REPORTER'S RECORD
DAILY COPY VOLUME 2
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 10th day of January, 2012, the following proceedings came on to be heard in the above-entitled and numbered cause before the Honorable John K. Dietz, Judge presiding, held in Austin, Travis County, Texas:

Proceedings reported by machine shorthand.

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I N D E X

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JANUARY 9, 2012

PROCEEDINGS

JANUARY 10, 2012

(Jury present)

THE COURT: Thank you, be seated. May I see counsel here briefly?

(Discussion at the bench as follows:)

THE COURT: Just be glad you're not in the office.

MR. JACKS: We're thankful.

THE COURT: Okay. How long are y'all going to take?

MR. MELSHEIMER: Your Honor, we had agreed to an hour and five minutes a side, and I think I'll take maybe a tad less.

THE COURT: Okay. And so do you -- I would prefer to break in the middle of that if you don't mind.

MR. McCONNICO: Do not mind.

MR. MELSHEIMER: I'm sorry, Judge. I misspoke. We agreed to an hour -- we agreed to 75 minutes a side. I apologize. I said an hour and five. I'm sorry.

THE COURT: Hour and 15. I liked your hour and five.

MR. MELSHEIMER: I misspoke.

THE COURT: That's okay.

MR. McCONNICO: Are we going to take up any of the evidentiary issues or just go right to opening?

THE COURT: We're going to go right to opening.

MR. McCONNICO: Then I'm going to tell some folks they don't need to be here if we're not going to do any evidentiary.

THE COURT: Yeah. The other thing is I have a doctor's appointment at 4:40, and I've got -- so I'm obviously going to be about five minutes late. So if we've got a bunch of other legal stuff, I'm probably going to have to do it in the 1:00 to 1:30 corridor.

MR. McCONNICO: We have -- no, I don't think we're going to have that much. We've got to decide by 5:00, and that's the first thing.

THE COURT: That was part of my pitch in my office. I'll see y'all --

MR. JACKS: Do you have the trial amendment? We filed a trial amendment this morning that withdraws our punitive damages on --

THE COURT: That does what?

MR. JACKS: Withdraws punitive damages on the common law claim which moots the bifurcation issue.

THE COURT: Well, they'll have a response to that, so I don't think I have to do anything right now.

MR. JACKS: You do not. I simply wanted to --

MR. McCONNICO: And we are going to have a response.

THE COURT: Of course you are. Thank y'all.

MR. SWEETEN: Thank you.

(End of bench discussion)

THE COURT: Everyone be seated, please. Who is going to give the opening statement for the plaintiff?

MS. O'KEEFFE: Your Honor, I am for the State of Texas and Mr. Melsheimer for the relator.

THE COURT: All right. You ready?

MS. O'KEEFFE: Yes, sir.

Good morning, my name is Cynthia O'Keeffe. Yesterday you met my colleague, Patrick Sweeten. We work for the State of Texas at the Office of the Attorney General Gregg Abbott. Mr. Sweeten and I work in the Civil Medicaid Fraud Division, and it is our job to investigate allegations of fraud that impacts the Texas Medicaid Program. It is Medicaid fraud that

brings us here together today.

This is a case about the systematic looting of money from the Texas Medicaid Program by one of the oldest and largest drug companies in America. It was not a one-time event, and it was no accident. The evidence you will hear in this case is about the systematic scheme that was devised by the defendants that specifically targeted Texas and the Texas Medicaid dollars this state spends on its poorest and most vulnerable citizens, most of whom are children. And we're here because the scheme worked. Johnson & Johnson extracted $579 million from the Texas Medicaid treasury. That money went into the coffers of Johnson & Johnson through the efforts of several of their subsidiaries, most notably, Janssen. Those were our taxpayer dollars that were meant to meet the healthcare needs of our poorest Texans.

Now, as Mr. Sweeten told you yesterday, at the Attorney General's Office we protect the rights of all Texans. You or someone you know may have been served by our office, possibly as a child for whom support was collected, or you may be aware of the efforts of our office to help consumers from being the victims of scams, or to protect children from being the victims of online predators. In many ways at the

Attorney General's Office, we act as the watch dog for the people of Texas.

As I mentioned, Mr. Sweeten and I are charged with the duty of investigating Medicaid fraud. Medicaid is a healthcare program. It's set up by the federal government, but it's run by each individual state. Both your state and federal tax dollars fund Texas Medicaid.

During this trial, you will find out that 70 percent or more of the Texas Medicaid population is children. Pregnant women and children make up the overwhelming majority of the Texas Medicaid population. Texas Medicaid helps pregnant women get the healthcare they need when they can't afford it and also helps elderly persons get nursing home care.

The law that charges our office with investigating Medicaid fraud is the Texas Medicaid Fraud Prevention Act. And the reason Texas needs a specific law to address Medicaid fraud is because the Texas Medicaid Program is huge. You will learn in this trial that Texas has one of the three largest Medicaid populations in the country. Medicaid expenditures in Texas consume 25 percent of our entire state budget.

Our duty under the Texas Medicaid Fraud Prevention Act is to root out fraud in the Medicaid

Program wherever it is found. If money is wrongfully obtained from Texas Medicaid, it is our job to come to court to recover money on behalf of the Texas taxpayers.

We're here today because a man you met yesterday, Allen Jones, brought fraud -- reported fraud to our office. You will learn how he was a Pennsylvania state fraud investigator doing his job when he uncovered a trail of money and corruption that led him to report to our office what he believed to be serious fraud and directly at the Texas Medicaid Program. Once our office learned of his claims, we began our investigation, and that is exactly how the Texas Medicaid Fraud Prevention Act works. It provides a way for people who have knowledge of Medicaid fraud in Texas to bring that information to the authorities who can do something about it. And in particular, it provides that people who have knowledge of wrongdoing can bring a lawsuit and, through that lawsuit, notify our office of their allegations, and that is what Allen Jones did.

The law requires that such a lawsuit be filed under seal. And what that means is that initially the existence of a lawsuit is not known to the public. And the reason for that is to give our office an adequate time to investigate the allegations to see if they're supported by the evidence. We receive many

claims of Medicaid fraud every year in our office, and we investigate them all. And some have no merit, and those we do not pursue. But if we find at the end of our investigation that the evidence does support the allegations, we believe the claim does have merit, then we unseal the lawsuit, make it known to the public and join with the person who brought the suit to pursue the case on behalf of the people of Texas. And that's exactly what happened here. This lawsuit was filed under seal and our office investigated for more than a year.

That investigation had several aspects. First, we reviewed millions of pages of documents. Second, we analyzed state programs and policies. Third, we interviewed Medicaid -- I'm sorry, we interviewed state witnesses. And fourth, we analyzed the Medicaid budget and the expenditures. And at the end of our investigation, we found that the evidence did support the allegations, we believed the lawsuit had merit, and so we unsealed the case and we joined with Mr. Jones and his attorneys in pursuing this case on behalf of the people of Texas.

Throughout this trial, you will hear how our investigation revealed that the defendants' plan had Texas Medicaid as the target. But Texas Medicaid did

not know that it had been deceived. You will hear how the defendants led Texas Medicaid people, people that were administrators at Texas Medicaid, to believe that the defendants' drug, their antipsychotic drug Risperdal, was safer and more effective than older antipsychotic drugs that were less expensive and had been on the market for years to treat the very serious mental illness schizophrenia. And you will learn that Risperdal is no better, and in some ways it is worse. You will hear about the very serious side effects of Risperdal and that taking Risperdal can lead patients, including children, to develop diabetes. And you will hear one of the most disturbing facts that was uncovered by our investigation, and that is that in the spring of 2000, the FDA, the Food and Drug Administration, notified the defendants of concerns about a link between taking Risperdal and developing diabetes, and yet, that was the very point in time when the defendants decided to aggressively ramp up their marketing of Risperdal for children, which was illegal.

And you'll hear how Risperdal has always been more expensive than the older drugs. How much more expensive? Well, there are a number of ways to measure that, but here's one. In 2004, a two milligram tablet of haloperidol, one of those older antipsychotic drugs

that I was telling you about, cost Texas Medicaid less than 10 cents. At that same point in time, the two milligram tablets of Risperdal cost Texas Medicaid $4.57. That's over 45 times more expensive. And in the trial you will hear how Texas Medicaid reimbursed millions of Risperdal prescriptions because they believed the defendants' story that while Risperdal might be more expensive per pill, that because it was a better drug, that it would be more cost-effective for the state overall. That mistaken impression, that mistaken belief on behalf of Texas Medicaid, was caused by Johnson & Johnson's deception.

During this trial, you'll learn that once the defendants executed their plan successfully in Texas, they exported it all over the United States by pointing to Texas as a model state to follow and using Texas state employees to boost their revenue and further their sales goals for Risperdal.

Here we are over six years after Allen Jones brought his claims to our office. During that time, we have reviewed millions of pieces of evidence. We have examined medical studies. We've looked at internal Janssen and Johnson & Johnson business plans and e-mails and memos. And we have taken the sworn testimony of over 140 witnesses. This is the first time

that the full picture of all the evidence has been presented to anyone.

The defendants executed their plan over many years, and now my co-counsel, Mr. Melsheimer is going to reveal the details of the plan to you. But throughout this trial, one fact will be familiar to you, and that is the motivation behind Johnson & Johnson's conduct. It's a simple motivation, and it's one that we've all grown far too familiar with in recent years. It is money and its frequent companion, greed.

MR. MELSHEIMER: May it please the Court, good morning. I'm Tom Melsheimer. During my time with you today, I want to review what I expect the evidence will show in this trial. The gist of it is this: Janssen, a subsidiary of Johnson & Johnson, engaged in a wide-ranging fraudulent scheme to market and sell Risperdal, a drug that was no better and in some ways worse than older less expensive antipsychotic medications.

Over the course of 17 years, Janssen sold $34 billion worth of Risperdal at a profit margin of sometimes nearly 97 percent. At times, the company sold $350,000 worth of Risperdal every hour. You'll see this in their documents.

How did they accomplish this? Four ways.

First, they made false statements about Risperdal being better than the older less expensive medications, including helping fund and manipulate treatment guidelines, treatment guidelines that made Risperdal appear to be better than the older drugs. And included in this scheme was a scheme to pay Texas officials to promote Risperdal for Janssen's own benefit at the expense of their duties to the state of Texas.

Number two, Janssen illegally promoted Risperdal for use in children even though the FDA had told them that they could not do that.

Three, Janssen made false claims that Risperdal was safer than the older less expensive medications, including minimizing serious side effects like hormonal side effects and diabetes.

