we can wait, whatever.

THE COURT: We'll wait, whatever.

MR. McCONNICO: I just need to take them up before.

MR. JACKS: And the clip is six minutes on her.

MR. McCONNICO: On her, but we do have some --

THE COURT: How much more we got with Shon?

MS. ARBAUGH: Nineteen minutes.

THE COURT: Nineteen minutes. Okay. But it'll only seem like 20. Okay. Bring them in.

(Jury present)

THE COURT: Okay. Everybody sit down. We're going to resume with Dr. Shon.

(Video played as follows:)

Q. What I really want to focus on -- and this is the next document I've marked, which is Exhibit 667.

A. Uh-huh.

Q. Do you recognize this document?

A. Yes.

Q. Did you draft Exhibit 667?
A. Well, several of our staff did that.
Q. Did you agree with the content of this document?
A. Yes, I did.
Q. Okay. So you've seen this document before?
A. Oh, yes.
Q. And what is it?
A. It's a response to some of the statements in the *New York Times* article.
Q. Which is Exhibit 666 --
A. Yes.
Q. -- is that correct? All right. If you'll look at the first bullet point in there under "Initiation and purpose of TMAP," do you see that?
A. Yes, I do.
Q. Why don't you read that first paragraph?
A. It says, "The reporter implies that Dr. Steven Shon initiated TMAP to promote use of the second generation or atypical antipsychotics."
Q. Now, let me stop you right there. Is that a truthful statement?
A. No.
Q. Okay. Go on.
A. "The project was actually a major collaboration

between TDMHMR, the psychiatry departments of UT Southwestern Medical Center, UT Health Science Center San Antonio, other Texas medical schools, the UT College of Pharmacy, and several consumer and family advocacy organizations. It was initiated because of concerns about the wide variation and prescribing practices by system physicians and complaints from consumer advocates about the negative consequences of this variation."

Q. Now, is that a truthful statement?

A. Yes, it is.

Q. Okay. And does that fairly summarize why TMAP was initiated?

A. Oh, yes.

Q. And does that accurate identify the people that collaborated to come up with TMAP?

A. Yes.

Q. Okay. Why don't you read the second bullet point?

A. "TMAP is not just a set of guidelines indicating which medications to use to treat schizophrenia (as applied in the" -- "in the article). TMAP is a disease management program based on algorithms that provide specific guidance around the 'how tos' of prescribing (dosing and titrating, switching and augmenting, frequency of physician visits, length of

treatment, evaluating response to treatment, et cetera) as well as recommendations regarding the sequencing of specific medication choices. TMAP also involves technical assistance and clinical support for clinicians in providing care, use of brief clinical rating scales to evaluate treatment response, uniform documentation of treatment decisions and outcomes, and an intensive patient and family education program."

Q. Is that a truthful statement?

A. Yes, it is.

Q. Do you believe that that paragraph accurately describes in general what TMAP does?

A. Yes, I do.

Q. In regard to medications, does TMAP dictate to the physician which medication to prescribe to the patient?

A. No, it does not dictate.

Q. Is that -- is what medication is prescribed to the patient left to the good judgment of the treating physician?

A. Absolutely. And if you read the documents, that's what it says. The documents say that physician judgment is paramount in the prescribing process. So that -- and we use these examples all the time, or we did in our training when I was involved, and that's that

if there are reasons why a first-line or second-line medication is not appropriate, and there are times when they are not, then you go to the third-line. So the physician really decides where to begin the prescribing process. It's not at all dictated by the algorithms themselves. They are just guidelines.

Q. Okay. Let's go to the next bullet point under "Funding for development and testing of TMAP." Could you read that, please?

A. "The reporter states that, 'Ten drug companies chipped in to underwrite the initial effort by Texas state officials to develop the guidelines.' This statement is completely false. Funding for development of the algorithms came from the state and federal funds."

Q. Do you agree with that paragraph?

A. Yes, I do.

Q. Okay. Is that truthful?

A. That is truthful.

Q. How about the next bullet point; could you read that, please?

A. "The TMAP investigators," and this is bolded, "did not," end of bold, "accept pharmaceutical funding for algorithm development and did not permit pharmaceutical company representatives to attend the

algorithm development conferences to avoid any influence or appearance of influence by the industry on the development of the evidence based, expert consensus recommendation."

Q. Is that an accurate statement?

A. Yes, it is.

Q. And you agree with it?

A. Yes.

Q. Was pharmaceutical company funding used for the development of the algorithms in TMAP?

A. We did.

Q. Why?

A. Because we were concerned that people might think that pharmaceutical -- pharmaceutical companies were driving decisions regarding the algorithms. So we always wanted to be clear that pharmaceutical funding was used for separate purposes and not development of the algorithms.

Q. And in fact, what was the pharmaceutical company money used for?

A. The things that were described in this document, development of material. So once the algorithms were developed and put together and often published, then we would put them into manuals. We would create a lot of patient/family education

materials. That was, in fact, a big part of the algorithm process. In fact, patient/family education materials were requested more than the algorithm materials. So issues about the disease process, diagrams about the brain and PET scans and what the brain of somebody with schizophrenia versus somebody without would look like and how those were different to show people that actually this is a brain illness and just like any other physical illness, cardiovascular disease, renal disease, and that it's not just something in -- in somebody's head that is just femoral and, you know, that is not really based in the biology of the human body and the human brain. And those are very convincing. People said, oh, yes, I can see somebody with bipolar disorder has -- the way their brain functions is -- is somewhat different than the way somebody without or somebody with bipolar disorder that's uncontrolled or unstable. Their brain actually is functioning differently, just like somebody with diabetes, et cetera. And therefore, these were some of the materials that were distributed and requested. Also, what you could do that was not medication oriented to help you understand your disease and to live with your illness or control your illness better, because the medication alone, just like medication for diabetes, if

you don't change your lifestyle, if you don't change the way you eat, the things that you do, your exercise, et cetera, then the medication alone is not going to have as much impact on the illness. And that was the same approach. That's a disease management approach. You look at all of the things that impact the illness and you try to affect as many of those as possible. So medication is only one piece of the treatment. And so our patient/family education materials focused on some of the other things that people and families could do to positively impact the illness. No, not for the development of the algorithms.

Q. Did you in your efforts with working with TMAP try to be open about how pharmaceutical funding was used?

A. Yes.

Q. Okay. Now, if you would read the first bullet point that goes underneath that.

A. "The TMAP algorithms were developed at three disease-specific conferences involving expert academic psychiatrists, psychopharmacologists, administrators, psychiatrists practicing in public mental health settings and mental health family and consumer representatives. At each of these conferences, the research literature regarding medications" --

"medication treatment for the focal disorder was presented, discussed and evaluated with regard to efficacy, safety and tolerability."

Q. Do you agree with that statement?

A. Yes.

Q. And is it your opinion that that's an accurate statement?

A. Yes, it is.

Q. Your role was purely an administrator?

A. Yes, correct.

Q. And did you participate in that conference as a clinician?

A. Not as a clinician. As an administrator.

Q. Okay.

A. Questions at times were asked to me, for example, well, what are the most prescribed medications and how do people prescribe these medications in your system? If I could answer those based on information that I had, I would answer those questions. So that -- but not in terms of making decisions about that.

Q. Did the schizophrenia algorithm prefer Risperdal over other second generation antipsychotics?

A. No, it did not.

Q. So is it -- as I read this -- and you correct me if I'm wrong, is it -- is it true then that a

clinician, in the clinician's judgment, could prescribe a first generation antipsychotic to his or her patient instead of a second generation antipsychotic?

A. Yes. They always can, and in various circumstances they should.

Q. They should?

A. Yes.

Q. Why?

A. Well, for example -- a couple of examples. If a patient is on an older antipsychotic and has been on it for a long time and is doing well, shows no signs of tardive dyskinesia or other side effects of that nature and is doing quite appropriately, then there's no reason to change. If they're doing well, they're stable and side effects are not apparent, then why would you want to change the medication they're on and go to a second generation?

Another example that we use in our training is, well, somebody who has perhaps responded very well to a first generation antipsychotic. Many of the patients in the public system have been in the system for decades, and let's say they've had good responses, but the reason that they've had problems is they've gone off the medication periodically. And if the history shows that the responses have been very good

and they, again, have showed no signs of neurological side effects, specifically tardive dyskinesia, then you go back to the thing that worked the best rather than starting them on something new that you have no experience with them on. So that be another instance where you would say, yes, let's go back to what worked very well for you, and then the issue of why they went off should be discussed and why it's better for them to stay on the medication.

Sometimes there's reasons why they've gone off that have to do with the medication. "I just didn't like it, the way it felt." Well, then you would consider something else. But frequently the patient will say, "Well, I was doing so well, I didn't think I needed it anymore," but you go back to that medication and that is frequently a first generation antipsychotic, and that's what you should do at that point.

Q. And was that message that you just gave given to doctors in their training of TMAP?

A. Yes, it was.

Q. Now, you did travel to other states to talk about TMAP; is that correct?

A. Yes, I did.

Q. And when you traveled to these other states, was a request made to you by a particular state to come

speak or did you just decide, hey, I'm going to go to some state and speak about TMAP?

A. No, this --

Q. How did that work?

A. It worked by a state expressing interest. Like any project that you might do some training on, you want people who want to do it, not -- it makes no sense to go in and say I'm going to teach something, and if people aren't interested, it's not going to have any impact. Plus we didn't have the time and that was not our mandate. That was not what we were there to do. So there were always requests from states to us to come and to talk about this project. Sometimes it was the state or sometimes it was a treatment system within the state, but it was done by request.

Q. And when you traveled to other states to talk about TMAP, was -- was that travel approved by your department?

A. Yes. The project itself was sponsored by the department, and our commissioners and our board knew about the project. In fact, I gave reports to our board and frequently would describe our team went to Tennessee last month or something like that and trained as part of the system, or to Pennsylvania, et cetera, so that, yes, our board, who our department reported to, was aware as

well as the commissioner.

