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THE COURT: Very unusual and unorthodox procedure, if I may say so myself.

(The jury enters the courtroom.)

THE COURT: All right, be seated. Members of the jury, next we will hear from the defense. Ms. Sullivan, when you are ready you may proceed.

MS. SULLIVAN: Thank you, Your Honor. Good morning, everyone. Almost done. Thanks for sticking with us. It's been a long couple of weeks and you folks have come in here in the snow, in the rain, in the ice, and even during the Polar Vortex, and we are grateful for your service. I am humbled by your service. You have come in here and served with grace and dignity, and great patience, even when the lawyers were all acting like children, and we all here appreciate that.

It's finally going to be time for the lawyers to stop talking and you get to talk to us with your verdict. And it's a big job, and you are serving as jurors in this country that has a great history of having jurors like you

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decide cases like this. And in this country, unlike many other countries, we don't have government or politicians or even judges deciding cases like this. The folks who set this system up a couple hundred years ago decided that parties could get a more fair trial if we had citizens like you coming in and putting aside whatever opinions or biases or prejudices and just listening to the evidence and deciding it on the evidence. Folks thought that citizens could give people a fair shake, even better than individual judges or politicians and government. And looking at this jury here, we know you can do that job. Of all the jurors that came in those many weeks ago during jury selection, you folks were the ones that both parties decided could be fair, could really do the hard work here.

And there is something else that you saw during this trial was hard work, and there has been some objections or rules and I am not allowed to put things on a projector so I have to use the elmo, and so Ms. Brown has agreed

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to help and assist and throw some evidence on the screen.

If we could, Ms. Brown, start with Slide one. One of the things we learned during this trial was how to discover and develop a medicine and that that was hard work, and it is hard work. You learned that it took ten years from the time that Risperdal was discovered in the lab to do all of the testing in the lab, and animal testing, and to satisfy all the FDA requirements to test it in people. And it's hard work. And you heard the doctors and scientists from Janssen who talked about the fact that they know, they know they have a big responsibility to patients. They know that patients depend on them to get it right, to do the hard work and to do the science. And it takes from eight to ten years on average for any medicine to get approved because it takes a long time. Most medicines, as you heard, never get approved by the FDA because the FDA, as even Dr. Kessler acknowledged, has really rigorous standards. Teams of FDA doctors comb through safety data

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and information and put companies through their paces to make sure that the medicines they approve are safe for patients and are effective for patients when they are approved. And it's hard work.

And you might have remembered when Dr. Caers, the scientist and doctor from Belgium was on the stand and Mr. Kline was cross-examining him, and he said to Dr. Caers, Dr. Caers, you ran the show, you ran the show at Janssen in terms of drug development. And Dr. Caers said, No, no, no, sir, it's not a show. Discovering and developing medicines, it's not a show. It's hard work, and we take that very, very, very seriously.

And you also heard from Dr. Coppola, who ran the drug safety section of the company in terms of postmarketing events, and she and her team rigorously looked through all of the safety data in terms of public studies, and internal information, and reports from patients who might have had a side effect, and looked for safety signals, again and again. They took that responsibility seriously

because they knew patients depended on them. It's not a show.

But I submit to you, some of what you saw in this courtroom was a show. And the Judge is going to give you an instruction at the end of this case and one of it is going to be to use your common sense. You can cut through a lot, you heard so much, and I don't envy you, so much information and studies and statistics, but the Judge is going to tell you that you can use your good old-fashioned common sense to get to the bottom of all of this.

And as you were listening to the evidence, what did your common sense tell you when you heard that this lawsuit wasn't started because a doctor told Mrs. Pledger that Risperdal caused a problem in her son, that this lawsuit wasn't started because Mrs. Pledger or her son had any complaints to any doctors at all, but that this lawsuit was started because Mrs. Pledger saw a plaintiff's lawyers' TV commercial, 1-800-Call if you have taken Risperdal, we will sue. And she called.

And they sued.

And what did your common sense tell you when you heard that the first person to tell Mrs. Pledger that Risperdal caused her son's breast enlargement wasn't a doctor, it was a plaintiff's law firm.

And what did your common sense tell you when you heard that the plaintiff's law firm filed a lawsuit claiming that Risperdal caused her son's breast enlargement years before they had any doctor to support that claim at all. They file a lawsuit saying, Yes, Risperdal caused this problem, and then two years later they paid Dr. Solomon $20,000 to come in here to say that.