And finally, number four, Janssen made false claims that Risperdal was more cost effective than the older less expensive medications.

Janssen's fraudulent scheme violated the Texas Medicaid Fraud Prevention Act. We're here today in this courtroom to present evidence of those violations. And at the end of this trial, you will conclude that Janssen has violated this statute and other laws.

Now, it turns out that part of your work

is already done. In 2004, the Food and Drug Administration caught Janssen making some of the same false claims you will hear about in this trial. In response, the FDA made Janssen send out this letter to over 600,000 healthcare professionals, including 18,000 in Texas.

In this July 21st, 2004 letter that Janssen sent out, they said as follows: They said that the FDA warning letter had concluded that Janssen had omitted material information about Risperdal, had minimized potentially fatal safety risks and made misleading claims suggesting superior safety.

Now, you may hear during this trial that the defendants don't believe they did anything wrong. But folks, the Food and Drug Administration wasn't the only group back in 1994 who thought Janssen had given out false and misleading information. It turns out Johnson & Johnson executives thought so, too.

Let's take a look at this slide from Dr. Scott Reines. It's an e-mail. He's an executive vice president with J&J and a medical doctor. And in April of 2004, he sent out an e-mail to folks within the company about this letter, this false and misleading letter that Janssen had sent out. What does he say? He says, first, "They never consulted the team or anyone in

PRD." PRD is the research arm of Johnson & Johnson. "No competent person would have let it go out. It's really a black mark for J&J." That's what Dr. Reines said in 2004, and I think it's going to be a little bit different from the story Janssen will tell you in this trial.

When Janssen received this warning letter and was forced to tell all these doctors of their misleading statements, it was pretty serious stuff. It was especially serious for a company like Janssen which had a corporate motto that said that "We believe our first responsibility is to the doctors, nurses and patients, to the mothers and fathers" of all who use our products. In other words, their credo says we're going to put patient first, not profits. Folks, at the end of the evidence, I think you will realize that patients were the furthest thing from Janssen's mind when it came to Risperdal.

So how did Janssen fail to live up to this motto so poorly? To do that -- to answer that question, we have to go back several decades and talk about some history. We need to start back in the 1950s. At that time, there were powerful drugs on the market which were typically called tranquilizers. They were prescribed for a variety of conditions: schizophrenia, but also

for conditions like insomnia or anxiety.

Now, one of the side effects of these drugs was something called tardive dyskinesia or TD. This is these uncontrollable tics or jerking movements. These debilitating uncontrollable side effects could sometimes be permanent. So because of that, doctors started using these tranquilizers, which they then started calling antipsychotics, only for serious mental illnesses like schizophrenia. Janssen had a drug like this called Haldol. It was actually invented by a guy named Paul Janssen, who was the founder of Janssen. Haldol was widely prescribed. And you know what? It worked pretty well. It worked pretty well.

Now, in the late 1970s and '80s, many drug companies, including Janssen, started on this quest to find drugs, antipsychotic drugs, that would be better and safer than the older drugs like Haldol. After all, if a company could come up with an improvement, a real improvement over Haldol, that would be a breakthrough for people suffering from schizophrenia.

In the 1990s, Janssen claimed it discovered just such a drug, Risperdal, also called risperidone. Janssen planned to introduce this drug as a breakthrough. And because they were going to claim it was a breakthrough, they knew they could charge a lot

more money than these older drugs like Haldol, which had become available in generic form. So months before they got their FDA approval, Janssen had some marketing -- internal marketing plans within the company about how they were going to launch their drug. Let's take a look at it.

This is their strategic launch plan for Risperdal in June of 1993, and they say, "A new antipsychotic should offer less side effects (EPS)" -- that's related to this tardive dyskinesia or TD that we talked about -- "combined with better efficacy ... when compared to current neuroleptics," in other words, be safer, better efficacy, work better.

Now, what else did their marketing plans have in mind back in 1993? Well, they said this as their competitive strategy: "We must convert as many patients as possible from conventional neuroleptics" -- that's the older less expensive drugs -- "to Risperdal." And then what do they say? "The ultimate objective is to create the perception that Risperdal will be the new gold standard in drug therapy." That was Janssen's plan back in 1993 before the FDA had even approved the drug.

Let me talk for just a minute about the Food and Drug Administration. One of the things the FDA does is it tells drug companies what they can say about

their drugs. It tells them what they can say and who they can market and promote their drugs to. A drug company can have all the marketing plans they want, but if the FDA says no, they're not allowed to promote for those illnesses or in those populations, or at least that's how it's supposed to work.

So you see in their marketing plan they knew they had to claim this drug was going to be an improvement, an improvement over the older drug. So they asked the FDA back in 1993 for a package insert, or the label, that would help implement the marketing plan they laid out. The FDA told Janssen no, you cannot say that Risperdal is better than Haldol.

In response, Janssen sent a letter to the FDA arguing why they should be able to make that claim, and look at what they said. They said, "Information contained in the package insert," or the label, "can have a significant impact on the sponsor's ability to promote a new drug product." In other words, they knew that they needed this label that said they were better than the older drugs, because they wanted to be able to promote it over the older drugs. The FDA did not agree with this, and they told Janssen so very clearly. They would not allow Janssen to make any claim that Risperdal was better than Haldol, and let's take a look at what

the FDA finally said.

Well, let me back up. They had some interior debate within the FDA about we can't -- they won't agree to the label. Why are we having this debate with Janssen? This is what the folks inside the FDA said. They said, look, this is a delay that's happening solely because of a sponsor's desire for labeling that will facilitate promotion. In other words, we've done our job; they just want a label that will allow them to promote their product.

They didn't agree with that. The FDA said no. What did the FDA tell Janssen? In the final approval they said, "We would consider any advertisement or promotional labeling for Risperdal false, misleading or lacking fair balance ... that risperidone is superior to haloperidol" -- that's Haldol -- "or any other marketed antipsychotic ... with regard to safety or effectiveness." In other words, you can't say it's better. You can't say it's safer.

Janssen still pushed back, but the FDA wouldn't budge. Here's an internal memo from the FDA where they conclude that we have -- that the FDA "has refused to accede to Janssen's demands because" what they want -- what Janssen wants on the label "invites a comparison that leads to the conclusion that Risperdal

has been shown to be superior to haloperidol when, in fact, it has not." And they told them that plainly.

The FDA was the first group to tell Janssen that Risperdal was no better than the less expensive drugs, but it wouldn't be the last. You're going to hear evidence in 2005, a government study called the CATIE study, an independent study untainted by drug company funding, reached the exact same conclusion. We'll talk about that a little bit later.

So how does Janssen react to this bad news back in 1993? Did they go back and rewrite their marketing plans? Did they decide to abandon this plan to create the perception that Risperdal was better than the older drugs? Did they go back to the drawing board and decide to follow the rules that the FDA had set? They didn't. They didn't.

How did they react to this? Well, let's take a look at the Risperdal business plan in the fall of 1994, about eight months after the drug's approved. What do they say? "Key Strategic Components: The overall objective is to make Risperdal the new gold standard for antipsychotic therapy and maintain the market leadership position."

How were they going to position as the new gold standard, that phrase we've heard before? Well,

here's what they say: "The position of Risperdal is the only first choice antipsychotic due to its efficacy for a broad range of symptoms, a safety and tolerability profile unmatched by any other antipsychotic," unmatched, safer than any other antipsychotic, better than any other antipsychotic.

So despite the FDA's clear statement that it's going to be false and misleading if you claim that Risperdal was better than Haldol, they plowed right ahead with it. Janssen, the evidence will show, plowed right ahead with their claims that Risperdal was better and safer. Starting in 1994 and until generics became available in 2008, Janssen and its sales representatives made this false claim of superiority over and over again throughout the country and right here in Texas and to Texas Medicaid officials.

Now, why in the world would Janssen risk doing exactly what they were told not to do? It's the same reason many people do what they're not supposed to do, and that's money. Let's take a look at the money Janssen was making in just the first eight months that Risperdal was on the market. This is from their 1994 plan. Risperdal has quickly established itself as the market leader, 20 percent of the entire company sales, eight months.

When the FDA approved Risperdal in 1993, they didn't know something, and really no one knew this until this lawsuit uncovered it, is that Janssen's plan to claim that Risperdal was superior was really only a small piece of their overall plan to turn Risperdal into a blockbuster.

Why would they need a false scheme or a fraudulent scheme to turn Risperdal into a blockbuster drug? Two reasons. First, Risperdal is designed to treat a very serious but very infrequent condition, schizophrenia. Thankfully, it only affects about 1 percent of the adult population.

Second problem, this drug was very expensive. It was 45 times more expensive than the older drugs. So how in the world do you turn that drug into a blockbuster under those circumstances? Well, here's how you start. You start with a Risperdal strategic reimbursement plan, which they created in September of 1992. This is a year before Risperdal was approved. And it talks about how Janssen was planning to generate revenue from this very expensive drug, and they focus specifically on who was going to pay for it. And in their own documents, they concluded that 60 to 80 percent of all schizophrenia treatments are for Medicaid, and that makes sense, because schizophrenia is

a very debilitating disease. Mean people who suffer from it can't maintain jobs, so they end up relying on the public sector. They knew that in order to turn this drug into a blockbuster, they had to find a way to get Medicaid to pay for it.

So one of their first plans was to gain credibility for TMAP for Risperdal by developing what's called a set of treatment guidelines that would favor Risperdal over the older drugs and over the competition. You're going to hear about this plan they carried out in several stages.

Let me talk to you about treatment algorithms or guidelines. Treatment guidelines or algorithms are supposed to be steps that a doctor is supposed to follow, try this first; if that doesn't work, try this; if that doesn't work, try this. It could be a good idea. But in this case, Janssen ended up creating, funding and implementing treatment guidelines that favored its own drug, Risperdal. You'll see evidence that Janssen hired three doctors to draft treatment guidelines, which Janssen referred to as the Risperdal treatment guidelines. Publicly they were called the expert consensus guidelines, or the Tri-University Guidelines, you'll hear that evidence, because the doctors were from three different

universities.

During the drafting process of these guidelines, Janssen actually had input into the questions to be asked the psychiatrists, the way the guidelines would be framed and how they could be best used to help market the drug. You'll hear that after these guidelines were formed, these three doctors that Janssen hired formed their own company called EKS. And Janssen paid that company $600,000 to go out all throughout the country and promote these guidelines, seemingly as an independent third party.