Q. There were circumstances that you would receive honoraria for speaking at other states; is that correct?

A. Yes. Yes, that's correct.

Q. And what would happen with the honoraria?

A. I would turn those over to the department.

Q. To the State?

A. Yes.

Q. Okay. Did you ever seek legal advice from anyone about receiving honoraria?

A. Yes, our chief legal counsel.

Q. And who was that? Cathy Campbell?

A. Yes. Cathy, yes.

Q. And did she tell you that the receipt of honoraria was okay?

A. No. She said that if it had to do with a project of the State, then that time was State time and the project was basically the project of the State itself, so anything connected with that should go to the State.

Q. And so she told you it was okay to get an honoraria, just turn it over to the State?

A. Yes.

Q. Okay. Did anybody ever give you advice contrary to that given to you by Ms. Campbell?

A. No.

Q. Okay. If you'll read the last paragraph, the last bullet point. I'm sorry.

A. "Dr. Shon did not accept compensation for his time in such cases because Texas state employees are prohibited from accepting compensation for presentations, consultation and other work related to their employment with the State. When offered compensation by organizations in other states or pharmaceutical companies, Dr. Shon asked that the funds be donated to TDMHMR."

Q. And do you agree with that -- those statements?

A. Yes.

Q. And do you believe those statements are accurate?

A. Yes.

Q. And those statements are consistent with what Ms. Campbell told you to do, correct?

A. Yes.

Q. During your tenure working for the State of Texas up until the time you left, did anybody ever tell you that you were doing something wrong with -- in conjunction with TMAP?

A. No.

Q. Did anybody ever tell you that it was wrong for

you to go talk about TMAP in other states?
A. No.
Q. Did anybody ever tell you it was wrong to receive honorarium and give those funds to the State?
A. No.
Q. There were circumstances that you did receive honoraria and kept it yourself, correct?
A. Yes.
Q. In those circumstances, did you get guidance from Ms. Campbell about the receipt of those honoraria?
A. Yes.
Q. And did she tell you that it was appropriate to receive honoraria in those circumstances?
A. Yes.
Q. Did anybody ever give you any contrary advice in that it was not okay to receive honoraria in those circumstances?
A. No.
Q. The circumstances of you leaving your employment with the State of Texas, is it -- is it fair to say you were essentially told that it was time for you to move on?
A. Yes.
Q. Did anybody ever tell you that you had done something wrong and that was the reason why it was time

for you to move on?

A. No.

Q. Did you ever get any indication or any hint from anybody within the State of Texas that you had done something wrong?

A. No.

Q. Do I understand this correctly that this settlement that's reflected in Exhibit 425 was done completely independently of TMAP?

A. Oh, yes. This was before TMAP was ever conceived.

Q. And so totally independently of TMAP, the State of Texas through this settlement agreement had agreed to fund the use of clozapine and Risperdal for the treatment of patients?

A. Yes.

Q. Did you ever advocate the use of particular drugs in any of your presentations?

A. No, not a specific drug to be used.

Q. So in order for a doctor to deviate from TMAP and apply some different medication regimen, that would have to be justified in the document, correct?

A. Well, any time you prescribe medication, you should describe in your medical record the reason. And that's all we required, was no more than what regular

medical documentation requires.

(Video stopped)

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

MR. JACKS: May we approach, Your Honor?

THE COURT: Yeah.

(Discussion at the bench as follows:)

MR. JACKS: Our next witness is Cathy Campbell. We have revised -- if we can find out what it is and then deal with it.

THE COURT: What is it?

MR. McCONNICO: They invoked the state attorney -- the attorney-client privilege, the State invokes it. And then when we ask -- I ask what did you tell Dr. Shon, they said we're not going to tell you because it's State attorney-client privilege. And then when they ask --

THE COURT: Is it played?

MR. McCONNICO: Yeah, it's on here. It's played. And then when we -- they ask --

THE COURT: You've got to get it down.

MR. McCONNICO: Okay. And then they ask, Okay, what was the policy? Would you have ever done this? Would you have ever said this? No, I never would have said it. So what they're basically saying is

they're not telling us what she told them, but then they're using her as their voice piece that I never would have told Shon --

THE COURT: Could I see the -- could I see the written transcript?

MR. McCONNICO: Yes. Here's the objections where they invoke the attorney-client privilege, and I put in brackets --

THE COURT: You've got to get your voice down.

MR. McCONNICO: I'm sorry.

THE COURT: And then --

MR. McCONNICO: This is the testimony we object to.

THE COURT: What's this?

MR. McCONNICO: That's where they invoke the attorney-client privilege.

THE COURT: Okay. Let me just look.

MR. McCONNICO: Yeah.

(End of bench discussion)

THE COURT: If y'all want to stand up and take a wiggle break, that's okay.

(Discussion at the bench as follows:)

MR. JACKS: I'm asking what the privilege claim was.

MR. McCONNICO: There was no privilege claim there, just invoked the attorney-client privilege. She didn't tell us -- she would invoke the privilege when a question was asked.

MR. JACKS: Business claims --

THE COURT: Can y'all go down that way. Do y'all need some time?

MR. JACKS: No, Your Honor, we can proceed.

THE COURT: All righty.

MR. JACKS: At this time, plaintiffs will call Gary Leech by deposition as an adverse party witness.

THE COURT: Okay.

(Video played as follows:)

GARY LEECH,

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

DIRECT EXAMINATION

Q. And I guess the first is, can you state your full name and your current residence address?

A. My name is Gary W. Leech, 9140 Sugarland Drive, Jacksonville, Florida, 32256.

Q. Now, Mr. Leech, it's my understanding that you worked for Janssen since 1982; is that right?

A. Yes. I'm not currently employed with Janssen.
Q. Your first experience with the drug Risperdal was in a sales role as a CNS representative through January 1995?
A. December of '94.
Q. And in December 1994, you took another position --
A. Correct.
Q. -- as a medical science liaison?
A. Correct.
Q. You're represented today by Mr. Jones; is that correct?
A. Yes.
Q. Are you being paid for preparation for testimony?
A. Yes.
Q. And is there a written agreement where -- that -- that sets out the agreement for payment for your preparation for this deposition?
A. Yes.
Q. Mr. Leech, I'm going to ask you -- and I just want to make sure I'm clear on this. You said that from January 1995 through October of 2003, that you were the medical science liaison for all of Texas, Oklahoma, Arkansas, Louisiana, and some of that New Mexico; is

that accurate?

A. Sometimes New Mexico. That got moved back and forth between the east and the west, depending on how many people we had in -- in our group.

Q. As a medical science liaison of those states, where was the majority of your work?

A. Of those states? The majority of the work was in Texas.

Q. I believe you testified earlier that there were times when you had input into selecting who would attend CNS summits; is that right?

A. Yes.

Q. Did you ever suggest that Dr. Shon attend a CNS Summit?

A. Yes.

Q. What was your reasoning for suggesting Dr. Shon?

A. He was the medical director in the largest state in my geography.

Q. The state of Texas?

A. The state of Texas.

Q. And that's why you invited him?

A. Yes. And -- yeah.

Q. Did you ever seek approval from Dr. Shon's supervisor for him to accept honoraria or any other kind

of monies in connection with his attendance at CNS Summits?

A. No.

Q. Mr. Leech, I'm continuing with Exhibit 829 and in the middle of the last paragraph. And Ms. Roman writes, "Gary's longstanding relationship with the UOT TMAP clinical influencers is invaluable." Did I read that correctly?

A. Yes.

Q. Do you think you did a good job developing a longstanding relationship with the University of Texas TMAP clinical influencers?

A. I believe I did a good job with developing a relationship with all of my key opinion leaders.

Q. Including the University of Texas TMPA clinical influencers?

A. Yes.

Q. Did it occur to you at all how TMAP or Risperdal's placement on TMAP would affect Janssen's business?

A. Yes, it occurred to me.

Q. What occurred to you when it occurred to you?

A. It occurred to me that if Risperdal was one of many compounds that could be chosen as a first-line therapy, that it could have a positive effect.

Q. On Janssen's business?
A. On Janssen's business.
Q. Exhibit 831 is an e-mail chain, the subject "Algorithm Advisory Board, June 5th, 2003, San Antonio Plaza Hotel." Do you recall there being a subsequent advisory board on June 5th, 2003 at the San Antonio Plaza Hotel?
A. Yes.
Q. If you'll go -- and I should have started with this e-mail, so I apologize, but the e-mail that starts toward the bottom from you to Debi. It's December 3rd, 2002. It precedes the e-mail we just read. "Alec Miller and I discussed a second algorithm advisory board and he proposed the week of June 3rd, 2003. June 5th is the preferred date. According to Alec, John Rush and Lynn Crismon are fine with the early June meeting. This is following the NCDEU meeting." Did I read that correctly?
A. Yes.
Q. So you and others at Janssen decided to host another forum with the TMAP opinion leaders in the hopes of gaining a favorable position of CONSTA on TMAP; is that correct?
A. On gaining a position on TMAP, to find out what they needed, and actually I included some of that in

here as to what Alec Miller wanted. Data on partial compliance, switching strategies and clinical experience in Europe.

Q. Is it your testimony to the jury that you personally, Mr. Leech, as an MSL in 2002 did not care either way whether Risperdal was in a favorable position or not on TMAP?

A. Oh, I cared.

Q. Okay.

A. Sure I cared.

Q. Why did you care?

A. Because Risperdal was a product that Janssen was selling, so if it was -- if it was placed on a favorable position, it would be better for the company.

Q. We talked about the fact that CNS Summits occurred annually, correct?

A. Yes.

Q. And you stated that you suggested Dr. Shon as an attendee at a CNS Summit because of his position as the medical director for Texas; is that correct?

A. Yes.

Q. Okay. Did you select Dr. Shon because he was published? Did that also --

A. No. I really -- I didn't really follow his publications.

Q. Did you select Dr. Shon to attend these CNS Summits because of his general clinical practice in psychiatry at all?

A. No. I didn't know if he had one.

Q. Did you select Dr. Shon to attend these CNS Summits for any reason that had anything to do with his work in California before he became the medical director in Texas?

A. No.

(Video stopped)

MR. JACKS: Your Honor, that concludes the offering of the portions of deposition of Mr. Gary Leech. May we approach, Your Honor?