And what did your common sense tell you when you heard after opening statement when Mr. Kline talked with you about the Pledgers and Mrs. Pledger, when you heard that he met her the same day I did, the same day you did. He had never met her before. 1-800-Call, we will sue, we will collect lawsuits, plaintiffs don't matter, the facts don't matter, the evidence doesn't matter. What does your

common sense tell you about what was really going on here.

And what did your common sense tell you when you heard that the only expert who could support their case that Risperdal caused Plaintiff's enlarged breasts wasn't an endocrinologist at all, I mean, we are in spitting distance of four major hospital systems, Penn, CHOP, Jeff, St. Chris. They couldn't find an endocrinologist not only in Philadelphia, they couldn't find an endocrinologist who specializes in hormones anywhere in the country, anywhere in the world to support their case. The only expert they brought to say that Risperdal caused Plaintiff's gynecomastia was a cosmetic plastic surgeon, who testifies a lot, over 60 times for plaintiff's lawyers, including since the 1990s for the plaintiff's firm here, and who, as you heard, on his website is better known for turning Philadelphia into the penile enlargement capital of the world. What did your common sense tell you when you heard that's the only scientist and doctor they

could get to support that claim. And then you heard that there wasn't one study that he could cite in his report, one medical article that he could cite in his report to support his argument that Mr. Pledger developed gynecomastia before puberty. It's not scientifically possible. But for $20,000 he came in here and said it.

And so we are here, and we are going to talk some about the evidence.

Now Mr. Kline stood here and he told you we are going to talk about the facts and the evidence. I have been doing this a long time, not as long as Mr. Kline, and I have never seen a closing argument where the lawyer doesn't show the jury a single piece of evidence. He stood here and he talked to you and he gave his version of the evidence, but he didn't show you any. So I am going to walk through some evidence, you have seen it but I want to make sure you have it in your mind when you go back to deliberate, that you really have the evidence and the facts as part of your discussion.

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Going back to talk about the company and the scientists and the doctors who actually do the hard work, not theatrics. I mean, I guess here, the Plaintiff's lawyers think that if you yell loud enough and you whisper, and you write a lot of stuff on the easel, much of it, as you have seen, wrong, that maybe you can distract the jury with these theatrics from the fact that they don't have the science, they don't have the medicine, they don't have the evidence to support this case.

And you saw Dr. Caers, and Mr. Kline, I think was the one that used this E-mail, you saw how seriously he took drug development, because people were trying to write a manuscript -- this isn't the Findling article but another manuscript, and he said to the people at Janssen, I am not going to let this manuscript out of the company. You have to have fair balance, you have to talk about the risks and the benefits. This is sloppy. Substantial changes are required.

He policed the drug development for

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Risperdal and he made sure they did it right. You don't stay in business as long as Janssen has by not doing medicine the right way. They know patients depend on them, they know the safety of their drugs is critical to their business.

Then, Ms. Brown, if you could show our jurors -- I mean, Mr. Kline got up here and he said, How dare they make Risperdal. Risperdal helped millions of patients. Millions. You heard from Dr. Robb. I mean even Mr. Kline, I think he called her a Super Doctor, the psychiatrist from Washington DC. She is one of the leading child psychiatrists in the world. She treats kids with serious psychiatric disorders. And the leading child psychiatrist in the world came in here, the doctor who probably knows more about antipsychotics than any doctor in the world came in here and said this medicine is great for kids, kids who have serious problems. She told you it has side effects. The antipsychotics, they are serious medicines with serious side effects, and both she and

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Dr. Mathisen talked about some of the serious side effects of these other medicines, like Clozapine kills blood cells, Zyprexa, diabetes and significant weight gain. You heard about Geodon that he is on now can stop your heart, can cause a fatal skin disease. Of all of them, she told you that for kids who have serious problems, bipolar disorder, schizophrenia, autism behavior problems, Risperdal is the best. Not perfect, not a wonder drug, but it has helped thousands of kids like Mr. Pledger with serious problems, and helped other children with schizophrenia and bipolar. And, Ms. Brown, if we can put up Slide two.

And it's helped those patients because the scientists at Janssen, they did the hard work. Once they got it approved in 1993 for psychotic disorders, they could have stopped studying it. You heard Dr. Robb, the psychiatrist from DC, and also Dr. Mathisen, Mr. Pledger's prescriber, talk about the fact that there were no medicines approved by the FDA for kids with psychiatric problems. There

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was nothing. And so doctors were prescribing these medicines approved for adults for kids. And once Risperdal was approved in 1993, and doctors started prescribing it for kids off-label, Janssen could have sat back and said, all right, we will just make the money, we don't have to do anymore studies, they are prescribing it anyway. But that's not what they are about. That's not what they did.