And additionally, you'll see that when these guidelines were actually published, Risperdal was the only new antipsychotic listed by name. That wasn't an accident, and it wasn't the result of some great scientific breakthrough. What do I mean by that? Well, this is a 1996 presentation by the reimbursement team within Janssen. The reimbursement team are not scientists. They're people in charge of getting the drug paid for. And in 1996, they listed some of their accomplishments in the past year. And what was one of the big ones? The Tri-University Schizophrenia Treatment Guidelines, these guidelines I've just told you about, the design, development and implementation. So they took credit for them as a marketing and

reimbursement tool, not as a medical breakthrough.

Now, having these guidelines around was not going to be enough to help Janssen turn the drug into a blockbuster. As you saw in Janssen's documents, they knew that Medicaid was going to be key for this drug's success. And Janssen knew also that if it could get this drug in a favorable position with the Medicaid Program, it stood to make a lot of money. And the Medicaid Program they chose, as you heard from Ms. O'Keeffe, was Texas, one of the three largest in the country. Texas was targeted by Janssen with visits from those three doctors they hired, paying money to implement the guidelines in Texas, and then payments to Texas officials to help promote the guidelines within Texas and throughout the country.

Now, you may hear Janssen say during this trial, oh, no, Texas came up with these guidelines on their own. Well, Janssen's internal documents tell a different story. Take a look at this document way back from February 1993 before the drug's even approved, an internal marketing plan discussed within the company. They talk about developing a model state program that could be a successful guide to schizophrenia management that could be promoted locally and nationally. So way back in 1993, Janssen had targeted Texas as this model

state program.

You'll also hear from a man named Dr. Alec Miller, who's one of the Texas officials involved with Medicaid. And he will testify that Texas adopted the Janssen guidelines 100 percent whole cloth, is the word he'll use, at a meeting in September of 1996. In the first version of the Texas guidelines -- and here they are. This is what I mean by the different steps of the -- it's called an algorithm or a set of guidelines, and this is the first one, risperidone, so conventional antipsychotic or risperidone. Now, it's in the first category, it's the first choice, but it's equal to the older less expensive medications. Now, Janssen thought this was good. It put their drug up there. It gave their drug credibility. It was going to allow them to claim ultimately that Risperdal was superior to the older drugs.

Take a look at an investor relations plan that talks about these guidelines being published in 1996, and they say that we're going to publish these guidelines and the use of them as standard of care and thus, Risperdal as standard of care for schizophrenia. So they knew back in 1996 when they were talking to potential investors or writing about that, that this guideline, this treatment guideline, was going to

position Risperdal as superior, which, of course, was the exact thing the FDA told them they could not do.

But being on the same level as the older drugs, of course, they wanted more. They wanted to get a perception of superiority. So how did they do that? Well, soon after the guidelines were adopted, the first string of them, Janssen went back to Texas and contributed money to get TMAP, the Texas Medication Algorithm Project -- that's what they called it, TMAP, the Texas Medication Algorithm Project -- implemented throughout the state. All told, Janssen and its charitable arm, the Robert Wood Johnson Foundation, contributed over $3 million to this Texas Medication Algorithm Project. And soon after Janssen began these contributions, soon after, along with other drug companies that were coming out with their own newer expensive drugs, the guidelines got changed by Texas officials to put the older less expensive drugs farther down on the list and to put the newer more expensive drugs as the first choice. So a drug that was 45 times more expensive was now going to be the first choice, and the less expensive drug was going to be two or three levels down. So in other words, they got TMAP, this Texas program, to make the exact same claim that the FDA had told them back in '93 they couldn't make.

Now, Janssen's own documents reveal what they thought the financial link was between their contributions to this Texas program and where Risperdal got positioned. Here's an e-mail we uncovered from July 2001 talking about the funding for this program. And they say "One of the reasons Janssen committed substantial funding for TMAP" -- that's the Texas program -- "was to develop a treatment guideline for schizophrenia that positioned atypicals as first line agents (at the time, atypicals were usually positioned after conventionals)." Atypicals, that's the newer more expensive drugs; conventionals, the older less expensive drugs. So they knew what the motivation for the money was and they knew what they got.

Now, now does TMAP, do these guidelines, do they represent objective medical opinion? You're going to see evidence that will allow you to see for yourself. Let's take a look at this exhibit, which is a summary of all the different treatment guidelines that were out there for schizophrenia in 1999. And this is a little bit hard to read, but let me take you through it.

The guideline characteristic here is first-line typical antipsychotics, in other words, were the cheaper, less expensive ones the first line, the first choice. In all of these other guidelines, the

ones developed by the American Psychiatric Association, the Journal of Psychiatry, the Veterans Administration, all of these, the cheaper older drugs were first line, except for one, TMAP. The TMAP project, no. The first line was the newer more expensive drugs.

Janssen's scheme, though, did not stop with getting TMAP implemented throughout Texas. They needed also to shove aside their competitors that also had new drugs out there and truly be number one in Texas. And to do that, they needed the help of certain Texas officials. One of them that you're going to hear about is Dr. Steven Shon. Dr. Shon was the medical director for the Texas Department of Mental Health, which means he had a lot of influence over the needy Texans in need of mental illness treatment.

As you'll see in here, Janssen made a series of illegal payments to Dr. Shon that effectively turned him into a salesman for Risperdal. They even had the man sign a consulting agreement in which he said that he had no obligations that would interfere with his obligations to Janssen. All the while, he was an employee of the State of Texas subject to their ethical rules.

What did Janssen get for its money? They got the man to fly all over the country helping sell

Risperdal and helping sell the false idea that Risperdal was better and safer than the older less expensive drugs. And this chart represents all of the different places Dr. Shon was paid to go by Janssen. He made numerous presentations about the Texas Medication Algorithm Project, TMAP, went to all these states to try to sell that to their states.

One of the presentations he made was pretty early on in October of 1997. It was an all-day meeting to brief the drug companies who had contributed to TMAP on how things were going. Well, it turns out for Janssen, things were going pretty well, because a percentage of patients in the mental health clinics for schizophrenia patients who had been prescribed Risperdal was 68 percent. That's a pretty good number for a drug that is no better and no safer than the older less expensive medications.

The doctors associated with TMAP also laid out the philosophy of what the program was designed to convey. And what do they say? The most efficacious and safest treatments are supposed to be first. And what were the most efficacious and safest treatments according to the TMAP guideline? The newer more expensive drugs like Risperdal. In other words, TMAP embodies Janssen's claim that the FDA told them they

couldn't make that Risperdal was superior to the other drugs.

In 2000 alone, Janssen paid Mr. Shon -- or Dr. Shon to spend almost half his time, almost half his time as a Texas employee on the road for Janssen selling Risperdal. How did that help Janssen? Well, it got other states to buy in to the program that they had helped implement here in Texas. And by 2001, Janssen's revenue for Risperdal alone, $1.8 billion.

And the folks within Janssen, they knew exactly who was responsible for that money. This is an internal e-mail about the importance of Dr. Steve Shon. What do they say? "Note: Dr. Shon can and is influencing not only the $50 million atypical" -- that's the newer drugs -- "in Texas, but likewise in many other states." And what's in all caps, not my all caps, theirs? "We will not let Lilly or Pfizer" -- those are two competitors -- "prevail with our most important public sector thought leader." They knew they needed Dr. Shon to help them keep up that 1.8 billion a year.

He wasn't the only Texas official, though, that Janssen hijacked to help them promote Risperdal. They also paid substantial sums of money to these individuals: Dr. Crismon, Dr. Miller, Dr. Chiles and Dr. Rush. Janssen used these doctors for their own

purposes, paying them in excess of $250,000 to fly all around the country at Janssen expense to spout Janssen's claims of Risperdal superiority, claims they knew they couldn't make.

I talked about a scheme to turn the drug into a blockbuster. Janssen's scheme to fraudulently market Risperdal and claim it was better and safer was not going to be enough to turn the drug into a blockbuster. Selling more drugs for schizophrenia alone was not going to be enough for them to make $34 billion. They needed to expand the market. Let's look at what they thought about this back in the early '90s.

They had been told by the FDA when the drug was approved in 1993, pretty simple, "Safety and effectiveness in children have not been established," period. Now, despite this clear statement that they couldn't promote it for pediatric use, Janssen planned to promote Risperdal for use in small children from the very beginning and to use it for conditions like anxiety, rebelliousness, attention deficit disorder and things of that nature.

Now, in this document here, Janssen identifies the problem I was just talking about. They talk about the anticipated growth -- this is their marketing plan. This is an interesting phrase. "The

anticipated growth of the antipsychotic market does not create enough room for the Risperdal sales forecast." In other words, there's not enough schizophrenic people to sell Risperdal to to get our sales forecast hit. So what do they say? We need to aggressively expand Risperdal in other states, and that's going to be mandatory. Now, what does that mean? That meant that they were going to have to establish it as a broad-use product. Again, this is in the fall of 1994. And what does that mean? A critical success factor for them in that market expansion -- they identified this back in 1994 -- was children, children.

Now, think about this. The success they're talking about here was not a medical breakthrough. It was a financial breakthrough. Janssen knew that if it could sell -- push its drug on children, it could help make the drug financially successful. So after 1994, every single Janssen business plan you will see will talk about targeting the vulnerable population of children to sell Risperdal to.

I want to make it clear that these plans were not just abstract ideas about how to accomplish a certain financial goal. They had very specific medical tools that they used. For example, in one of their early marketing plans, not a medical analysis, what did

they say? They said, Well, you know what? We need an oral solution. Why? Because it's easily mixed with liquids, and that can be used for kids, because everybody knows that kids don't like to swallow pills.

Liquid formulas alone weren't going to be enough to push Risperdal onto the children of Texas. In the same marketing plan where they talk about this children being a critical success factor, they talk about this. They talk about this idea of market expansion by seeding the literature. What does that mean? That means putting in articles out there in publications that say favorable things about Risperdal. Now, these weren't going to be articles that just popped up in a random journal by an academic or a doctor. These were going to be articles that Janssen had a hand in writing. Janssen had an extensive seeding and publication plan.

Now, you may have thought before this trial that these articles were designed to uncover scientific truths or solve important medical problems, but that is not how Janssen viewed these studies, make no mistake. They viewed them, the evidence will show, as a vehicle for their marketing messages. What do I mean by that? Well, let's take a look at this. You'll see this in evidence.

This is a publication program status report by a company that Janssen hired called Excerpta Medica. This is a company they hired to help them seed the literature with favorable studies about Risperdal. They did this dozens of times. You'll hear from Janssen employees that the topics of the articles and the conclusions were decided before the authors were even identified, before they even knew who was going to write it. Let me show you what I'm talking about.