MR. McCONNICO: We have no offer for Mr. Leech.

(Discussion at the bench as follows:)

MR. JACKS: We need to move this big screen before -- I can question from counsel table. But if I stand at the lectern, I can't be seen with the screen, and I'm told it won't take long to move it, but --

THE COURT: Question from counsel table. Can you do that?

MR. JACKS: I sure can.

MR. McDONALD: How long do you have with

him?

MR. JACKS: Hmm?

MR. McDONALD: How long do you have with him? Because I'm not going to want to question him from counsel table because I can't see him.

THE COURT: You want to question him from the podium?

MR. McDONALD: Yes, because I can't see him from where I'm sitting.

THE COURT: Okay. All right. Y'all have worn me down. How long is it going to take to move the table? Ten minutes is the answer.

MR. JACKS: No, I'm told it can be done in two or three minutes.

THE COURT: Oh, okay. Two to three minutes?

MR. JACKS: Let me ask.

(End of bench discussion)

THE COURT: We're going to be moving furniture here for a second. So again, if y'all want to stand up and take a wiggle break, that's fine.

While y'all are doing that, I am going to step very quickly to my office and come right back.

MR. JACKS: Sure. Thank you, Your Honor.

(Brief pause)

THE COURT: Are we ready?

MR. JACKS: We are, Your Honor.

THE COURT: Call your next witness.

MR. JACKS: Plaintiffs call Dr. James Van Norman.

THE COURT: Doctor, would you come forward? If I can get you to raise your right hand for me, please.

(The witness was sworn)

THE COURT: Okay.

JAMES VAN NORMAN,

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. JACKS:

Q. Would you state your name, please, sir?

A. Jim Van Norman.

Q. It's Dr. Van Norman; is that correct?

A. Yes.

Q. What kind of doctor are you?

A. I'm a psychiatrist.

Q. Are you a medical doctor licensed to practice here in the state of Texas?

A. Yes, I am.

Q. How long have you been licensed to practice medicine in Texas?

A. About 23 years.
Q. What -- where do you work?
A. I work right now at Austin Travis County Integral Care, which is the community mental health center here in Travis County.
Q. I don't know if anyone else is having trouble hearing you, but I'm having a little trouble hearing you.
A. Okay.
Q. Would you mind either speaking up or speaking a little more closely into that microphone, Dr. Van Norman?

What is Travis County Integral Care?

A. It's a nonprofit 501(c)(3) community mental health center.
Q. All right. Now, we've heard mention of community mental health centers. What generally in Texas are community mental health centers?
A. In general, we provide services to the folks with severe persistent mental illness who are either uninsured or have Medicaid, mostly through contracts with the Texas Department of State Health Services.
Q. Are there clinics comparable to yours around other parts of the state?
A. There are. There's about 39 community mental

health centers scattered across the state.

Q. And do I understand you to say that each of those clinics, including yours, has contracts with the State of Texas to treat severely mentally ill patients?

A. Yes, they do.

Q. Is -- you said this was a nonprofit outfit. I take it this is not a private practice.

A. No, it's not. It's public community mental health.

Q. Do y'all tend to treat rich folks or poor folks?

A. Poor folks.

Q. Does that include Medicaid patients specifically?

A. Medicaid, some Medicaid and Medicare, and then a whole lot of folks with no insurance at all.

Q. A little bit of background about you, Dr. Van Norman, before we go further. Where did you grow up?

A. I grew up mostly in El Paso, Texas.

Q. And are you married?

A. I am.

Q. To?

A. Dr. Susan Stone.

Q. And what kind of doctor is Dr. Stone?

A. She's a psychiatrist.
Q. Kids?
A. Yes, two kids.
THE COURT: May I ask, do y'all argue much?
THE WITNESS: She wins.
THE COURT: Oh, okay.
Q. (BY MR. JACKS) It works that way pretty much around my house too, Dr. Van Norman. What -- could you tell us your educational background, please, sir?
A. I got my bachelor's degree at Austin College in Sherman, Texas, after that went to get my pre-med requirements at University of Texas El Paso, and then went to University of Texas Health Science Center in Houston for medical school, then trained in the Department of Behavioral Health for my psychiatry residency there at UT Health Science Center in Houston.
Q. Okay. During what years were you in medical school or your residency?
A. Started medical school in 1982 and finished my residency training in 1991.
Q. And upon completion of your medical training, you were -- had completed a residency in psychiatry; did I understand that correctly?
A. Correct. That made me board eligible as a

general adult psychiatrist.

Q. And did you become board certified in that field?

A. Yes, I am board certified.

Q. Upon completion of your residency in 1991, what employment did you undertake?

A. I joined the University of Texas Health Science Center Department of Psychiatry as an assistant professor.

Q. And what did you do as an assistant professor?

A. While I was -- I taught and supervised medical students and residents. The bulk of my time was involved in operating the short-stay triage center at Harris County Psychiatric Center there in Houston, which was basically assessing folks brought in on emergency detentions and involuntary interventions.

Q. So it was a facility that would see and treat patients with mental illness?

A. Just strictly folks with mental illness, severe persistent mental illness.

Q. And you said this was the triage unit. What does that mean?

A. The idea was that some folks that we could stabilize quickly and then move them into the community, and other people needed longer stay and we would move

them up into the regular longer-stay wards, but the idea was to try to more rapidly get folks into the hospital and allow increased access to that service.

Q. Was that a high-volume or low-volume practice?

A. Very high volume.

Q. When you completed that job, what did you do next?

A. I continued to work at the triage unit as an employee of the Harris County mental health mental retardation authority for probably another year or year and a half and then took over as the medical director for the Northwest Community Service Center, which was an outpatient clinic for Harris County Mental Health Mental Retardation Authority.

Q. All right. And again, would you describe -- in both of these settings, how would you describe the patient population that you saw as a physician?

A. It was folks about -- in terms of funding, about 65 percent with no method of funding and about 35 percent with Medicaid or combination Medicaid and Medicare. Clinically, it was -- usually runs about 25 percent folks with schizophrenia, about another 25 percent with bipolar or schizoaffective disorders and then around 50 percent with severe depression.

Q. And this case involves some antipsychotic

drugs. Did in those days you as a physician have patients who required the use of antipsychotic drugs?

A. Yes.

Q. In -- after you had gone through these jobs and job -- and employers you've described, what did you do next?

A. I had an opportunity to come here in 1994 to work for what was then Austin Travis County Mental Health Mental Retardation Center, and since we've changed our name to Austin Travis County Integral Care.

Q. And when you came here in 1994, was it -- what position did you assume?

A. I became the medical director for the community mental health center.

Q. Is that the job you've still got?

A. It is. I'm still the medical director.

Q. In the years you were in Houston treating patients at the University of Texas Health Science Center and then at the MHMR facilities, were -- in all cases, was that a high-volume or low-volume medical practice?

A. In Houston and in -- well, in Houston they were always high volume. Here, as I took on more administrative oversight duties, the volume decreased, but still any of our clinics is a pretty high-volume

service site.

Q. Okay. In -- in the years that you've served as a physician, have you always treated patients?

A. Yes.

Q. Actively?

A. Yes.

Q. Before today, when was the last time you treated patients?

A. Yesterday afternoon.

Q. What kind of patients?

A. Folks with schizophrenia, bipolar disorder and psychotic depression.

Q. And in your practice, does your clinic treat homeless people?

A. Yes, we do. In fact, I work in the homeless clinic doing outreach to the homeless individuals.

Q. When treating -- do you treat adults only or do you treat kids through your clinic as well?

A. In general, I just see adults. But occasionally when I'm working at our psychiatric emergency service, children and adolescents can present and show up there in which case it's my responsibility to provide services, treatment to them.

Q. All right. And are there -- for your clinic as a whole, do you -- does your clinic treat both adults

and kids?

A. We treat both adults and kids, yes.

Q. What -- in connection with your work, and I understand you see patients. Do you also supervise the work of other physicians?

A. I supervise all of the prescribers at our organization, so that includes not only doctors, but also advanced practice nurses and at least one physician assistant.

Q. And so all those people write prescriptions?

A. Yes, they do.

Q. Including prescriptions for antipsychotic drugs when needed?

A. Absolutely.

Q. Did -- and how many physicians or prescribers do you supervise?

A. About 15. Some of them are part time, but overall, 15.

Q. The equivalent of 15 full-time people?

A. Correct.

Q. All right. When -- in your clinic, what is the approximate breakdown between Medicaid and non-Medicaid patients?

A. Among the adults, it's about -- it's 65 percent non-Medicaid, 35 percent Medicaid.

Q. How about the kids?

A. The kids, we're closer -- between CHIP and Medicaid, probably closer to 90 or 95 percent covered.

Q. Is -- in your practice and in your clinic, do you-all treat people in the hospital or do you only treat people who are outpatients?

A. Austin Travis County Integral Care only runs an outpatient set of services. For inpatient we contract with the two local private hospitals or use the Austin State Hospital for inpatient care.

Q. Does your clinic operate on a budget?

A. Yes.

Q. How many patients are you budgeted for annually?

A. The center's contract expects that we would have in active service in any given month about 3,000 clients for the adult side and 550 kids in the Child and Family Services side.

Q. Do you -- does your clinic meet those numbers or exceed those numbers?

A. We exceed those numbers. We serve 6500 adults active at any given point in time in any given month and kids 1100.

Q. So twice or over twice as many as you're budgeted for?

A. Yes.

Q. In -- in your position as medical director of this facility for now since 1994, I guess coming up on 18 or so years, are you familiar with the other facilities in town who also treat large volumes of patients?

A. I am. I am.

Q. Are there any you can think of who treat more than are treated through your clinic?

A. For adult populations, the VA clinic might approach the numbers that we have. For Child and Family Services, I think the next closest size provider is probably the Austin Child Guidance Center.

Q. Do they come close to meeting your numbers?

A. I don't think they do.

Q. And did I ask you to think about being able to answer the question of over the years of your practice how many patients you estimate you've treated who required prescriptions for antipsychotic drugs of one kind or another?