The FDA, you heard, was encouraging companies, Can you study these medicines in kids, can you study Risperdal in kids, there is a need. And you heard that outside doctors and scientists from this research institute RUPP, for autism, did a big government-funded study that said, wow, there is nothing for autism and Risperdal looks like it can really help these kids.

So Janssen did the hard work and they did the studies, and you heard they have done more studies, undisputed in this case, that the doctors and scientists at Janssen have done more studies in kids, pediatric safety studies than any company in the world. It is

the most studied antipsychotic in kids. And they published all of it, they gave all of it to the FDA, and they worked hard and they got the approval.

And everytime, we heard, when a company submits an application to the FDA for approval, there are literally teams of FDA scientists that go through that data and look at it, look at the safety data, look at the effectiveness data, and they got it approved again and again and again. And every time the FDA approves it, they look at your label again. And you saw, they mark it up and say, no, we don't want you to say this, say this. And in 2006, this medicine was approved for kids exactly like Austin Pledger.

And there was big press about it. Doctors were thrilled. Finally, we have got the FDA approving a medicine that actually works and can help these kids. And you heard it helped Austin Pledger.

Ms. Brown, if we could put up Slide four -- I am sorry, the next -- you got it, thank you.

And so you heard from Mrs. Pledger and you saw the records that when he was a young kid, when he was only five years old he had, like a lot of kids with autism, he had these serious behavior problems. And these are the records from kindergarten, the biting, the pinching, the hitting. Mrs. Pledger described the tantrums, the head banging, the screaming, and she sought help. How can I help my child. And she went to Dr. Mathisen. And he is not in Thorsby, Alabama, in the sticks, I think, as Mr. Kline suggested. He is in Birmingham, as you heard, in one of the major medical institutions in the South, as Dr. Vaughan said. And you heard him talk about the fact -- and this chart was used when Dr. Mathisen was here -- you heard him talk about the fact that Risperdal was the best choice. He told you Geodon can stop your heart. He acknowledged it causes fatal skin diseases, and ruled out Zyprexa, Abilify was too new, he didn't believe it had enough safety data. And he told Mrs. Pledger he had used Risperdal for other autistic patients and it helped them.

It worked for them. And so he used it on Mr. Pledger.

And Dr. Mathisen is going to be a really, really important witness in this case, and you folks probably remember him, he was the first witness they called. But his testimony is critical here because the Judge is going to give you an instruction, and so the case is did Janssen adequately warn, but the law is that our duty is to warn the prescribing physician. And so when you fill out the verdict sheet, you are going to have to decide did we adequately warn Dr. Mathisen, not Mrs. Pledger, because Mrs. Pledger can't just go to a store and buy Risperdal, the doctor has to prescribe it for you. So the issue is did we adequately warn Dr. Mathisen.

And I wish I could put up the trial testimony so you could see it, but the rules here are that I can read it and not put it up, so I want to read you -- well, first let's put up the label. Let's put up Slide three, and then I am going to read you some of the Dr. Mathisen's testimony.

So this is the 2002 label, and you folks have seen it a fair amount in the trial. And one of the things that's clear -- now this isn't a case where there was no risk information in the label about the side effect, this isn't a case where the risk information was buried in the back. You heard that the Precautions section of the label, you heard from both Dr. Mathisen and Dr. Robb, the child psychiatrist from DC, say that the Precautions section is a really important section of the label. Warning and Precautions are the big risk sections. And right in one of the most important pieces of the label in terms of side effect information is this risk that risperidone elevates prolactin levels and that gynecomastia had been reported. It was there right from the beginning, in black and white.

And this is the label that's approved for adults, but as you heard Dr. Robb say, when you look at the adult label and you are prescribing to kids, you got to see, you know, we don't have a kid label yet, you have to see

what the risks are in kids.

And Dr. Mathisen testified here -- I am sorry, can we go to Slide five.

One other piece of this label that's really, really important. What Dr. Mathisen saw and what was in the label -- and two different places it was in the label -- was that, heads up, safety and effectiveness have not been established in children.

And why is that important. Well, that's a stronger warning, I would submit, than saying it's 1 percent gynecomastia, or 2 percent gynecomastia, or 3 percent gynecomastia. That says, Dr. Mathisen, Prescribers, we don't have any safety data in kids, proceed with caution.