You'll see chart after chart like this in this document. Here's a topic of an article: the effectiveness outcome of Risperdal. Who's the author going to be? Don't know. Who's the writer going to be? Don't know. What's the statu? Well, Janssen's developing the draft.

Down here, Risperdal Medicaid outcomes. The author, well, we know who that is. It's someone named Gianfrancesco, but who's actually writing it? You'll find that EM stands for Excerpta Medica, Janssen's own publication company. And even though the FDA told Janssen you cannot promote for use in children, what are they doing in their publication plan? Well, let's have an article reviewing antipsychotics in children that we will target at pediatricians.

The goal of these articles was not to

advance scientific learning. It was to advance Risperdal. All you have to do is look at Janssen's own internal documents. Here's a discussion among some people editing a document within Janssen that's going to be published, and they say, "Although we like to think we develop these manuscripts for scientific purposes, the real value is when a sales rep can reference them, show them and present them."

The seeds that Janssen planted bore very much fruit. By 2001, from Janssen's own files, children accounted for one quarter of all Risperdal prescriptions. In fact, Janssen employees decided that it was so successful that they need to have a standalone business plan to help them push Risperdal onto children. Here is that plan. Here is the June 2001 business plan. And this is where they evaluate their strengths and weaknesses and threats, and let's review.

Well, what are the strengths in the child and adolescent markets for Risperdal? Well, they're the leader. And one strength is we've got that oral solution, so kids don't have to take pills.

What's one of their weaknesses? Well, there's that safety perception problem, EPS and TD, tardive dyskinesia. Prolactin, we'll talk about that in a minute. Weight gain. What's another weakness? It's

illegal. Lack of promotional platform/indication. In other words, that's a fancy way of saying -- "current clinical data does not meet FDA stated needs." That's a fancy way of saying we can't do it, and that's a weakness.

And what are the threats that they identify in the third slide? Well, one threat is public relations. Don't want anyone finding out. Adults might be really upset that kids are getting this powerful antipsychotic. And what's another threat? Regulatory, legal and payers. And to me, the evidence will show, I think that's the most disturbing, because instead of viewing the regulators, the legal folks at FDA, and the payers, the Medicaid people, as partners in protecting this most vulnerable population, Janssen viewed that as an impediment to their market share. They viewed it as a risk of getting caught.

So one month later in July of 2001, Janssen prepared another business plan for children. And what do they say? We're going to remain the gold standard in the C&A market. I want to make sure you have a picture of what this means. Half of Risperdal child and adolescent patients -- again, from Janssen's own documents in July of 2001, half of them are under age 13. I heard that, and I thought that says one

thing. What's the picture of that, though? That's half their market for this powerful antipsychotic, was kids under 13, 5 percent of the -- 5 percent, zero to six years.

So how did Risperdal get to be the gold standard? How'd they get to be the gold -- that's a phrase they like to use. You'll see it in their documents. How'd they get to be the gold standard? Something called off-label promotion. What do I mean by that? Well, you may remember that was discussed a little bit in the jury selection. Off-label promotion is this: Unless the FDA has given an approval for the drug's use in a particular population or for a particular illness, it is illegal for a drug company to promote or sell that drug to that population or for that illness. So in Risperdal's case, that means you cannot promote, market or sell for use in children. Now, if a doctor independently decides that they want to prescribe a drug, they can still do that. That's different. But the drug company can't push it on the doctors. That's off-label promotion.

Now, the FDA said that, but this was not news to the company. This was not news to Janssen. You'll see a memo from Alex Gorsky, who at that time was the president of Janssen and is now the number three man

in the company, the old Johnson & Johnson company. He sent out a memo every year telling people within the company, promotion of unsupported or off-label claims are not only illegal, so we know they're illegal, but they compromise the reputation of the company.

So just like Janssen did not heed the FDA when they told them you could not promote to children, they did not heed or follow their own internal policies and they pushed Risperdal for children. In fact, you'll hear evidence that in 1997, they tried to get the FDA to approve an indication for children. What does the FDA say? "There is an inadequate support for the changes." "You have provided no data."

Now, they weren't sending the FDA all these business plans and all their marketing ideas. They were sending what they thought was scientific data. And they say, consequently, it's not approved. Why? Because what you're wanting to put in the label would only "promote the use of this drug in pediatric patients without any justification." Now, they had their own justification. It was to make more money. But there was no scientific of medical justification. The FDA told them that.

So as early as 1994 then, you'll hear evidence that Janssen pushed Risperdal for use in

children throughout Texas and elsewhere, and they talked to Medicaid providers like Dr. Valerie Robinson, someone you'll hear from. She's a child psychiatrist. She only sees children. You'll hear testimony that between 1994 and 2003, a Janssen sales rep named Jeff Dunham called on her 94 times. She was not the only -- was not the only adolescent child psychiatrist that Janssen targeted. Sales representatives throughout Texas were pushing Risperdal for use in children to psychiatrists all over the state. You'll see call notes, something called call notes where the salespeople had to write out their sales calls, time and again to child psychiatrists pushing Risperdal.

You'll also see documents about sales promotions. They tried to make this fun. They tried to have sales contests and promotions within the company to see who could sell the most Risperdal. You'll see this memo in May of 2004. Abilify, that's a competitive drug. You may have seen it advertised on television. "Abilify is gaining ground with C&A" -- that's child and adolescent -- "psychiatrists and we need to make sure Risperdal is growing with this customer segment. Let's make it happen." And you'll see evidence that their aggressive marketing campaign worked.

How will Janssen respond to this? I'm not

sure, but I think they will say that in 2006 and 2007, they did get a narrow approval from the FDA for a narrow use in children, not broad use, not children generally, and certainly nothing that would justify all the off-label promotion they did from 1994 onward.

You heard Ms. O'Keeffe talk about diabetes, so I want to transition into that subject and talk about what else was going on in 2001 when Janssen was really gearing up to push this drug into children. As Risperdal's use became more widespread, cracks began to appear in the foundation, which I think you'll conclude is what happens when your foundation is built on deception. As so many patients, including children, began taking Risperdal. Some serious and potentially deadly side effects began to develop. One of them was this tardive dyskinesia, this movement disorder, that was one side effect.

There was another side effect I want to talk to you about that Janssen concealed. It's called hyperprolactinemia. Hyperprolactinemia. Prolactin is a sexual hormone. Hyperpro -- and if you have elevated levels of it, it can cause serious problems. Hyperprolactinemia can result in premature breast growth and lactation in girls. It can result in breast growth and lactation in little boys. These were the types of

side effects -- these side effects were the kinds of things that Janssen concealed.

One of the most serious ones, though, was diabetes, a lifetime disease. It turns out that weight gain is a risk when you take Risperdal and these other antipsychotics, and that when you gain weight, that's a risk factor for getting diabetes. So in May of 2000, May of 2000, the FDA asked Janssen and all these other drug manufacturers for all the information you have about your drug and diabetes, because the FDA was getting reports that people were developing diabetes from taking Risperdal, and they wanted -- and other antipsychotics, and they wanted to find out what was going on.

It turns out Janssen knew quite a bit about diabetes that they never shared with Texas or the FDA. Janssen knew that weight gain was an issue back in 1999, a full year before the FDA asked for the information. They had done a study called RIS-113. And this study revealed that Risperdal when compared to Zyprexa, another antipsychotic drug, that both drugs caused medically serious weight gain. And on September 9th, the executives -- 1999, the executives became aware of this study within Janssen. And what did they conclude? They say, well, this one may be of

limited value because, among other reasons, unusual weight findings. You'll see that e-mail. Despite that, they didn't include this study to the FDA when they asked -- when the FDA asked for information about diabetes. They didn't disclose it to Texas Medicaid officials. And they didn't even disclose it to the FDA a couple of years later when the FDA told them and all the other new antipsychotic drug manufacturers that you had to have a new kind of warning on your drug about diabetes. Instead, Janssen kept telling the world that Risperdal did not have a diabetes risk.

Let's go back to the very beginning when we first started talking. This is that letter that they sent out in November of 2003 that the FDA later determined was false and misleading and made them send out a correction letter to 600,000 doctors around the country saying we lied to you. This is that letter. And it says in the letter that Risperdal is not associated with an increased risk of diabetes. So they're telling people -- with full knowledge that there was such a risk, they're telling people that there's not.

So every scheme, no matter how successful, eventually runs out of gas. And in 2005, the evidence will show, Janssen's scheme began to unravel. The

National Institute of Mental Health -- it's a government agency sometimes called NIMH -- did a long-term comprehensive study of almost 2000 patients taking Risperdal and other antipsychotics. It was called CATIE, which I've got to read this. It stands for the Clinical Antipsychotic Trials of Intervention Effectiveness. We're just going to call it CATIE. And CATIE concluded what? It concluded that after all this study, untainted by any drug company marketing, untainted by any seeding of literature, untainted by any influence, CATIE concludes that Risperdal and the other newer more expensive drugs were no better and in some ways worse than the older drugs. A few months later over in England, a study called CUTLASS -- I'm not going to tell you what that stands for, but CUTLASS also confirmed the results of the CATIE study.

This was bad news for Janssen. What did they say about it in their internal e-mails after these studies came out? Let's take a look at an e-mail with some key executives within the company in December of 2005. They say, "Importantly ... the UK version of CATIE (called CUTLASS) was presented, unfortunately confirming the results of CATIE that atypicals are no better than conventionals." In other words, the ones that are 45 times more expensive are no better than the

other ones that are a lot less expensive.

This was unfortunate. It was bad news. But you're going to hear evidence that Janssen tried to undermine and criticize the CATIE study. They tried to undermine and criticize the CUTLASS study in doctor's offices, in Medicaid offices, all throughout the country.

The results in CATIE, though, were not a surprise to Janssen, really. And why do I say that? Well, let me take you back to 1991. They did a study called RIS-7, Janssen did, comparing Risperdal to perphenazine, another older less expensive antipsychotic. And what were the results of RIS-7? No better, that Risperdal was no better than perphenazine.

So the CATIE results were a surprise to the medical community because the drug company's marketing had been so pervasive and so successful, convincing everyone that it was a breakthrough, but companies like Janssen knew well before that the drugs were no better and no safer. They knew they weren't a breakthrough. They knew they were not justifying their 45 times higher price.

So the evidence will show that Janssen made false claims of superiority. The evidence will show that Janssen illegally and uninterruptedly promoted

the use of this powerful antipsychotic in children, that Janssen made false claims of safety about the drug, minimized side effects like diabetes and prolactinemia, and that Janssen also made false claims that, hey, it's a lot more expensive, but you're going to save money in the long run. You're going to hear that that claim was also false.