A. For just that so population with antipsychotics, I would bet close to 10,000 patients over the last 20, 21 years.

Q. You mentioned that you treated a higher volume of patients before your administrative duties became

greater than you do now, but currently, on an average basis, how many patients do you see in a year's time?

A. I'm betting about 500 folks in any given year.

Q. In addition to your personal practice in treating your patients, do you have any responsibility for monitoring the practice and the healthcare given by those physicians who you supervise?

A. Yes, I do. We have a peer review or quality assurance program that we monitor prescribing practices to make sure that the folks are practicing medicine in accordance with, you know, the best thinking, the best evidence.

Q. And how do you go about doing that?

A. Usually what we do is pull charts, random charts on, say, each quarter, ten charts off of each doctor. We trade off. You don't review yourself. But we look at does diagnosis match the treatment, how are the patients doing in terms of side effects, are they having good or poor outcomes on their current medications that might suggest discussion amongst the med staff of some alternate strategies and approaches for given patients.

Q. In the now 20 plus years of your practice, has all of it been public clinics?

A. Yes, it has.

Q. In Austin, in Travis County, do patients who are less well off have the option of going to see private practitioners, as a rule?

A. As a rule, no.

Q. Why not?

A. If -- most of the folks that we deal with who don't have any insurance equally don't have any funds to pay for a private practitioner here in town. And frankly, most of the psychiatrists in town don't -- private psychiatrists in town won't accept Medicaid, because they feel like the rates are too low.

Q. Let me shift gears with you, Dr. Van Norman. You know that the drug Risperdal is the subject of this lawsuit; is that correct?

A. I do.

Q. When you began your practice in Houston and UT Health Science Center and then at the MHMR facilities there, was Risperdal available as a drug?

A. No. It was not until 1994 when I arrived here did it start to come onto the market.

Q. Did -- were there any what have been called second generation antipsychotics on the market in the years after you completed your residency and before you came to Austin?

A. There was just one, clozapine, which is an

atypical second generation, but no others.

Q. We've also heard the term Clozaril. Is that the same drug?

A. Yes, that's the brand name.

Q. All right. And was that drug commonly prescribed in the early '90s when you were in the early years of your practice?

A. No, it wasn't. It's really reserved for folks with schizophrenia who have not responded to other agents, mostly because you have to have -- there are some risky side effects, but frankly, there's just the logistics. You have to have blood drawn weekly for the first six months, and that can be a real challenge for the sort of folks that we work with in terms of transportation, getting to and from labs. So we reserve it for folks who have not responded to other agents.

Q. So did you primarily in those days use what we've heard called first generation antipsychotics?

A. Yes.

Q. There were -- including a drug called Haldol? Is that a drug you were familiar with in that time?

A. Yes.

Q. Or haloperidol?

A. Yes.

Q. The jury's also heard of a drug called

perphenazine. Is that a drug that was used, at least at times, in those years?

A. Yes, it was.

Q. Were there others?

A. Yes. We would use thiothixene, also known as Navane, Thorazine, Mellaril on occasion. Those are the -- probably the more -- Prolixin.

Q. When -- you said that when you came to Austin in 1994, that was about the same time Risperdal came on the market. Did -- did you begin using Risperdal some of the time?

A. Slowly. A little -- I tend to be a little cautious as new meds come onto the market just to be sure that we don't have any surprises.

Q. All right. Did you receive visits in your clinic from representatives of Janssen, the manufacturer?

A. Yes.

Q. How frequently would you receive visits from Janssen representatives?

A. I would say more or less monthly.

Q. And what would generally happen when they would come into your clinic?

A. They usually would bring in some samples that we might want to distribute to clients. They would also

bring in glossy folders and posters to talk about their medication and really to sell the use of the medication to me and other doctors in the clinics.

Q. Over the years since, has it been a continual practice of Janssen representatives to call on your clinic?

A. Yes, it has.

Q. And is that still taking place?

A. It's not taking place any longer. About September we stopped allowing drug reps to come into the clinic, the building.

Q. All drug representatives, not just Janssen representatives?

A. Correct, all drug reps.

Q. All right. And you said September. Is that September 2011, a few months ago?

A. Yes.

Q. And was that -- who made that decision?

A. I did.

Q. Can you tell us why you made that decision?

A. The -- I always have been a little bit uncomfortable with the impact that drug reps can have on prescribing patterns, but really the -- I think the tipping point was that we were going for accreditation by an organization called Joint Commission, which lays

out standards of how you conduct business, both clinical and physical plant, to get basically the gold stamp of approval. And in going through Joint Commission accreditation, there are very strict rules about how you handle samples. And in discussing with the medical staff, they all agreed that was just way too heavy a burden, and so we agreed that it was time to stop the drug reps from coming onto our properties.

Q. In the years -- and particularly, I want to focus your attention to the early years, back in the mid to late '90 and early 2000s. When Janssen drug representatives would come to your clinic, would they ever talk with you about Risperdal in particular?

A. Yes.

Q. And did they deliver -- well, would sales messages be a fair term or not?

A. I think that would be a fair term.

Q. Did they deliver sales messages about Risperdal in particular?

A. Yes, they did.

Q. In those years, do you recall any of the sales messages that you heard from Janssen representatives about their drug as they were promoting Risperdal in your clinic?

A. I do. The biggest selling point as I recall

was that these medications -- this medication, the second generation called Risperdal, was much more effective on -- not only on managing the positive symptoms, things like hallucinations and delusions, but was also really effective at managing the negative symptoms and improving those. And the negative symptoms are things like not wanting to go out and get a job or just having no enjoyment in life because the effect of the illness has just undercut that ability to get up and get out into the community.

Q. And what illness are we talking about when you say -- describe these symptoms?

A. Schizophrenia.

Q. Was anything ever said by the Janssen representatives having to do with the safety of Risperdal as compared with the older drugs?

A. Risperdal was represented to me as being a safer medication than the first generation antipsychotics, that we didn't have to worry as much about the extrapyramidal motor symptoms that sometimes would happen with higher doses of first generation antipsychotics, and as an added benefit, that in the long run it was less expensive to the system because these medications were so -- to the service delivery system because these medications were so effective, they

would keep people from going into the hospital.

Q. All right. So let me -- so there were representations made about the effectiveness of Risperdal?

A. Yes.

Q. Its safety?

A. Yes.

Q. And its cost-effectiveness?

A. Yes.

Q. In your work as a medical director, do you have any responsibility for the pharmacy budget in your clinic?

A. I do. The pharmacy reports directly to me.

Q. And is -- when prescriptions are written, are they filled through your pharmacy?

A. Prescriptions written for folks who have no insurance are filled through our pharmacy services program. For people with Medicaid, they go and get their medications through the Texas Vendor Drug Program, so the State of Texas pays for those medications.

Q. Is the Vendor Drug Program also sometimes called Texas Medicaid?

A. Correct. It is part of the Medicaid Program.

Q. When the Risperdal first came into use in your clinic, did -- were you aware of its cost as compared to

the cost of the older drugs?

A. Yes.

Q. And what was the difference?

A. Oh, I can't remember at the time, but 300, 400 times. I mean, you could get Haldol for 10 or 15 bucks, and so -- I'm sorry, 40 to 50 times. So a month's worth of Risperdal could cost you 400 or 500 dollars versus, say, 10 to 20 dollars for haloperidol.

Q. In your practice, are there still times when you prescribe Risperdal or risperidone?

A. Yes, there are.

Q. Is -- do you generally prescribe the brand drug Risperdal or risperidone?

A. Well, now risperidone, since it's become a generic, and it's slightly less expensive than the brand name used to be. So prior to generic, it was Risperdal, and then afterwards, now preferentially risperidone.

Q. In connection with -- I need to ask you about something called TMAP. You know what TMAP is?

A. I do know what TMAP is, yes.

Q. Texas Medication Algorithm Project?

A. That's it.

Q. All right. Were you involved at all in the development stage of TMAP back in the '96 time period?

A. I was involved in some of the early planning

efforts here, based here in Austin, and then I did attend the consensus con -- the first consensus conference on major depression down in Galveston.

Q. All right. And did you attend either of the other two consensus conferences held in 1996, that is schizophrenia or bipolar?

A. I did not.

Q. In the years following the first TMAP algorithm, did something named TIMA come along?

A. Yes, the Texas Implementation and Medication Algorithm project, yes.

Q. All right. T-I-M-A?

A. T-I-M-A.

Q. All right. So we've got TMAP, which is the algorithms, and TIMA, which is what?

A. TMAP was the chance to begin to pilot and understand and develop the whole set of algorithms. Once Department of State Health Services staff, Dr. Shon and his collaborators, were -- felt that they brought those algorithms further enough along to then start disseminating into all the community centers, then it migrated into the -- morphed over to the TIMA, T-I-M-A, project. So that was -- the TMAP was only for certain target sites, and then once that was successful, they moved it to all the community centers.

Q. All right. And when you say they moved into all community centers, did -- under TIMA, did TMAP algorithms come into use in the community health centers across the state?

A. Yes, they did.

Q. If -- if you were to hear someone say that TMAP or TIMA has nothing to do with Medicaid, is that the proposition with which you would agree or disagree?

A. Oh, strongly disagree.

Q. How so?

A. Because most of the clients with severe persistent mental illness, i.e., those that would need something like Risperdal or haloperidol, any of the first or second generation antipsychotics, are going to be, frankly, very frequently Medicaid recipients. And as we said earlier, most Medicaid recipients are treated for psychiatric illnesses in community mental health centers across the state.

Q. Now, when you say that TMAP and TIMA were rolled out or implemented through the community health centers around the state, including yours, did that in any way affect the procedures or practices that physicians in your clinic began to have to follow?

A. It did. The first was it became very clear from the algorithms for, say, schizophrenia that the

second generation medications were the preferred agents from the point of view of the State or Texas Department of State Health -- well, Texas Department of Mental Health and Mental Retardation at the time, so that, first off, second generations were the preferred agents, and then secondly, we got reams of new paperwork forms that we had to fill out in service of the Texas Implementation of Medication Algorithms.