I mean, that is a pretty strong warning to doctors. Enter at your own risk. We don't have safety data.

And Dr. Mathisen's testimony was pretty clear that he knew that gynecomastia was a risk and he knew that there was no safety data in kids, that it was not approved in kids, and I am going to read you -- and I apologize for

reading it because it's a little cumbersome, but it's really important because the issue is was Dr. Mathisen adequately warned.

And so Dr. Mathisen was asked:

"Q And, Dr. Mathisen, you were well aware of the fact in 2002 when you were prescribing it to Mr. Pledger that Risperdal, like other antipsychotics, would elevate prolactin and potentially cause prolactin-related side effects like gynecomastia?

"A Yes. We knew about the rise in prolactin.

"Q And you knew about the fact that prolactin-related events like gynecomastia had been reported?

"A High prolactin can cause those side effects, yes.

"Q Yes, exactly, Dr. Mathisen, it was no secret to doctors that higher prolactin levels in the body could cause gynecomastia?

"A That's no secret, no.

"Q Pretty well known, in fact, it's been well-known for decades?

"A Yes.

"Q And you were aware of it when you were prescribing to Mr. Pledger?

"A Yes.

"Q In part, because of your experience, but in part because it was in the label, in the Precautions section?

"A Yes.

"Q So the Janssen label made clear this wasn't established as safe and effective in kids yet?

"A Correct.

"Q There was a risk of elevated prolactin and gynecomastia in adults?

"A Yes.

"Q And at the time, you made the decision to prescribe it in kids because it was the best option you had?

"A Yes.

"Q And you knew when you were prescribing it to kids that there was a potential that the risk outlines for adults could be greater in kids?

"A That was always a possibility."

He knew that the risk for gynecomastia could be greater in kids, because it says on the label, safety not established in kids.

"Q But you made the decision as a treating doctor?

"A Yes.

"Q With full knowledge of the potential risk?

"A Yes."

And so when you get this verdict sheet at the end of the case, and hopefully, you will be good enough to fill it out for us, the verdict sheet, the first question: Was Janssen negligent by failing to provide an adequate warning to Dr. Mathisen about the risk of gynecomastia to Austin Pledger while taking Risperdal?

And when you are thinking about the evidence, I would submit that your answer to that question should be no. Because clearly, the label said elevated prolactin, risk of gynecomastia in the Precautions section. Dr. Mathisen said he knew about those risks. The label also said safety not established in

kids. And Dr. Mathisen said, I knew that, and I knew the risk could be higher in kids.

So he knew that information. And I would submit the best evidence as to whether or not the label was adequate is did the prescriber know. And in this case he acknowledged he knew. He knew.

There is something else that you heard -- incidentally, Dr. Kessler, Mr. Kline talked about Dr. Kessler. And one of the things I am going to talk to you about in terms of using your common sense is the kinds of experts that came in here. And I submit to you, sort of as part of the show, they had experts who are regulars on the litigation circuit. They had the lawsuit regulars. Dr. Kessler testifies an awful lot against pharmaceutical companies. He was at the FDA 20 years ago, but since then he has made a lot of money testifying against pharmaceutical companies. And he hasn't met a warning label he likes yet. Every time he comes in, he testifies against Bayer, Merck, GlaxoSmithKline, Pfizer, Wyeth. Merck failed

to warn, Bayer failed to warn, yep, $1,000 an hour, Pfizer failed to warn, everybody fails to warn. He made a quarter of a million dollars, you heard, just in this case.

But even Dr. Kessler, who is on the lawsuit circuit, testified about 25 times he said in the last five years, even Dr. Kessler when asked said about the label:

"Q And what is the Precautions section of the label?

"A It's part of the label that says be on the look out, heads up.

"Q Now did both the 2002 and the 2006 labels indicate, did they both indicate that gynecomastia could be associated with this drug?

"A I think that would be fair."

So Dr. Kessler, their expert, acknowledged the 2002 label indicated that gynecomastia could be associated with this drug, because it did.

"And both labels said prolactin elevations could be found in this drug?

"A Yes, I think that would be fair.