All these parts of the scheme violated the Texas Medicaid Fraud Prevention Act. Why? Well, by making false statements to and concealing material information from Texas Medicaid officials, that is a violation of the Medicaid Fraud Act. You'll hear more about these Texas Medicaid decision-makers in the trial. Briefly, these folks are in charge of making decisions about what drugs go on the formulary in Texas and what drugs can be reimbursed. Let's talk a little bit about that.

In order to get a drug available to be reimbursed by Texas Medicaid, you have to be on something called the formulary. You have to participate in what's called the Texas Vendor Drug Program. I know there's a lot of acronyms. Sometimes that's going to be called VDP. And Janssen submits an application to the Texas Vendor Drug Program, and they certify that the information contained in the application, that this

product is not now in violation of either federal or state law. That's what they say. They made this representation in 1994, and they made it six other times when they got approval for new formulations of Risperdal. Each time, this representation was false because Risperdal was in violation of state and federal law. As we discussed, Janssen was promoting Risperdal for unapproved uses. They were trying to promote the drug and did promote the drug for children. They made off-label and illegal claims that the drug was superior to the older less expensive medications. And so Janssen's certification that they were in compliance with the law was false.

But getting the drug on the formulary, you'll hear, is really just the beginning here in Texas. Janssen also had to make sure that even though they were on the formulary to be reimbursed, that Texas didn't get wind of any of these issues and put on restrictions, reimbursement restrictions, or conditions that could hurt Janssen. So Janssen frequently represented to Texas Medicaid officials these same misrepresentations, that Risperdal was better, that it was safer, and that it was more cost-effective in the long run, that it had a low risk of diabetes, that it didn't cause hyperprolactinemia, all these things that Janssen knew

to be false.

Now, what will you hear from Janssen in defense of this? Well, throughout the time this case has been pending, we've heard a lot of attempts by Janssen to excuse or justify their conduct. I submit to you that the evidence will show that those are just smoke screens. Those are smoke screens to conceal their conduct.

But that's not just a characterization that I make, all right? Let's look at an internal e-mail between our friend Dr. Reines and a colleague at the pharmaceutical research group of Johnson & Johnson. This is an exchange they were having about some communications that Janssen was about to make to the public about the risk of stroke in the elderly for taking Risperdal. There was a problem they uncovered that it turns out that Risperdal was a stroke risk for the elderly. That's what a CVAE is, a cardiovascular adverse event. That's a stroke.

They were talking about how this data was going to be shared with the public, and they were having a debate about whether the data was going to be shared accurately and truthfully. And Dr. Reines communicates to his friend Fred, "I'm going to have to learn not to trust their communications." And what does Mr. Grossman

say? "They just never stop spinning." And I don't think they're going to stop spinning in the month of January 2012 in Travis County, Texas.

Let me take a moment to preview what the damages are going to be in this case. Texas Medicaid, as you heard from Ms. O'Keeffe, has been reimbursed 500 -- has reimbursed $579.6 million worth of Risperdal. Under that statute we just discussed, the Texas Medicaid Fraud Prevention Act, Texas is entitled to that money back because it was paid under false pretenses.

Now, there are other ways of measuring the State's damages as well. We're going to bring you a nationally-recognized healthcare economist, a woman named Dr. Rosenthal, and she will also give you some tools to help measure the State's damages and how the State's been hurt.

Texas law also provides for penalties. When you make false statements in the Texas Medicaid Program, you can be penalized. Each false statement carries with it a separate penalty. And the evidence is going to show that Janssen made thousands and thousands and thousands of false statements. For example, 18,000 of those letters that the FDA determined was false and misleading went to Texas Medicaid doctors. So when you add up the dollars in this case, it's going to be a

staggering amount of money. It's going to be hundreds of millions of dollars. But that's not our fault. That's Janssen's fault. Janssen is the one that created those large numbers by its decades-long, illegal marketing and promotion of Risperdal.

I'm about done. And before I finish, I want to say just a couple things about the kinds of evidence you're going to hear in this case. You've heard a little bit about this from Judge Dietz. You'll hear from witnesses who testify under oath, live witnesses, and you'll hear that several different ways. Sometimes you will hear from a live witness who will come to court and give testimony. Sometimes, in fact, quite a bit of times, you'll hear videotaped deposition testimony. In this case in particular, it makes sense for us to present a lot of testimony to you by under-oath videotapes. And I think you might hear from 20 or so witnesses that way. Now, many of these witnesses are former Janssen employees that we cannot compel to come to Austin. Our goal will be to have some live witnesses every day and a few videotaped witnesses. For example, the first witness you'll hear from, maybe after lunch, is from Thomas Anderson. He's a former Janssen employee, and he'll explain how Janssen helped create these treatment guidelines that favored Risperdal

and how they got those guidelines implemented in Texas, in part, by making contributions here in Texas to make that happen.

You'll also hear from expert witnesses. These are people with special expertise who have been retained by the Attorney General's Office in this case or by Mr. Jones to help explain what happened. You'll hear from a guy named Joseph Glenmullen. Dr. Glenmullen has spent thousands of hours over a five-year period analyzing medical studies and all the facts and circumstances of Risperdal. You'll hear from Dr. Arnie Friede, an expert in the FDA process, who will explain to you how that works. You'll hear from Dr. Bruce Perry. He's a child and adolescent psychiatrist, and he'll tell you all about Janssen's illegal promotion of Risperdal in children.

You'll hear from a man named Dr. Robert Rosenheck. Dr. Rosenheck is actually one of the authors of that CATIE study that debunked the myths that Janssen had been propagating on the medical community. He'll testify how Janssen's claim that Risperdal was more cost-effective was phony. Those are a few of the experts you'll hear from.

You'll also hear and see documents. A lot of this case is going to be documents. You just saw

probably 30 or 40 of them in my opening, and you'll see the whole document in evidence. Those are all documents that we uncovered in this case. Those are all documents that no one knew about before the State of Texas intervened in this case and brought this case for Medicaid fraud.

I want to end this morning by showing you one final document. This is a letter that William Weldon, who was the chief executive officer of the whole company, that whole Johnson & Johnson company -- he's the head man. He wrote this in November 2011 to a newspaper that had written an article about some of the events that you're going to hear about in this trial. And what does he say? He says, "The events you are writing about are a rehash of unfortunate issues that we have acknowledged and addressed over the past few years." "We don't claim to be perfect and we own our mistakes. We would never put anything ahead of patient health and safety." "We have accepted responsibility."

During this trial, you're going to get a chance to hold Mr. Weldon to his pledge. You're going to get a chance to evaluate whether Johnson & Johnson and Janssen has acknowledged mistakes that they have owned their mistakes, that they have never put anything above patient health and safety and that they have

accepted responsibility. You'll get to evaluate whether they've done that in this case, and I submit to you that you ought to hold Mr. Weldon to his words.

Often in this country we can feel powerless to combat the actions of large companies. Our jury system empowers you like no other system in the world to send a message to companies like Janssen, a message to tell the truth, don't conceal it, a message to put patients first, not profits, and a message to refuse to let -- refuse to let corporate greed feast on taxpayer dollars. Thank you for your time.

THE COURT: I want the audience to stay seated, and I would like the jury to retire for about a ten-minute break. Thank you. We're in recess.

(Recess taken)

(Jury not present)

THE COURT: Mr. McConnico, did you want to argue at all?

MR. McCONNICO: Oh, Your Honor, I think I might.

THE COURT: Okay.

MR. McCONNICO: I'd like to take up the argument at this time rather than wait.

THE COURT: Did you want any props?

MR. McCONNICO: I think we're going to

have some up here, Your Honor.

THE COURT: Oh, okay. Because I'm sure they would loan you some.

MR. McCONNICO: Oh, some of them are going to be the same.

(Jury present)

THE COURT: After 21 years, there are two kinds of juries. There are juries who have assigned seating, and then there are juries that it's a new assignment every time they come in and out. So it's good to see that y'all have gotten assigned seating. Thank y'all.

Mr. McConnico, do you wish to give an argument?

MR. McCONNICO: I do, Your Honor.

THE COURT: Thank you.

MR. McCONNICO: Good morning. I'm Steve McConnico, again, and I'm here representing Johnson & Johnson and Janssen. I appreciate and the people I represent appreciate very much the sacrifice you're each making. This is going to take a while and we appreciate it.

I approach this a little bit different than what you previously heard this morning. This morning you heard a lot about what other people did, but

not a lot about what the doctors that actually treat schizophrenics do. When I got into this case, I thought -- fortunately, this isn't true, but if one of my kids had schizophrenia or had a real bad bipolar problem, what would I do? I'd try to find the doctors that treat more of these patients than anybody around. I'd try to find some doctors that have had some success doing it, and I would see what they had to say, people that really know about this, that are not just lawyers, that are not just paid experts, that are not just people that are paid to read documents, but doctors that treat real people and get them well. Sometimes you can't get them well; you can just control the problem. That's what we did, because what their case boils down to is this. For all -- everything you've heard, it boils down to a very simple proposition. Were the first generation antipsychotics, like Haldol -- were they every bit as good, safe, didn't have as many side effects, as that second generation antipsychotics, like Risperdal?

And so we went to the people that have treated adults, treated children, with both of them, and said, what do you think? They're not Johnson & Johnson employees. They're just doctors that treat these folks. And the first one we went to was a guy here in Austin named Dr. Jeff Nelson. Dr. Jeff Nelson has treated more

adults that have schizophrenia than anybody you're going to hear from in this lawsuit. He has been the director of our local mental health/mental retardation center. He is now the director of the Veterans Administration clinic here that treats people coming back from Iraq and Afghanistan with posttraumatic stress syndrome. Right around the corner, when they had people that were really in trouble with schizophrenia at the jail, he treated those. He's had a very large private practice for years. So we went to him and we said, okay, what do you think? And first, he's going to tell you what is schizophrenia. And it was interesting, because yesterday when I asked the lady that worked in the psychiatric ward what it was, she said these people are not connected with reality. They're paranoid. They don't trust anybody. That's exactly what he told us. He said it is a debilitating disease. It completely destroys lives. And once you have it, generally, you always have it. You treat the symptoms.

Now, he will also tell you that when he started -- and he's about my age, a year or two older, although he looks younger -- that when he started doing this, the first generation antipsychotics were just coming out. And they were coming out in the '60s and the '70s, and you've already heard about some of these,

and they were a breakthrough. We don't have nearly the number of people in our mental hospitals today that we did back then, and one of the reasons is that these allowed people to get rid of some of the demons that were in their minds, because when you have schizophrenia or a really bad psychotic problem, you hear voices. They're not real. You see visions. They're not real. And those voices and those visions are generally not happy voices and visions. They're destructive. They're telling you to do things that you shouldn't be doing.