Q. You mentioned that each of the community mental health centers has contracts with the State?

A. Yes, they do.

Q. How frequently are those renewed?

A. They're renewed every year.

Q. So every year there's a new contract?

A. Correct.

Q. At and after the time when TMAP and TIMA were rolled out in all the community mental health centers around the state, were there any provisions in the contract that pertained to TMAP algorithms specifically?

A. Yes. The contract had at least one place, and in some contracts I've seen several mentions, that indicated that for managing medications and treating folks with the illnesses addressed by those algorithms, the algorithms should be followed and treated as guidelines and preferred guidelines.

Q. So in the contracts you had with the State, there was some provision that the TMAP algorithm should be looked to by the physicians in your clinics?

A. I would say it was a requirement, that that was the standard. The guidelines that were implemented by the State was what we had to use. In -- inside the guidelines, there is language that in the event you go to a different step, take medicine out of order, you have to document why you're doing it. But the algorithms were the required and expected method of treating and delivering services.

Q. All right. I want to be sure I understand this because there's been some testimony from Dr. Shon in this courtroom that -- on this same subject, so I want to be sure I understand how it worked in real life.

If a physician -- once these provisions got into your contract, if a physician was prescribing a medication called for by the algorithm, in the case of the schizophrenia algorithm, let's say Risperdal, did they have to do any extra paperwork to document the reasons why they were using Risperdal?

A. No. If you -- if you went with Risperdal with -- with the medicine that was on the first line of the algorithm, you -- your documentation was less than -- if you decided you wanted to jump a step or two

in the algorithm for whatever reason, you had to document why you were doing that.

Q. So if you -- if the doctor wanted to prescribe Risperdal, there was no extra paperwork other than recording in the patient's chart, which was required anyway. But if they wanted, say, in a particular patient to use a drug on the third or fourth tier down, say one of the older drugs, they had to justify why they were doing that?

A. You do have to justify why. I would point out that even under the TIMA, there was a whole lot of extra paperwork anyway as -- even for using Risperdal, which made it fairly burdensome, and then to add on, if I want to jump a step, I've got to even do more documentation. It was just a further disincentive from straying from the algorithms.

Q. Did -- in addition to the contract provisions, were there any sorts of other training or education or anything else that -- where doctors were instructed about the TMAP algorithms?

A. There was. Dr. Shon and Dr. Lynn Crismon set up what they refer to as a train the trainer program so that, in general, medical directors from each of the community mental health centers would come to Austin and be trained in the rating scales and really trained how

to train the rest of the medical staff in the rating scales, reviewing the algorithms, so that we could then promulgate these ideas with our medical staff.

Q. Now, I want to be clear about this. If a physician felt that in a particular patient they shouldn't use drugs, say, of the new class but the patient would do better on one of the older drugs and wrote that prescription, documented it the way they were supposed to document it, would they be punished for having done that?

A. No.

Q. Were there any audits or was there any processes by which the state MHMR office, the central office here in Austin, could determine whether the practices were being followed, that is, adherence to documenting why a doctor prescribed the less expensive drug, if they did? Were there any processes for that?

A. They eventually developed some audit tools that were administered by the community mental health centers. Clinical record reviewers would go through our charts and rate whether or not we were adherent to the TIMA algorithms.

Q. In the case of your clinic, were you?

A. Incompletely. Sometimes the biggest failure was in getting lab work done. And that frequently was,

frankly, because our clients sometimes, again, have great difficulty getting to labs. So that was -- that was probably our biggest liability.

Q. You say liability. Were there potential consequences if an audit from the central office determined that a particular clinic was not adhering to the algorithms and the TMAP practices?

A. Yes. The contract has sanct -- had the option of sanctions. At the time, Texas Department of Mental Health and Retardation could levy sanctions, financial penalties against community centers that weren't -- that were in violation of really most any part of the contract.

Q. Did you go through the trainer training program?

A. I did.

Q. And then were -- did you take that back and carry out some sorts of instruction or training with the physicians you supervised?

A. We did. We walked -- clearly walked through the algorithms, made sure everybody understood the steps and made sure they understood lab monitoring, what the expectations there were, and then the rating scales that had to be completed.

Q. Was that the limit of your and the physicians

in your clinic's exposure to instruction or training or education about TMAP or were there other places and other occasions when there would be similar sorts of education or instruction about TMAP and using TMAP and following TMAP and so forth?

A. The medical directors for the community mental health centers around the state get together and meet quarterly, and Dr. Shon would usually attend those. And almost regularly at those meetings, Dr. Shon would have updates and news about the TIMA for medical directors to take back to their medical staff.

Q. Now, in the -- I don't have an organization chart here, but in the hierarchy, okay, here's your clinic right here and you're the medical director?

A. Uh-huh.

Q. Did you have a boss, by the way?

A. I do have a boss, David Evans. He's the executive director.

Q. So here's Mr. Evans, and then we run up to the central office, and Dr. Shon has the title of medical director, too; is that right?

A. Correct.

Q. Does he have -- is he higher in the hierarchy than you?

A. Yes.

Q. Or was he?
A. Yes, he was.
Q. I guess he's not anymore, is he?
A. No, he's not.
Q. Did --
THE COURT: If I may interrupt, we're going to take a break.
MR. JACKS: Thank you.
THE COURT: I'll see y'all back at 3:15.
(Recess taken)
(Jury present)
THE COURT: Thank y'all. Be seated.
Q. (BY MR. JACKS) Dr. Van Norman, we've talked about TMAP, TIMA, the contract, the paperwork, the training, the seminars, the -- let me talk about the TMAP schizophrenia algorithm itself, because that's the algorithm that most pertains to this case. In -- by the time the TIMA was rolled out and put in place in all of the community health centers like yours around Texas, what were the relative positions of the more expensive newer drugs like Risperdal versus the less expensive older drugs?
A. The first-line treatments were clearly the second generation antipsychotics such as Risperdal, Zyprexa, Seroquel. The first generation antipsychotics,

the older ones like Haldol, perphenazine were much farther down in the algorithm.

Q. As someone who was a medical director of one of the community mental health centers subject to the supervision of the Texas,at that time, Mental Health and Mental Retardation Department, what was the take-away message?

A. The take-away message was clearly that the first line, the best choice of medications, are the second generation newer agents and not the first line -- not the first generation. In the whole implementation and roll-out of the TIMA, the constant refrain was that, you know, it's time for you guys in the community centers to come up to speed, to start treating in the 20th century or 21st century, and use those second generation and quit being old fashioned and resistant to change.

Q. Well, what effect did that have on the prescribing practices of your doctors and yourself for that matter?

A. It pretty radically shifted. It was clear that the constant drumbeat message that the -- if you're using those first generations, you're behind the times, you're not giving the clients fair treatments, was the kind of thing that tends to sway doctors that maybe they

need to change even if they may or may not have reservations.

Q. Do -- did you ever raise yourself, as the medical director and the -- by the way, where is the Travis County Integral Care clinic? Where is it located?

A. Our biggest adult clinic is on East Second at Chicon over on -- just on the other side of I-35.

Q. All right. And then are there other facilities --

A. There are.

Q. -- besides that one?

A. Yes, there are. We've got one up on -- now one up on Rundberg, and then we have the Child and Family Services on Riverside.

Q. Okay. When -- did there come a time when you raised any questions with Dr. Shon about TMAP, TIMA, all of this stuff?

A. I did specifically around the position of the first generation medications in the algorithm. We were -- our center was beginning to have some real cost strains in trying to afford the second generation medications. And Dr. Shon had indicated that we could skip to the first generation medications; we just had to document why we were doing it. The argument back was

that that just makes it look like we're practicing cheap second-class medicine when they're so far down the algorithm; if it's okay to jump to those as a first choice and it's a reasonable clinical decision, then why don't you put them up in the first level?

Q. Did he -- how did that work out for you? Did he do it?

A. Dr. Shon never did anything like that, no.

Q. Any other time when you raised any questions about TMAP, TIMA, any of this stuff?

A. At one point, I was in conversation with Ms. Cindy Hopkins, who's an assistant to Dr. Shon, about a separate matter, but in the process of the discussion, asked her semi seriously what's happening to all this drug company money that's coming into the state. It was about 24 hours later that my boss David Evans called me into the office and indicated that if I -- it might be wise for me to write a letter of apology to the commissioner from whom he heard as well as Dr. Shon that I maybe shouldn't have implied that there was drug company money swaying decisions at the state level.

Q. Did you have -- how much knowledge did you have about drug company money coming into the state with respect to TMAP and TIMA?

A. I didn't have any direct knowledge, but at the

time, being Texas, we were under budget constraints, and so travel budgets for state employees were really constrained and nonexistent, and we -- almost all of -- certainly I was aware that Dr. Shon and some of the other principals in the TIMA and in TMAP had been traveling certainly around the country making presentations. So the question was, where's all this money coming from to pay for travel when nobody else -- you know, auditors are not able to travel out to El Paso because they ran out of the budget, so where is this coming from.

Q. How frequently did Dr. Shon travel the few miles to any of your clinic locations here in Austin?

A. Never.

Q. Was that typical of what you were used to as compared to its predecessor in that office?

A. His predecessor hadn't been a person to visit our clinics either, so neither one of them would come out.

Q. You've testified that in the early days of your practice you used the older drugs, that's all you had, and then you've described about what happened when the Risperdal came on the market, you began receiving visits from representatives of the Janssen company, and TMAP came along. With respect to the things the Janssen

people told you about the greater efficacy, the better safety, the better cost overall, in the early years, did you believe that, believe what you were told?

A. Initially, we took it with a grain of salt, but thought, okay, this is supposed to be the best thing ever, and all the press was saying this gets almost miracle cures in these early days, so inclined to give it a little bit of the benefit of the doubt and try it and see if it had the impact that they were advertising.

Q. And then TMAP comes along?

A. TMAP comes along and really ramps up the pressure and the messaging that, you know, use those second generation medications first, that's the cutting edge, that's where cutting edge psychiatry will be.

Q. In your own practice and to the extent, because of your monitoring of their practices, the physicians who work with you, by the time of the TIMA roll-out and after that was underway, which drugs were you prescribing?