And going back to Dr. Mathisen, he made an important decision, and Mrs. Pledger talked about it, for his own reasons and it's his choice. Even though he testified that he knew about the risk of elevated prolactin and the risk of gynecomastia, and even though it was in the label, Dr. Mathisen didn't tell Mrs. Pledger about that. But he had the information. He was adequately warned by Janssen. His testimony was clear that he knew. And the label clearly had it. But Mrs. Pledger said he only talked to her -- oops, I am supposed to read that. I am sorry, Judge -- he only talked to her about weight gain. Mrs. Pledger was asked:

"Q Did Dr. Mathisen tell you any of the other risks of the medicine?

"A He told me about the weight gain and that was all."

But that's Dr. Mathisen, that's not Janssen. Janssen is not in the room with Mrs. Pledger. Dr. Mathisen had the information and he decided not to pass it on to Mrs. Pledger. And not to pass on something

that was in the Precautions section of the label, and you heard from Dr. Robb, the psychiatrist from DC, she said she and her colleagues, of course, were talking to patients back in 2002 about the risks in the Precautions section. She and her colleagues were saying, yes, if it's in the Precautions section you tell the patient you have a risk of elevated prolactin and you have a risk of gynecomastia. But Dr. Mathisen didn't do that, even though Janssen gave him the information. He was adequately warned and he made the decision not to tell Mrs. Pledger.

Now you heard Mr. Kline talk a fair amount about the sales rep Mr. Gilbreath, and I think he mentioned samples, and he had Mr. Gilbreath, the guy from Alabama who was the Janssen sales rep on the stand for about two days. Well, two things: First, Dr. Mathisen, I think you heard he called, he wanted to see. Jason Gilbreath didn't just show up at his office. Dr. Mathisen called and said, I want to see a Janssen rep. And one of the reasons he wanted to see a Janssen

rep, first, he treated adults, and he made that clear in his testimony. He was asked.

"Q So at the time you were prescribing Risperdal to Mr. Pledger in 2002 through 2006, you were also treating some adult patients?

"A Yes, I was."

And so since the medicine at that time in 2002 was FDA approved for adults, and Dr. Mathisen had some adult patients, perfectly legitimate to be talking to Dr. Mathisen about the FDA-approved use, which is what Mr. Gilbreath did.

And you heard Mr. Gilbreath and Mr. Kline talk about there are rules that companies have to follow. You can't talk about risk information or safety information or benefit information about a use that's not FDA approved. So he wasn't allowed to talk to Dr. Mathisen about the use in kids but he could talk about the use in adults, which is why he was there, because Dr. Mathisen had -- he didn't have a lot of them but he had some adult patients, and they were entitled to that information.

And Dr. Mathisen also wanted samples. And I think that Mr. Kline, I forget the numbers he put up there, 15,000 doses, whatever, but all those samples went to help patients. Why is Dr. Mathisen prescribing it? Because it's helping his patients. He made it sound like it's sinister that Janssen is giving samples to a doctor to help patients, some who can't pay, some who maybe have a time lag on insurance. Dr. Mathisen is helping his patients with samples from Janssen that he is asking for.

What you didn't hear was any evidence that Mr. Gilbreath didn't follow the rules. In fact, he was so strict about it, when Dr. Mathisen asked about this new study, this government-funded study that showed that Risperdal was really beneficial in autism patients, Dr. Mathisen said, can I get a copy, and Mr. Gilbreath said I can't talk to you about off-label uses. But you can respond to a doctor's question, so he sent the question back to corporate, and then corporate sent Dr. Mathisen this letter in response. And

Ms. Brown can help me out here.

The letter that went back to Dr. Mathisen in 2002 said, "We are providing the attached information in response to your specific request," and it says right there, it's not intended as an endorsement or promotion of any usage not contained in our label. And they attach the label that has the information about gynecomastia and elevated prolactin, they tell them to go look at the label, and they say it's approved for treatment in schizophrenia, and then they list all -- and what they do is send Dr. Mathisen all of the published studies on use of Risperdal in autism, done by Janssen or done by anybody.

They are saying Janssen failed to warn. Well, they gave a whole list of every side effect seen in every one of those studies on Risperdal, including sedation, including tremor, including tachycardia, including the neuromuscular side effects, EPS, and including gynecomastia. So not only are they providing information, they are providing the good and

the bad. Here are all the side effects seen on all of these studies, Dr. Mathisen, since you have asked, including gynecomastia.

And I think Mr. Kline said, Well, you only sent them one study about gynecomastia. Well, that was the only one that showed that side effect. You can be sure if there were other ones that showed that side effect in terms of the published literature, they would have brought it to your attention.