You know, it's just happenstance, but a year ago, we had -- there were five people killed in Arizona. A Congresswoman was seriously shot. The person that did it was a schizophrenic. Not all schizophrenics do that. He's being treated now with Risperdal. He wasn't being treated then. But sometimes schizophrenics do some pretty horrible things, because the voices, the visions are telling them to do it.

These helped. They helped a lot. They quieted -- the voices became quieter. People could get out in society. They could work. They could do things. But they had side effects. And the side effects you heard a little bit. The first one was called the Thorazine shuffle, because Thorazine was one of the first antipsychotics. It's interesting. And maybe

while we have more time, we'll understand how it kind of developed. I thought it was very interesting to hear that story. But it causes people to walk with a gait that you might see in a monster movie where they can't control their body and they walk very locked up, so they call it the Thorazine shuffle.

And then after that you heard about tardive dyskinesia. We're going to call it TD. And that's where people's voice -- their face muscles quiver uncontrollably. They can't control their chin. They can't control their lips. You're going to see a video of this. It is really disturbing, but this is reality. Sometimes with this particular problem it's permanent; once you get it, you've got it forever.

Next you have akathisia. You can't sit still. You'll see a video of this. You're moving all the time. You can't be still.

Next you've got dystonic reactions where your head locks back, your eyes roll back, your body locks in a contorted position. Now, once you get that, the doctors say that is really bad, because once you do it, it is so frightening and so scary, you don't want to stay on the drug. And as this gentleman said, a lot of people can function on these drugs, and off these drugs, yesterday, the gentleman sitting right over here on this

panel, they can't function. So keeping people on the drugs is very, very important.

Next -- all of these we're going to call EPS except tardive dyskinesia. And you're going to see that as we go through that. Now, these were bad. And so these side effects are going to be important to this case, because we -- Johnson & Johnson and Janssen had one of the first generation antipsychotics. It's called Haldol. You've already heard about it. The other major pharmaceutical companies, they had their antipsychotics. But people knew that they needed something to get rid of these bad problems.

When we talk about cost-effectiveness, you knock down some of these where people aren't disabled with these, that's very cost-effective. So they were thinking, how are we going to do it? It wasn't just that, because one other part of having a bad psychotic problem is what's going to be called the negative effects of that psychotic problem. We've talked about the positive effects of seeing the visions, not being connected with reality. Also, a lot of people just suffer from absolutely no motivation. Kids don't want to go to school. Older adults don't want to go to work, don't want to be with friends, don't want to be with family, want to be isolated from the whole world. They

knew about this, so they started working to say, can we improve these antipsychotics? And they did.

And so the second generation comes up, and this is in the '80s. And every doctor that I'm going -- we're going to put here is going to say we knew about these side effects and we knew about these earlier drugs not taking care of the lack of motivation and ambition. So these medications come out. Risperdal comes out right at this point. They've talked about how much Risperdal costs. Generally, throughout this whole period of time, you know what was the cheapest second generation drug? Risperdal. They were more expensive, given, because it costs a lot of money to develop these drugs.

So when they come out, the doctors that actually treat these people, like Dr. Nelson, is going to say, when I was in my residency, we saw many more people that had these problems with tardive dyskinesia where they couldn't control their movements, many more with this shuffling gaited motion where they couldn't walk in a right way, and we saw much more of these negative problems. They saw that clinically treating people and then the studies proved it.

These come out and those problems are less. Now, that's -- when you come down to the bottom

line of this case, were these drugs superior to the first generation? The overwhelming -- doesn't have to be, but the weight of the evidence is going to be at the end of this case they were, because there's going to be less of these problems, and second, they're going to treat the negative symptoms. So before they came out, did we promote it? Yes. We're a business. We did promote it. We do not deny that. But what we were promoting, was it correct? It was correct.

Now, at the same time, were doctors -- also we heard about the children. And the next doctor you're going to hear from is Dr. Mao. I said, okay, what doctor in Texas probably treats more of these children than any doctor in the state? I think it's Dr. Mao. Dr. Mao is in Houston. She's a professor at the Baylor College of Medicine. She is head of DePelchin Center where they treat children that are seriously compromised. She is going to tell you when she was doing her residency in Houston as a medical student in the 1980s, they were already giving children at that point in time, back in the 1980s -- before Risperdal ever came on the market with the first generation, they were giving children the first generation antipsychotics off label. Why? These children -- they had tried everything else. They had

gone to every possible level to take care of these children. These kids were a danger to themselves and to others. These are not simply hyperactive children with attention deficit. These are children that are going to hurt themselves or hurt other people, sometimes hurt the people they love the most. They had no choice. Either that child was going to be institutionalized or they were going to try this and keep it with its family, try to keep it in some type of school environment, and that would be the best for the child. They were doing that in the 1980s.

The idea that these drugs were given to children because we pushed it and that's how it all came into being is simply not true. Doctors were doing it then because they had to do something, and they saw that it was working. We knew that. Johnson & Johnson knew that doctors were giving drugs off label. And yesterday you heard one of the jury members say it's frequently done because a lot of times the doctors know best. We don't give the drugs; the doctors do. Doctors, also said yesterday, which is common sense, generally give several different types of drugs to find the best one for the particular plan. The idea that we're some kind of master puppeteer that can control all these doctors all over the world and the country and say you're going

to give this drug is simply not common sense. They're seeing the individual patient and deciding what is the best drug for that particular patient. And that's what we've heard, that generally they go through a process making that decision.

Now, interesting thing about Dr. Robb, not only is she academically very qualified, not only does she treat a lot of kids -- and this is the next doctor we're going to talk about, Dr. Robb -- but going back to Dr. Mao, she has an autistic son. She has a son taking a second generation antipsychotic. She lives with somebody that needs this. And she is going to tell you that the second generation are far superior, including Risperdal, to anything that came before.

Next, a lot of this is going to be science. You heard about these studies. You've heard about, well, the studies say, you know, that this particular drug -- this particular study says it's not any better than what came before. I said, what doctor knows more about these studies, putting it all together, than anyone? And we came up with Dr. Robb, coming now to Dr. Robb, who is a professor of child and adolescent psychiatry at George Washington Medical School in Washington, D.C., works with all types of children in healthcare there. She is going to explain that

scientifically -- why scientifically the second generation drugs, including Risperdal, are far superior to the first. She's going to explain why pediatricians and people that treat child and adolescent psychiatry for children that need the treatment have been for decades giving these drugs off label. There are rare circumstances, but it happens.

So those are going to be our three main experts. They're people that treat real live patients. They're -- this kind of is going to separate into two world. There's going to be one world of the doctors that are actually out there treating people, and there's going to be another world of people in here just reading documents and saying I've read all of this for this lawsuit and this is what I think for this lawsuit. I'm going to vote for the real world where these people are actually treated every way through this trial.

You look at who they have brought as an expert, who they're going to put on as their doctors. These two fellows you've already heard about, Glenmullen and Rosenheck. None of these people actually treat psychotic patients today. I made one mistake. This guy treats one, one. We're bringing you people that treat folks day in and day out all the time. That's all they do. He treats one. That's it. And that one patient he

treats, he gives Risperdal. That's it. The drug that they are saying is so bad, doesn't work, the actual expert that is going to appear in this case uses it.

Now, he's charged almost $2 million to read documents for the plaintiffs in this case and to give his testimony, and he's going to admit that. He's going to say I spent that much time reading studies, going through this. But actually, who do you actually treat? One patient. He is basically making his living as an expert witness. That is a separate world. The real world are where these people are really treated. Now, he's not a child and adolescent psychiatrist. Can't testify to that.

Dr. Rosenheck is treating no psychotic patients. In the past 25 years, he hasn't given an antipsychotic drug. He has -- he writes articles. One of the articles, which you've heard about diabetes -- in one of his articles, he says that our drug Risperdal doesn't have as much of a risk for diabetes as the other -- some of the other second generation antipsychotics. He says in one of the articles that the second generation antipsychotics like Risperdal don't cause as many of these movement symptoms as the first generation, just what we're saying.

Then they have a Dr. Perry that you've

heard about who is a child and adolescent psychiatrist, but he is going to tell you that the American Academy of Psychiatry today recommends the use of Risperdal and the other second generation antipsychotics over the first generation for the treatment of children and adolescents. Now, if they're not superior, why is the American Academy saying give those before you give the first generation?

Then you heard about the studies. Well, in 2010 we had this study. This is after -- the one study they really talked to you about was CATIE. And this is a report -- let's go back where we were. By the Texas Health and Human Service Commission, five years after the CATIE study, it's a report to the Texas Legislature. We've got a job to do; this is what we're going to tell the Texas Legislature.

And what do they say about Risperdal? They say it is the most studied antipsychotic in child psychiatry, the most. There are so many studies here, it would make your head spin about this drug, not one or two. And they can cherry pick one or two to make their argument, but you've got to put them all together to see what is the consensus.

They go on to say approximately 62 percent of all pediatric prescriptions are prescribed off label.

That has consistently been true through the years. Why is that? The pediatricians do that, not the manufacturers, because children are very hard to test, do the testing that the FDA requires. My children are mostly all grown and out of the house now, but when they were little, if somebody had wanted them for a drug testing program, it wasn't going to happen, and that's the way most parents are. So that's why you don't have the testing for children that you do for adults.

The next slide. What do they -- they say that these antipsychotic medications have legitimate therapeutic uses in children. One more. Based on the legal measure of the standard of care, off-label prescribing is the norm in all pediatric care. So putting up this specter of off-label marketing is somehow some great sin is simply not reality in the world that doctors practice.

Now, we get into what are better. What are they telling the Legislature? When it comes to this, the second generation -- and that's what that stands for -- SGAs, however, are reported to be better tolerated in children than the first generation.

The next one. This was the first generation drug that Janssen had. It's called haloperidol. You're going to hear it called just

Haldol. Haloperidol causes more severe EPS than risperidone. Then it goes on, perphenazine cause more EPS than risperidone. EPS is one of those symptoms they tried not to have. So they're telling the Legislature that the first generation are causing more of those symptoms that they want to prevent than the second generation, specifically Risperdal. That's just the opposite of what they got up and told you just a few minutes ago. They're having it both ways.

One more. Now, CATIE is the one study that you've heard about. CATIE was done -- published back in 1995. That was it. That's all they talked about. The doctors all knew about CATIE. Dr. Nelson is going to tell you, sure, we knew about these studies; we're giving these drugs. He said, we talked about it, read it, knew about it, but it didn't change anything that we did. It was not like Janssen could hide that study. They didn't hide it. It was public.