A. I was tending to use the second generation antipsychotics, such as Risperdal or Zyprexa or Seroquel.

Q. Did you use all those drugs?

A. I did.

Q. Do you still sometimes?

A. I do, yes.
Q. The -- I think this is clear, but I want to be sure it's clear. Are you here to say that Risperdal is a bad drug, shouldn't have been approved, shouldn't be on the market, anything of that sort?
A. No, not at all. No, I just -- it's a medication that has some side effects that if they're not carefully managed or addressed can become serious health problems, but it's an effective medication.
Q. When you -- is it still the case today in treating patients that you tend to prescribe the second generation antipsychotics like Risperdal?
A. That's less my inclination currently since about 2005 when first the CATIE study and then 2006 with CUTLASS began to think that maybe some of the advertised benefits of the second generation medications had been oversold and began to realize that we certainly would save a lot if we could begin to use the first generation medications rather than the second generation.
Q. Did you start doing that in your own practice?
A. I have, yes.
Q. What -- of the older medications, which ones do you prescribe to your patients when they need an antipsychotic drug?
A. Either Haldol, haloperidol or perphenazine tend

to be the medications I choose.

Q. Now, with respect to -- let's take Haldol. That was a drug -- or haloperidol in the generic. That was a drug that you had lots of experience with when you were in Houston before there were a bunch in the way of second generation drugs, right?

A. Right.

Q. Do you use haloperidol today in the same way that you did then?

A. No. What we've come to realize is that when I was in training, we would tend to dose haloperidol at, say, 10 to 20 milligrams a day, which is a lot, and we would see lots and lots of side effects, the muscle rigidity and stiffness. Now we've realized that in, say, the two to five milligram range, you can get probably exactly the same response without the extrapyramidal muscle stiffness, Parkinson's-like symptoms.

Q. Okay. So today when you're writing a prescription for haloperidol, what dosages are you most commonly using?

A. I usually start at two milligrams in an adult.

Q. And then from there?

A. Maybe gradually nudge it up if they're not having a complete response, but usually five milligrams

is about as high I go -- as I'm willing to go without adding other medications to control side effects.

Q. Okay. Would -- do you any longer commonly, as common practice, prescribe haloperidol in the 10 to 20 milligram range?

A. No, I haven't done that in years.

Q. With respect to Risperdal, if you're writing a Risperdal prescription, in what dosage range do you write that?

A. Three to six milligrams in an adult.

Q. All right. But not in the 10 to 20 milligram range?

A. No, won't even go to nine milligrams in most cases.

Q. Why not?

A. Will not.

Q. Why not?

A. It's really not necessary, and you start seeing side effects, running risk of extrapyramidal symptoms, the muscle rigidity, and you get problems, even worse weight gain and glucose sugar intolerance, so it's just safer to stay on the lower end, if you can manage your symptoms.

Q. With both drugs?

A. Yes.

Q. If I heard you right, you said you began making changes after the CATIE study in 2005 and CUTLASS in 2006. Why do those studies -- why do they have such importance to you?

A. Well, both of them were what's called effectiveness studies so that they're looking at how do you use the medications in real life. In efficacy studies where you're sort of -- where you're trying to get FDA approval for a medication, you've got unrealistic situations, all kinds of exclusion criteria, so it doesn't mimic what you do in a clinic with real people coming in with multiple kinds of problems. So both CATIE and CUTLASS indicated that for -- in terms of effectiveness and the side effects, that the first generations were every bit as effective as the second generations and that there wasn't any long-term pharmacoeconomic savings by going to the second generation. So for a community mental health center strapped for funding, medications that are less expensive, equally effective, similar side effects burden, even if they're different side effects, it just made all the sense in the world to really make an effort to shift back over to the first generation medications where it was clinically appropriate.

Q. So with both of those -- did the same people do

both studies, CATIE and CUTLASS?

A. No. CATIE was in the United States out of the VA system, and CUTLASS was in England with the national health institute there.

Q. Both government-funded studies?

A. Correct, so they were careful to make sure there was no bias injected by drug company funding, so felt like it was objective, unbiased research that was worth relying on.

Q. Now, when you began using more heavily the older drugs like haloperidol and perphenazine, did you continue to have your patients monitored in the same ways you've described that you would monitor patients within your clinic?

A. In terms of our quality assurance peer review process, yes, we looked at the same parameters. But with the first generation medications, there's less of a worry to monitor lipids, to be sure you're not getting increased cholesterol. There's not as big a problem with weight gain, so there's less of a worry about developing Type 2 diabetes. So the laboratory monitoring is somewhat different.

Q. Okay. So are you telling -- are you telling us that there's some side effects that are a greater concern with the newer drugs than the older ones?

A. In my practice, yes.

Q. And which ones specifically do you worry about less with the old drugs than the new drugs?

A. I worry less about -- with the first generation medications like haloperidol and perphenazine, I worry less about weight gain, lipids skipping out of control, sugars, blood sugar being out of control. That's a bigger worry in the first gen -- second generation medications like, particularly, Zyprexa, Risperdal and Seroquel are big offenders for the weight gain, which brings along with it the risk of coronary artery disease, heart attacks and long-term disability.

Q. Have you in your practice seen such side effects with some patients who have taken the newer generation drugs you just named, Risperdal, Seroquel and Zyprexa?

A. Yes. And early on when the first gener -- second generation medications were starting to be used, the discussion among us in medical staff meetings was not infrequently almost astonishment the amount of weight that people could put on in between, you know -- typically in a maintenance situation, we see somebody about every three months. And people would come in three months later putting on 20, 30 pounds when they're on the second generation medications. And so that's

been a growing concern that we've -- I certainly noticed it and seen it in my patients that weight gets way out of control.

Q. With respect to the new generation drugs, are there any other side effects you've seen in your own practice with them that you didn't see with the older generation drugs?

A. The -- in the doses that we -- say, Risperdal, I've seen women develop what's called galacturia. Basically they start leaking milk from their breasts in response to increase in the prolactin in the system because of the effect of --

THE REPORTER: I'm sorry. In response to?

THE WITNESS: Increased prolactin levels which tells the body -- tells the body, oh, I must be nursing a baby, so it responds that way. And so I've had it relatively low doses. And one of the patients I saw yesterday on one milligram of Risperdal is having trouble with galacturia, with leaking breast -- milk from her breasts. And never seen that with haloperidol, say one milligram, you know, is kind of equivalent range. So that's an issue. It's not a common one, but it's a distressing one to patients.

Q. I take it this was not a nursing momma.

A. No, no, no, not at all.

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

(Discussion at the bench as follows:)

THE COURT: How much time do you have for your cross?

MR. McDONALD: It's getting longer and longer.

THE COURT: I know. How much time?

MR. McDONALD: Half hour, maybe a little more.

THE COURT: You've got about five more minutes.

MR. JACKS: Okay.

(End of bench discussion)

Q. (BY MR. JACKS) I want to ask -- particularly, I want to be clear about extrapyramidal symptoms. These are the movement disorders?

A. Yes.

Q. How about TD or tardive dyskinesia? Have you seen that in patients that you've had on the older drugs in your practice?

A. I have seen it in patients who have been on the medications for a long time. I have not had anybody develop it while they're on the older medications under my care. Usually they come to me and they've already

developed tardive dyskinesia.

Q. From years past?

A. From the accumulation of taking the medication over the years, but they developed it, yeah, again, after years and years of taking medicines, developed it and would wind up staying in the community health center setting.

Q. And did those patients take only the older drugs or both older and newer?

A. Obviously prior to introduction of the second generation antipsychotics, it was only the older. Since then we've had -- I've had some with the tardive or movement disorders who have been exposed to both second and first generation medications over their lifetime.

Q. Last area I want to cover with you. Are TMAP and TIMA still in force in Texas?

A. No, they're not.

Q. When did that change?

A. It changed, I think, August a year ago, if I remember.

Q. And how did that change take place?

A. Before Dr. Emily Becker joined -- moved in the Department of State Health Services from Austin State Hospital to become the medical director for behavioral health, there had been discussion among the medical --

the medical directors of community mental health centers some concern that we were under this guidelines -- or these instructions in the contract to use TIMA, but there had been no efforts to update any of the algorithms. And suddenly we began to worry we were being forced to practice on a set of guidelines that had become obsolete or at least partially outdated.

When Dr. Becker took over as the medical director at Department of State Health Services, she had the same concerns and began to work with leadership at Department of State Health Services to remove TIMA and to look for other more current guidelines.

Q. And did that happen?

A. That did happen.

Q. And what guidelines now are there for -- referenced by you and physicians in your clinic?

A. For treatment of folks with schizophrenia, it's the -- what's called the PORT, P-O-R-T, guidelines. And for depression, it's the American Psychiatric Association's major depression guidelines. For kids, it's the -- a set of foster care treatment guidelines that were developed basically -- basically at Department of State Health Services.

Q. With respect to schizophrenia, do the PORT guidelines distinguish in any way between the older and

the newer antipsychotic drug?

A. They do not.

MR. JACKS: Pass the witness, Your Honor.

CROSS-EXAMINATION

BY MR. McDONALD:

Q. Dr. Van Norman, my name is John McDonald. I have a few questions for you. You mentioned this briefly, and I want to be sure the jury understands about TMAP. It involved three different algorithms or three different disease states, correct?

A. Yes, that's right.

Q. And those were what?

A. Bipolar disorder, schizophrenia, and then major depression.

Q. Okay. And you were actually involved in the development of the major depression disorder, correct?

A. I was involved, in fact, in the major depression nonpsychotic algorithm. There was subsequently a branch for the psychotic -- for major depression with psychotic features.

Q. Okay. And you had no involvement in the development of the schizophrenia algorithm; is that right?

A. Correct.

Q. Okay. You would agree with me that the

treatment algorithm within TMAP is not a mandate to the doctor about what to prescribe, correct?

A. Could you clar -- in terms of a mandate, what are you -- how do you mean that? That tells me exactly what to prescribe?

Q. Well, it doesn't dictate what a doctor should prescribe, correct?

A. No. It's a strong urging that you should make those choices based on the algorithms, so medicines in the first tier, that's what you should choose.

