REPORTER'S RECORD
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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

PLAINTIFFS' WITNESSES

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