It was criticized because CATIE only compared the second generation antipsychotics to one -- one first generation antipsychotic. It was a drug called perphenazine. No one ever uses it. It's rarely, rarely used. So the doctors said, why didn't they compare it to something that we use?

And then they go down -- and anybody who's

ever had TD they exclude from the test. But the most important thing is, after the doctors looked at all of this, read it all -- and it was not like Janssen could put a blackout on it; they couldn't -- CATIE did not change their prescribing. The doctors kept prescribing the second generation, because they knew from their own experience, the second generation were treating the negative symptoms of schizophrenia and other forms of psychosis, and they weren't having as many side effects. This has been tested in the market, and the marketplace found that the second generation drugs were better than the first.

One more. Now, this is interesting. The State went out -- and they talk about our seeding the literature. You heard that. The State hired an independent third-party contractor. This isn't somebody hired by Janssen or Johnson & Johnson. They hired an independent to go out and look at the literature and give them some conclusions. This is called *Provider Synergy*. It came out in 2005. It says all of the atypical antipsychotics -- and you're going to see atypical is the same as second generation; atypical includes Risperdal -- have a lower incidence of EPS compared to the traditional antipsychotics such as Haldol. They're saying that these movement problems

that we were telling you about that are so destructive, their own outside consultant is telling them that they have a less risk with the second generation, just the opposite of what you heard a few minutes ago.

Next slide. Additionally, they appear to be more effective than the traditional antipsychotics -- and that is another word for the first generation -- in relieving the negative symptoms of schizophrenia. And those are the symptoms that make you want to shut down, to not be involved with anybody or anything.

So the idea that they weren't any better and they're not as good is debunked by their own outside contractor. You just heard an hour of argument that, look, these aren't one bit better. But when they hire somebody that's a third party to come in and tell the Legislature, they tell them just the opposite. And that is not Johnson & Johnson speaking to the Texas Legislature. That's the Health and Human Services Commission through their own outside third party that they hired.

Now, even more important, I really do think that actions are bigger and stronger than words. It's easy for somebody to get up and use a lot of words, but doctors that have to treat somebody day in and day out -- and the idea that doctors don't have their

patients' best interest foremost in their minds and they just want to help some drug company doesn't sail, doesn't fly. And what did the doctors do? You bet they kept giving the drug. And that was the reimbursement. We don't run away from that. We admit it. The reason the doctors did it is because they saw it worked.

Their whole theory is we pulled some smoke screen off the whole medical community. If we did -- which we didn't -- it was decades ago, and they had decades to test this in the marketplace. Are you going to keep using a drug that doesn't work that's no better than the first drug that's cheaper? That doesn't make one bit of sense. The reason it happened is because it was better.

Now, what happened is interesting here because knowing -- when they say about giving it to children and how difficult that is, there were even department of state health service guidelines about how much to give to children when it was off label for children. They had a guideline saying this is how much to give for children even when it wasn't on label.

The next one. All of these -- after this lawsuit was filed, after this case was filed, they have approved putting 175 of our generic Risperdals on their formulary, which they told you about. If we're cheating

people and it's so bad, they've approved 175 additions of our drug to the formulary. Not only that, but they have made it a preferred -- it's always been on the preferred drug list, where doctors do not have to call up and get pre-approval before they prescribe it.

Now, they've known about this, as they got up and told you from the very beginning, since 2004. If that's true and they had all this information, why in the world did they have our drug on the preferred drug list in 2004, 2005, 2006, on? Why? Actions speak louder than words. They wanted the doctors to give it because the doctors wanted to give it because it helped patients.

So they're suing us basically when they made it easier for doctors to give our drug. The State is now suing us for all the drugs that were given even though they knew this and they made it easier for the doctors to prescribe it.

Let's talk about a different subject. You've heard a lot about this November 2003 letter that was sent to doctors. Let's go back to where we were, the slide before. They say it was false and misleading about the diabetes associated with Risperdal. We're going to dig into that letter a little bit more. We're not just going to hit the surface, because they want a

big violation, thousands of dollars for every doctor that ever got that letter, saying we lied to the medical community and we ought to be penalized thousands of dollars for each letter. So let's dig into it and see what it says.

This is the words. "Evidence also suggests that Risperdal is associated with a lower risk of diabetes than some other stated atypical antipsychotics." That's it. That's what the words are that they say are false.

Now let's go and look at this. They said we also -- and you heard a few minutes ago -- hid diabetes and didn't tell people that Risperdal could cause diabetes. The idea that any of these second generations can cause diabetes has never been hidden. That's the label that went with the letter. Do you know how many times we told people about diabetes and the label, the real label that went with the letter? Let's look at the next one. Eight times. Eight times in that label there were these statements that -- about diabetes. It wasn't hidden from anyone.

Yesterday when we were talking with someone that had given these drugs, I said, do you balance the risk versus the benefit? She said, yes, we sure do. Where do you learn about the risks? One

place, the label. This is the label. Eight times we tell people about diabetes. The idea that we hid diabetes from somebody is completely false. It was there front and center.

Then we sent them every peer-reviewed literature that had come out about this risk. A list of those went with the letter. No one is denying that every peer-reviewed medical article about this subject went with the letter. Peer reviewed means when other experts, doctors, look at it and say this is true, go over it. If it's not true, they give their input, and say this is how you need to change it. That went with the letter.

And finally, we're comparing ourselves to other second generations. We're saying we think -- right at the first, what they say was false is we think that we're causing less diabetes than some of the other second generation antipsychotics. You know what? We were right.

A couple of years later -- another one of the second generation antipsychotics is Zyprexa. Some of you have checked and said you knew about that. The FDA said you've got to change your label, Zyprexa -- it's by Lilly -- because you're causing more diabetes than Risperdal, than some of the other first generation.

So what we said was exactly correct. It took the FDA a couple of years to catch up with it, but they did, and they agreed with us, and they told Zyprexa to change their label.

Next one. If you compare the Zyprexa label -- this is with the letter we sent out. Risperdal is associated with a lower risk of diabetes. You go down here to the Zyprexa. They do say this is the same as Zyprexa, appears to have a greater association than some other atypical antipsychotics with an increase in glucose level. An increase in glucose level is a hallmark of diabetes. So we were right. We might have been right a year or two earlier than we should have been, but we were telling the truth. And the truth is the truth. That wasn't false.

Now, what did the FDA do? This is something else. This came out in 2009. It's a study comparing all of these drugs for the ratio for risk of diabetes. The lowest of any of them is our drug Risperdal. We were at the bottom when they did the study. And you're going to hear another doctor named Dr. Newcomer, who I didn't put up, but he knows more really about diabetes and these drugs. That's what he's spent his whole professional career. And he went out and they did this large study all over the country

comparing these drugs, and he said that really Risperdal for the risk of diabetes is at the low end, is down there, because it doesn't have as big a risk as the others.

One more. So what did the FDA do? You know, they said the FDA sent us a warning letter. They did send us a warning letter. We sent out a letter to the doctors because we didn't want to keep contesting this with the people that govern us, regulate us, but at the same time, what we said in the letter was the truth. We say what the FDA tells us, we send that out to the doctors, and it's over. They closed the matter. They're finished with it. They could have done a lot. They could have done like what the State's saying, we want all -- we won't let you sell the drug or we want all the money back you made. They didn't do anything. They just closed it. They didn't do what the State of Texas and Mr. Jones are doing, saying we want a bunch of money.

Yesterday there was some talk, well, it's okay for the State because nobody individually gets the money. That might be true for the State. It's not true for Mr. Jones. Mr. Jones and his attorneys stand to make a lot, a lot of money out of this, and that's just the fact. Now, that was over. It was done.

The other thing -- and I'm going to talk about part of this, is -- because they brought it up in opening statement, is somehow we hid this RIS USA-113. That -- go to the next slide. And I won't talk about ERI right now. We'll talk about that in trial if they bring it up. In this 113 study, at least nine patients were given the wrong drug. Now, when you do these drug tests, you get an outside vendor to do them. Here in Austin, we have a lot of outside vendors -- not a lot, but several that do these outside tests, have done them for years. But you hire somebody outside generally to do the test. Usually they know what they're doing. I'm not saying these folks didn't, but somehow someway they gave nine people in the test the wrong drug. The drug wasn't what they should have been getting. It was possible more people got the wrong drug, and so consequently, it was a broken study. There was no way to see if the results were reliable. It was nothing that the FDA could use. Did we not give that to the FDA? You bet we didn't give it to them. The only people that are going to criticize that are like Dr. Glenmullen who's never conducted one of these studies. The doctors that have and scientists that conduct these studies all the time will say when you have a broken study that you cannot rely upon because

you know something was done wrong and somebody got the wrong drug or this amount, then you don't provide it. We didn't. But what they do when the FDA -- and they said we hid all this from the FDA, we didn't tell the FDA, we weren't totally open.

In 2000 when the FDA asked for this information, you know how much information we gave them? Let's go to the next slide. This is studies from all these places. We gave them 20 volumes of material. We gave them 66 trials done in 40 states, 26 countries, 11,422 patients, 1500 investigators, gave them 20 volumes of that material. The idea that we hid anything just doesn't fly. And we also gave them all of the information -- safety information that was developed in that RIS-113 study that he said we hid. We didn't give them the final results because there were no final results because of the errors. So we were very open with the FDA on this.

There was also some statement about prolactin. Our drug does -- and the label says this, in rare circumstances does cause the prolactin. That's not hidden. That was said. It's been said in the label. It is extremely rare when that happens. But that is not a side effect that was ever in any way disguised from anyone, and it is really very rare and doctors monitor

it.

The idea that we ever hid anything about diabetes is simply wrong. Anything we had about diabetes that was relevant and open, we immediately provided when we did the studies.

Now, let's talk about the off-label marketing because they spent a lot of time that we were marketing this drug to be used for things that FDA didn't approve. Start at the beginning. There is absolutely nothing wrong with a doctor prescribing a drug off label. Something as simple as aspirin taken every day for blood thinner, which I do every morning, because my doctor tells me I should at my age, which kind of made me mad, but anyway, that is not really a prescription that is approved for aspirin. It's off label, even though aspirin is not a prescription drug. Many drugs are given -- prescribed off label. The doctors are going to tell you that. There's nothing wrong with that. But you cannot market a drug off label and promote it and tell people to give it for an off-label use. And it was our policy. You saw an exhibit -- and we'll get into it later -- where Janssen was very clear and said we don't want you marketing our drugs off label. But with children -- far before we ever got into this issue, children were taking

antipsychotic drugs off label, as I said at the very beginning, because that was all the doctors could do in fairly desperate end-of-the-road circumstances. We knew it. They're telling here the department studies and expert clinical experiments often support the use of medication for an off-label use. It's recognized.