Q. It's a suggestion to you about what to use, right?

A. It could be seen that way.

Q. Okay. The physician retains the ultimate authority about what to prescribe to his or her patient under the TMAP algorithm, right?

A. In collaboration with the client, with the patient. So if the patient's got a medication that was effective in the past, that should be what's jointly decided between the patient and doctor.

Q. Sure. And so we've been talking about first generation antipsychotics, and if a patient was receiving a first generation antipsychotic, the patient should continue to receive that despite the fact that the first generations were not in the first tier of the

schizophrenia algorithm, right?

A. Yes.

Q. Okay. You yourself have deviated from the TMAP algorithm, correct?

A. Infrequently.

Q. You've done it --

A. Yes.

Q. -- right? And you've never been sanctioned for doing so, have you?

A. No, I haven't.

Q. Okay. TMAP is more than just an algorithm, right?

A. Yes.

Q. Okay.

MR. McDONALD: Chris, can you pull up DX 7?

Q. (BY MR. McDONALD) I'll let you have this too so you can have a hard copy as well. So Defendants' Exhibit 7, Doctor, is the physician manual for the schizophrenia algorithm, correct?

A. Yes.

Q. Okay. And this is kind of the whole package, 50 pages of really what doctors are supposed to do with schizo -- the schizophrenia TMAP algorithm; is that right?

A. Yes.

Q. Okay. If you turn to the first page, if you look there in the first paragraph, in this highlighted portion, it says these guidelines, algorithms, do not apply to all patients and each must be adapted and tailored to each individual patient. Proper use, adaption, modifications or decisions to disregard these or other guidelines in whole or in part are entirely the responsibility of the clinician who uses the guidelines. And you would agree with that, right?

A. Yes.

Q. And that's the practice you followed?

A. Yes.

Q. And that's the practice that the people working for you followed when they were using TMAP, correct?

A. I believe so.

Q. All right. Why don't we look -- go to the next tab I've got there, and I can't even tell you what page it is. It ends in 820. This -- and it's displayed here if you want to look at it -- is the actual schizophrenia algorithm as of the date of this manual, which is January 2000, correct?

A. Yes.

Q. Okay. And it says here at the top, "Any stages can be skipped depending on the clinical picture,"

right?

A. Yes.

Q. And that goes along with what you said before; you have the ability to skip any of these steps when you're treating someone with this algorithm, right?

A. So long as we appropriately document --

Q. Sure.

A. -- to make it clear.

Q. And to be clear, Doctor, you're not suggesting to this jury that you would ever not give a patient what you thought was the appropriate medication just because you had to fill out some additional paperwork, are you?

A. No, I'm not.

Q. Okay. And that's nothing you would ever sanction from somebody that works for you, is it?

A. No.

Q. Okay. If you go to the next tab I have in there, and this is the instructions for using the algorithm, if you can see there at the top, instructions for using the algorithm. And here we have "It is important to remember that the algorithms are intended to guide medication selection, not dictate it. Clinical judgment takes precedence." The same thing we've been talking about, correct?

A. Yes.

Q. So that's throughout these guidelines to physicians, that despite what the algorithm says, your clinical judgment is really what takes precedence, correct?

A. Yes.

Q. Okay. If you look further down here in the introduction, we have a section here that says -- it's talking about the typical antipsychotics, and it says the typicals were not included as first-line treatments because compared to risperidone, quetiapine -- which is Seroquel?

A. Yes.

Q. And olanzapine, which is Zyprexa?

A. Yes.

Q. They caused more bothersome side effects, have greater potential for producing tardive dyskinesia, are less effective for or less causative of negative symptoms and are no more effective for positive symptoms. That's what the manual says, correct?

A. Yes, it does.

Q. And that's what you understood the state of the medicine to be in 2000 as well, correct?

A. I probably still had some questions at that point in time but didn't have any published evidence to base my concerns on.

Q. It's still true today, though, isn't it, Doctor, that the older antipsychotics have a greater potential for producing tardive dyskinesia than the newer generation drugs, right?

A. I don't think that's set in science, yes.

Q. That's not -- you're saying that's not your opinion?

A. From my experience, I don't think that that's what I've seen.

Q. You would agree, though, that there's a lot of science out there that disagrees with your opinion in that regard, right?

A. I'm not sure that's true.

Q. Okay. Well, we'll hear from a lot of people later. You continue to prescribe Risperdal to patients today, right?

A. Yes.

Q. And you continue to prescribe Zyprexa -- I mean -- yeah, Zyprexa and Seroquel to patients today, right?

A. Yes.

Q. And you do that because in your opinion, those are the best medications for the patients, right?

A. Yes.

Q. We've talked a little bit about side effects,

and you said that there are serious -- there are serious side effects from Risperdal you talked about, right?

A. Yes.

Q. There are serious side effects from all of these drugs, aren't there?

A. On a spectrum, yes.

Q. We're not talking about baby aspirin, right? These are serious drugs for people with serious illnesses, right?

A. Yes.

Q. Okay. And as long as you know about the potential side effects, you monitor those side effects to ensure that they remain in check, right?

A. Yes.

Q. And you talked about weight gain or issue -- potential issues with diabetes with Risperdal, right?

A. Yes.

Q. And that's a side effect you know about, right?

A. It is.

Q. And you've known about that side effect for a long time, right?

A. Yes.

Q. And it's something that you've been monitoring for a long time, and you know to look for it when you're treating a patient with Risperdal, right?

A. Yes.
Q. Okay. Currently you see one to two patients a day; is that about right?
A. On average, that -- I mean, I tend to have one clinic day that I see the patients, so I see eight to ten in a day.
Q. One day a week or something like that?
A. Right.
Q. Okay. Primarily sitting here today -- and I'm not meaning to take anything away from you -- you're more of an administrator; that's kind of how your career has progressed, that as of today you're more of an administrator than a clinician?
A. It is probably about 50/50. I do backup for the rest of the clinics when their docs are missing or absent.
Q. Okay. You've -- again, you continue to prescribe Risperdal, right?
A. Yes.
Q. And you've prescribed Risperdal to children, haven't you?
A. On at least one occasion.
Q. Sure. And the one occasion that you talked about in your deposition when my colleague took your deposition was actually for a child that you thought was

eight or nine years old?

A. Yes, that's my memory.

Q. Okay. And so -- and that was done before Risperdal had an indication for use in children, right?

A. I believe so, yes.

Q. All right. So that would be off label?

A. Yes.

Q. And prescribing drugs off label is not uncommon; is that fair?

A. I think that's fair, yes.

Q. Okay. And so prescribing Risperdal off label to an eight or nine-year-old child wasn't something wrong that you did, right?

A. No.

Q. And you did it because you thought that prescribing Risperdal to an eight or nine-year-old child was in -- I don't even know if it was a boy or girl -- his or her best interest?

A. Yes.

Q. Okay. And I think you actually sought additional advice from somebody else before making that prescription.

A. I did.

Q. And that was a recommendation to you that you agreed with?

A. Yes.

Q. Okay. You talked a little bit about CATIE. After CATIE came out in 2005, you did continue to prescribe Risperdal, as we talked about, as well as other second generation antipsychotics?

A. Yes, that's correct.

Q. And CATIE specifically actually didn't study second generations against first generation drugs, did it?

A. That's not my understanding.

Q. Isn't it true that CATIE studied second generations versus perphenazine?

A. Yes, which is a first generation.

Q. And only perphenazine, not Haldol, just perphenazine?

A. Correct.

Q. And you would agree with me that perphenazine is not a particularly popular antipsychotic that's used, right?

A. Not anymore.

Q. Right. It's used very infrequently, right?

A. Correct.

Q. And in CATIE, this infrequently used first generation antipsychotic was studied against numerous second generation antipsychotics, right?

A. Yes.

Q. And isn't it true that the patients that were used in the CATIE study, any patient that had a history of tardive dyskinesia was excluded from receiving perphenazine, right?

A. Yes.

Q. And so there was such a concern about tardive dyskinesia in first generations that only the good, I guess people that had no prior conditions, got perphenazine and anybody who had any kind of prior condition of tardive dyskinesia got the second generation antipsychotics, right?

A. I believe that's true.

Q. Okay. You also talked about CUTLASS. CUTLASS was a study that was done in England, correct?

A. Yes.

Q. And it compared second generations with, again, one typical antipsychotic, correct?

A. No, that's not as I read the study.

Q. Isn't it true that the typical antipsychotic used in the CUTLASS study is not even available in the United States?

A. The one -- one of the medicines of the first generations is not available in the United States.

Q. And what was the other first generation that

you think was used?

A. Haloperidol is in the CUTLASS.

Q. You don't currently restrict doctors that work for you in your clinic from using -- or prescribing Risperdal, do you?

A. No.

Q. And that's not something you would ever condone, is it?

A. No.

Q. You believe that a doctor should have available -- multiple drugs available when treating their patient, right?

A. Yes.

Q. And that's because there's not a one size fit all drug or medicine for these patients, right?

A. That's correct.

Q. Some work better than others for the patient?

A. For a given patient.

Q. Right. Some may work well but have -- may cause serious side effects for whatever reason, correct?

A. That's right.

Q. And the side effects aren't consistent from patient to patient to patient, are they?

A. No.

Q. And the effect of this is not necessarily

consistent from patient to patient to patient, right?

A. That's correct.

Q. You have to try what you think in your clinical judgment is the best drug to try first and hope it works, right?

A. Yes.

Q. And if it doesn't and it's -- or it's not tolerated, then you try another one, right?

A. That's right.

Q. Okay. When you prescribe Haldol to patients today, you carefully monitor those patients for side effects of TD or EPS, right?

A. Yes.

Q. I think the jury has heard a lot about TD and EPS. Can you describe to them as somebody who's -- you've seen TD patients, right?

A. I have, yes.

Q. Can you explain to them really what is tardive dyskinesia?

A. Tardive dyskinesia is -- the name is basically Latin for -- it's a movement disorder that develops late. So the idea is after you've been taking some medications for long periods of time, you can develop movement disorders. Sometimes it's a writhing of the tongue, maybe smacking of the lips, sometimes it's

finger movements, almost all unconscious and uncontrollable. They're different from the things we're talking about the EPS, which is the extrapyramidal symptoms, which is closer to Parkinsonism, and those are usually short-term, almost immediate side effects from the medications at improper doses that look a lot like Parkinsonism. So people can get muscle rigidity, trouble swallowing their saliva, so they kind of drool some. But those are more easily addressable with short-term side effect medications, the EPS symptoms.

Q. Scary side effects to the patient, correct?

A. Can be.

Q. Okay. And compliance for this patient population is a real critical thing, isn't it?

A. Yes.

Q. And so one of the issues that you have with a scary side effect like tardive dyskinesia or EPS is that if a patient develops such a side effect, the real worry is they'll stop taking the drug and they'll never want to take anything else again, right?

A. I think with any severe side effect that's a risk.

Q. Sure. And that's a big problem in this population, compliance and continuing to take their medications, right?

A. It is.

MR. McDONALD: Just bear with me for one moment. I'm trying to short-circuit this for us all.

Q. (BY MR. McDONALD) You talked -- you talked a little bit about weight gain with this second generation antipsychotics, correct?

A. Yes, I did.

Q. Okay. And the various second generation antipsychotics have varying degrees of weight gain, side effect, correct?

A. That's true.

Q. And the risk of weight gain is different between Risperdal and, let's say, Zyprexa, correct?

A. Slightly different, from my understanding.

Q. Zyprexa has a higher risk of weight gain than Risperdal, doesn't it?

A. Slightly higher risk.

Q. Just slightly?

A. In my experience in working with the medication.

Q. You wouldn't agree that it's quite a bit greater?

A. That's not been my experience.

Q. You've known about this weight gain risk again with these drugs for a long period of time, correct?

A. That's basically true, yes.

Q. And the same with diabetes; the risk for diabetes is greater with Zyprexa than with Risperdal, right?

A. Again, it's probably linked to weight gain, so in my experience, I've had almost as much trouble with either one of them in terms of weight gain and glucose intolerance.

Q. And if you see a patient that has -- or develops a side effect of a problem with weight gain with Risperdal or Zyprexa, you monitor it, and if it's the best thing to do, you switch them to another drug, right?

A. Right, frequently.

Q. Or even just lower the dose, right?

A. More often switch to a new medication that's more weight neutral.

MR. McDONALD: Okay. I'll pass the witness.

REDIRECT EXAMINATION

BY MR. JACKS:

Q. Quickly, Dr. Van Norman, in your practice with your experience using both older and newer drugs, have you -- do you also look for signs of developing EPS or tardive dyskinesia in your patients who are on a newer

drug?

A. Yes.

Q. Or an older drug?

A. Yes.

Q. Have you seen any striking differences?

A. Not in my -- in my experience, no. They're looking very much the same.

Q. With respect to weight gain and diabetes, have you found a stronger association with the newer drugs or the older drugs?

A. With some of the newer drugs.

Q. And you named, I believe, Zyprexa, Seroquel and Risperdal as being the main offenders --

A. Yes.

Q. -- were your words?

A. Yes.

Q. With respect to the CATIE study, you were asked a question about whether patients in certain parts of that study were in some groups where the people with TD were excluded. Do you remember that?

A. I do.

Q. Is it not in fact the case in the CATIE study that for the part of the study that was comparing perphenazine with the newer drugs, when that head-to-head comparison was being made, that patients

with TD were excluded from both groups?

A. That's my -- how I recall the study.

Q. Because if you wanted to see if anyone developed TD during the study, you didn't want the data tainted by having people in either group with TD to start with, true?

A. That's true.

Q. And with respect to the negative symptoms, you remember -- I believe you said that you were told by the Janssen representatives that Risperdal was better for the negative symptoms of schizophrenia than the older drugs. Did I hear that right?

A. You did.

Q. In your practice and in your experience, as you've used the drugs side by side, have you noticed any marked differences in the ability of either the older or the newer schizophrenia drugs to treat those symptoms?

A. No. Especially when you with the first generations control with appropriate dosing, I have not noticed a difference.

Q. All right. If you overdose with the older drugs, are the symptoms produced some which are the same as the negative symptoms of schizophrenia?

A. Yes.

Q. It makes them less outgoing?

A. That's correct.
Q. Makes them want to stay home?
A. Yes.
Q. Not go to school?
A. Yes.
Q. Or to work?
A. All true.
Q. But when you dose them properly, how do they compare with the newer drugs?
A. In my practice and my experience, they look virtually the same.
Q. Boil it down. Based on your practice and your experience as a physician in the real world, are the newer drugs like Risperdal better, yes or no?
A. No.
Q. Safer?
A. No.
Q. But they're still more expensive, aren't they?
A. Much more expensive.
THE COURT: John.

RECROSS-EXAMINATION

BY MR. McDONALD:
Q. Have you ever done any kind of scientific study between the first generation and second generation antipsychotics?

A. No. Me personally, no.
Q. Never conducted any kind of clinical study between the two?
A. No.
MR. McDONALD: That's all I have. Thank you.
MR. JACKS: May Dr. Van Norman be excused?
THE COURT: Yes. Doctor, thank you for your testimony. You may step down.
May I see you two lads here?
(Discussion at the bench as follows:)
THE COURT: Are we done here or do we want to wander around some more in the *Physican's Desk Reference*?
MR. JACKS: We're done. I mean, it's --
THE COURT: How are we doing on progress?
MR. JACKS: Really good.
THE COURT: He's a quick learner.
MR. MELSHEIMER: No, we are. We're compressing as we go.
(End of bench discussion)
THE COURT: I'll see y'all in the morning.
(Jury not present)
THE COURT: Okay. Everybody relax.
Law nerds, I need y'all to get you -- the

stuff you want me to look at before tomorrow morning up here so I can start reading. Motion to exclude opinions -- yeah.

MR. McCONNICO: We've distilled it down.

THE COURT: Is this -- wait, wait, wait. Is this my for the record or is this we're going to take one more kiss at the pig?

MR. McCONNICO: One more kiss at the pig. This is the argument to exclude.

THE COURT: Okay.

MR. McDONALD: Well, I'm not -- well, I don't know that we've ever had a real --

THE COURT: Extensive discussion.

MR. McDONALD: -- discussion about Friede, right. We've submitted stuff to you and you've indicated to us on several occasions that you had concerns or troubles, but I don't know that we've ever had an argument about it.

THE COURT: Well, let me look at it right now. Do we have Friede? Do we have a pristine copy of Friede's opinions? Do we have any copy of -- has Stacey left? Do you have -- I think I've got -- I know I've got it in electronic form.

MR. JACKS: On January 3rd I delivered letter briefs to you on three subjects of which he was

one. Attached to that was, among other things, the spreadsheet about him. That was off of his report.

THE COURT: Okay.

MR. JACKS: That letter brief still says I think the things we would say about the admissibility of his testimony. I will say that --

THE COURT: Okay. Time out. Time out. Let me read this, because what I need is I will need his -- either the spreadsheet or his report, but let me read this first without any talking so I can understand.

MR. JACKS: Okay.

THE COURT: It would be most helpful if on these six points you could tell me -- I now have Friede's report -- where I look.

MR. JACKS: Do you have a copy of that? Are you looking at it?

MR. McCONNICO: We gave you one, that little one. We might give you another one, but I handed you one.

MR. JACKS: Oh, here we go.

THE COURT: Somebody's working on figuring out where in his report --

MR. McCONNICO: Yes, sir. We're ready to respond when you need more.

THE COURT: What I need is I need

information. I don't need argument. I need where to look so I can look at it with my own eyes.

MR. McCONNICO: In the report.

THE COURT: The report is 106 pages the last time I looked.

MR. JACKS: Can we have another copy of our letter report for the judge's convenience?

THE COURT: If it helps, I've got -- I think I've got something of a deposition here.

MR. JACKS: Actually, I have a copy.

THE COURT: May I talk to y'all for a second? So what y'all have given me is Texas law on lay opinions concerning mixed law and facts. So what you've given me is a conclusion with bullet points. Well, just as you would, if I gave you -- if I go pull out a -- one of my school finance briefs and I gave it to you and I said, "Okay, should I admit this or deny?" and you go, "Well, let me see it." And so what I'm trying to see is the actual opinion that leads y'all to believe that he is saying that -- obviously he just says that y'all have violated the hell out of this, that and the other and that y'all gave false certifications in this and he gives some specific opinions. And all I'm wanting to see is -- I don't need to see maybe every exhaustive opinion, but if you will give me enough that -- you're

trying to hand me something that looks like what I've got. And so if I could see with my own eyes, either in the report or when you took his deposition, and you got them to repeat all those loathsome things he said and then -- prank with him a little bit.

MR. LAUER: I've added those to this, Your Honor.

MR. McCONNICO: We've added --

MR. LAUER: We've added citations to the report --

MR. McCONNICO: Not what you have, but right here.

MR. LAUER: We just did right now, so I can replace that copy with this.

MR. McCONNICO: And then we've highlighted a page from the deposition.

MR. LAUER: And then we've highlighted things from the deposition.

MR. McCONNICO: But it might be helpful if we actually give the actual deposition pages.

THE COURT: So Page 61 -- and so when I look at this, it's Page 61 of his report?

MR. LAUER: Yes, sir.

MR. McCONNICO: Yes, sir.

THE COURT: Okay. All right.

MR. McDONALD: That's one example, yes.
THE COURT: Okay. That's one example.
MR. McCONNICO: We'll find some more. And there are also citations over on the second page.
THE COURT: Yeah, I know, but right now I'm going to look at Page 61.
MR. McCONNICO: Yes, sir.
THE COURT: And then I should strike gold --
MR. WINGARD: The paragraph that starts with "In some" --
THE COURT: -- or lead or methane or dirty water.
MR. McCONNICO: Judge, 73 is the same.
THE COURT: Okay. I'll get there in just a moment.
Y'all don't want Della to write this down, do you?
MR. JACKS: No.
(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 11th day of January, 2012.

/s/: Della M. Koehlmoos
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