Next. But their policy is -- and they showed you this letter, and we agree with them. It was our clear-cut policy not to give off-label marketing. And this was from Alex Gorsky, who was the head of Janssen.

Now, what we could do is if doctors have questions about it, we can answer the questions. And the idea that we're just going to see -- every time we went to see a child and adolescent psychiatrist, that was off-label marketing, is simply wrong, because reality is child and adolescent psychiatrists -- the next -- let's go one more. What we're -- at this point in time, we're seeing that they're giving the drug off label. Janssen and Johnson & Johnson know it. So they say if the doctors are doing it, what should we do? We should get FDA approval for it. Did we go out and try to get FDA approval for it? We sure did. Did we have a business plan of how we were going to market the drug once we got the approval? We sure did, because I think

if the doctors are doing it, then it does, and you should try to pursue getting the FDA approval. It was the correct thing to do.

And what did the FDA do? They tell you that they only gave a very narrow approval for the use of this drug with children and adolescents. Not true. Schizophrenia in adolescents age 13 to 17, FDA approval. Bipolar I disorder in adults and children and adolescents age ten to 17, approval. Autistic disorder in children and adolescents age five to 16, approval. So the idea that we were doing something sinful, we were helping people. If this helps people, then -- and they're using it, why not get the FDA to approve it? And the FDA approved every one of those uses. And those are really the issues that we're looking -- and those are the groups we're looking at in this lawsuit for children and adolescents.

Now we'll get to the call notes. The call notes are where you're going to see many of these that are just blank. And these sales reps can go see child and adolescent psychiatrists -- let's look at the next -- because what do they really do? And we just pulled it down from a website about describing what a child and adolescent psychiatrist does, and you're going to hear this. But before you can be a board certified

child and adolescent psychiatrist, you've got to be an adult board certified psychiatrist. That's first. So many of these also see adults. And they're saying, well, if you're going to see a child and adolescent psychiatrist, you're guilty per se because you can't be marketing to them. Wrong. We can answer their questions. Second, if they're also seeing adults, which they are entitled to do, we can go and see and market to them as an adult psychiatrist. And three, many of these are just a blank page. They're saying just because you have a blank page on a call note, you're guilty. Doesn't make sense. And finally, they're not going to show you any doctors that actually gave any of these drugs off label because of a visit from a representative of a drug company. The lady yesterday said we go and we give them articles, that's it. But the idea that a drug rep is telling a doctor how to prescribe a drug doesn't work. These drugs are prescribed by doctors, and they're doing it based upon what they're seeing with a real live actual patient.

Now, are some of the call notes and some of the things that you're going to see and already have seen -- are they wrong? Talking about how to promote this with children. You bet they're wrong. They shouldn't have been done. They're not defensible. Some

of these people did make mistakes. It is a very large company. It has thousands of employees. And out of those thousands of employees, there were some mistakes, not a lot. They were pretty rare. They showed you some e-mails. When you have that big a company, are people going to write some e-mails that are a little hyperbole, a little exaggerated in the heat of the moment? Yes. They're correct. They've gone through millions and millions and millions of pages. And if you do that in any business, you're going to pull out a few where people are exaggerating, people are kind of taking liberties with what they say, but that's going to happen with a business. But was it the company policy overall to take a few rare examples? Obviously not.

Now, let's talk about TMAP. How did TMAP start? Well, they say -- I think we might even agree on this, about the Tri-University Guidelines. All the Tri-University Guidelines are is that they sent out requests to the 99 who they agreed upon -- and it wasn't Janssen. It wasn't Janssen doing this. All these doctors came up and said, who are the 99 psychiatrists and experts that treat these types of mental illnesses that we all recognize as really knowing what they do? Let's send out a set of questions of how they treat patients that have this problem, and let's see what they

do. And let's see if there's a consensus on how to treat this, and if there is, let's share it with the rest of the medical community. That's what they did. They got these guys at big medical schools like Duke, other places, Cornell, and said let's see how these folks do it.

Now, did Johnson & Johnson once -- did they help fund that? They sure did. That's what they ought to be doing. They ought to try to see what the experts in the field are doing, and then they should tell people. And then from that, people here in Texas said, well, let's see what we can do about this in Texas and see if we can come up with an algorithm of how to treat certain things.

Is it related to Medicaid? No. It's called the Texas Medication Algorithm Project. It's just treatment in the whole. It's not specific for Medicaid. They can't show you one Medicaid prescription that was written for Risperdal because of TMAP. Can't show you one. They're saying that TMAP was some just great thing for this company. They cannot prove one prescription of Risperdal went to one Texas Medicaid recipient because of Medicaid -- because of TMAP.

Second fact about TMAP: Doctors aren't required to use it. Doctors can do whatever they want

to, because they're actually seeing the patient, seeing what drugs work. If they want to change a drug, they can do it. It doesn't require a doctor to do anything. It's just an aid.

Third, the guidelines that came under TMAP didn't have any special favoritism to Risperdal. They treated Risperdal the same as it treated all the second generation antipsychotics. Let's put that up. This is -- let's -- these are the guidelines. This is really how it looks. We're not going to go through this, because I'll be honest with you, I don't understand how they use it except at Step 1. They put these drugs all up there together in alphabetical order, and the doctors -- they're all treated the same. Risperdal is not treated any different than Zyprexa or these other drugs. They're treated the same way. It hasn't gotten any special favorable treatment. That's -- that's where the doctor starts, and it's there with the rest of them, treated exactly the same.

Fourth, they said they showed you Dr. Shon. This is not the brainchild of Dr. Stephen Shon. The way this came up was they got a group of other experts. It's a group of people. They got patient advocates, people that advocate for the mentally disabled. They got the disabled families. They got

college professors. They got all these people together and they came up with it. The idea that this was the brainchild of one man is simply wrong.

Now, no money from this -- came to this while they were doing it from Johnson & Johnson. But you know who asked the -- asked Johnson & Johnson to contribute to this to implement it after they got it up and running? The State. And Johnson & Johnson complied.

And then they say, well, you bought off all these people involved with it, and you got Dr. Shon flying all over the country doing this. Well, the State audited it. They did an audit. Let's look at this. They went back and the State did an audit. In the executive summary of the audit, donations and related expenditures were processed in accordance with established agency procedures. They didn't find -- didn't in any way get after these guys, just said, you know, yeah, you can do this on the side, and they did it, and they said you accounted for it the proper way.

Now, who was on some of these committees that they're saying that were somehow, in their words, bought and sold and bribed? Chairman of the University of Texas pharmacy department, professors down at the

University of Texas Medical School in San Antonio. Those are the types of people that we're looking at. We're not looking at a bunch of just charlatans that you can come out -- you know, these are people that professionally know what they're doing. Personally trying to educate other doctors on how to treat certain mental illnesses is what these folks ought to be doing. There's nothing wrong with this. And at the end of the day, end of the day, they're not going to show you, again, one Risperdal prescription that any Medicaid person received because of this, not one. They're not going to show you that somehow because of this Risperdal's use just exploded. They're not.

Now, the reason Risperdal did well was -- and the others was because they were superior. It's that simple. The marketplace proved it. The patients did come first. The patients also prospered from this. So when they say we made false allegations, they have to show that we made false allegations saying that this drug -- this drug wasn't as good or was inferior to the first generation. They're not going to do it.

And where they ended by showing you that doctor's -- that person from Johnson & Johnson that said patients come first, these drugs help people. And if they knock down these negative symptoms and make them

where they can get out and work in the world, if they knock down some of these horrible side effects, that is putting patients first, and we don't apologize for that.

Finally, I will say this: You've heard a lot of emotional appeal this morning. You were chosen, every one of you. Some of you said that, you know, pharmaceutical companies, you might have some distrust of them, but you also told us you would listen to the real evidence, the hard evidence, and we trust you to do it, and you will. And since 2004, the State claims to have known that Risperdal -- about Risperdal. They have put no restrictions on this. They've not alerted one Texas doctor that you shouldn't be using this and you should use the first generation. They've done the opposite. They've put it on the preferred drug list where doctors could easily prescribe it. I agree that how they ought to be looked at is through their actions. And despite all of that, they now want all the money back, you just heard it, millions of dollars, they paid for it, even though their lawyer gets up at the very first and says we're not going to say it's a bad drug. We admit it's a good drug. It might not be as good as the first generation, but we admit it's good. We admit it helps people. But nevertheless, give us every dime back we paid for it. Folks, if it help

Texans stay in school, keep a job, stay out of a mental institution, not commit a crime, then it's helped every one of us, and to ask for every dollar back is simply unfair. I appreciate your attention. We look forward to working with you.

THE COURT: Why don't we get some lunch and I'll see y'all back about 1:40. Thank y'all so much.

(Lunch recess taken)

(Jury not present)

THE COURT: Are we calling Ms. Hunt?

MR. JACKS: Yes, Your Honor, this afternoon, after the deposition testimony of Mr. Thomas Anderson.

THE COURT: Prior to calling Ms. Hunt, I'm going to have an out-of-jury hearing so that you can make your full and fair exposition of all your objections.

MR. JACKS: Yes, sir.

THE COURT: Okay. So give me a high sign.

MR. JACKS: We will. Mr. Anderson's deposition is just under 40 minutes. It's 39 minutes long, I think.

THE COURT: Okay. Lash me to the mast. It's from Odysseus.

MR. JACKS: I understand, the sirens.
THE COURT: Right.
MR. JACKS: Oh, and I'm told there's a six-minute clip following Mr. Anderson's clip.
THE COURT: Oh, okay.
MR. JACKS: It's a counter -- defendants' counter to the Anderson clip is the six-minute part, so 45 all together.
THE COURT: Okay. Tell Stacey to bring them in.
(Discussion off the record)
(Jury present)
THE COURT: Mr. Jacks, are y'all ready for the presentation of evidence?
MR. JACKS: We are, Your Honor.
THE COURT: And is this a deposition, a video deposition?
MR. JACKS: Yes, Your Honor. The first witness will be Mr. Thomas Anderson by deposition. Before proceeding to that, Your Honor, at this time, plaintiffs would invoke the rule. Mr. McConnico and I have conversed, and we are willing, subject to the Court's discretion, to exclude experts from the rule.
MR. McCONNICO: That is correct.
THE COURT: Okay. So -- and y'all have