So they gave Dr. Mathisen sort of an extra warning about Risperdal in that letter, following the rule.

And this issue of off-label marketing and promotion, the Plaintiff spent a lot of time on it, but it really doesn't have anything to do with the case, because when you get to your verdict sheet to answer, there is not going to be any question about did Janssen market off-label or not. I am not sure why they were doing it, but it's not an issue that you are going to have to decide in the case.

And Janssen, as you saw, followed the rules with Mr. Gilbreath sending the question

back to the company and the company responding in the appropriate fashion.

And you also saw that the company, again because there are rules on what you can say about a use that's not approved, they responded to Mrs. Pledger's question when she called. They said, we are responding per the package insert. They talked to her about the package insert, which is the label, the approved use, and they sent her back to her doctor, because they are not allowed to talk about off-label, FDA-not-approved uses. So they gave her the label information and they sent her back to her doctor, but they certainly responded, as Mrs. Pledger acknowledged, to her inquiry.

Now, the FDA is an important piece of this because the Plaintiffs have claimed negligence and a negligent failure to warn, but companies like Janssen are heavily regulated by the FDA. There are tons of rules and regulations you have to follow, and you just can't say anything you want on your label. And in fact, it's really, really

strict when it comes to FDA unapproved uses.

So you heard that in 2002, Risperdal was approved in adults but it wasn't yet approved in kids. And notwithstanding that, Janssen asked the FDA, because they knew, they knew that doctors, like Dr. Robb and Dr. Mathisen and others, were prescribing Risperdal to help kids with autism and with other psychiatric problems, and they said to the FDA, in 1996, can you at least let us put safety dosing information in the label for kids, because we want to make sure doctors are using it safely. And what they wanted to do was tell doctors don't use it in babies, don't use it in infants and to give them the low doses they could use in children and adolescents.

So they asked the FDA, we know it's not approved yet, we are still doing the studies, we just started doing the studies, but we know doctors are widely prescribing it, because there have been a lot of studies, including by the government, showing that it worked for kids. And the FDA wrote back and said, no

way. No way.

This is the letter from the FDA -- and, Ms. Brown, can you just show the letterhead so our jurors can see it's from the FDA -- in 1997. And they say, Your rationale for proposing this supplement -- that means a supplement to your label -- appears to be that simply that since Risperdal is being used in pediatric patients this use should be acknowledged in some way in labeling. And they go on to say, "To permit the inclusion of the proposed vague references to the safety and effectiveness of Risperdal in pediatric patients and the nonspecific cautionary advice about how to prescribe Risperdal for these unspecified target indications would only serve to promote the use of this drug in pediatric patients without any justification."

So they wouldn't let us put basic safety dosing information in it for kids.

And so the Plaintiffs are saying we were negligent because we didn't put safety information about kids in the label. Well, first, as you saw, it was in the label from

the beginning of the risk of gynecomastia and that safety was not established in kids. But you also see that the FDA said, no way. You can't even put the safety dosing information in.

So when Dr. Kessler, the lawsuit expert, comes in here and says, Oh, they could have put it in the label, they could have put the 2.3 percent in a Dear Doctor letter, they wouldn't even let us say don't use it in babies because they didn't want us to go in and say, oh, look we have something about kids in our label so you can use it for kids. They are very strict about what you can say for off-label uses.

And they brought this guy that used to work for the FDA in here and he talked about the fact that, notwithstanding what the FDA told us here, we could have said something about the risk in kids, but did you notice, he didn't show you any regulation. He was their regulatory expert. He didn't show you any regulation. He sat there and read from something. He never showed it to you. He

never put it on the screen. Where was the proof? They have the burden of proof, where is the proof that the FDA would have let us put something about risk in kids in the label? They never showed you that proof because it doesn't exist. I will rely on the real FDA. We didn't bring in a lawsuit expert, I will rely on the real FDA. And the real FDA said, no way. If it's not approved you can't talk about it in your label. Good, bad or indifferent, you can't say anything about it if it's not approved.

All right, let's go back to Mr. Pledger. One of the other things you heard, and I think the only person in this courtroom, all the witnesses and lawyers, the only one that said Risperdal didn't work for Mr. Pledger was Mr. Kline, because the evidence was overwhelming on the fact that Risperdal helped this child. His mother said it, Dr. Mathisen said it, Dr. Robb. You noticed they didn't call a psychiatrist in their case at all? Because a psychiatrist like Dr. Robb say this is a Godsend for kids.

It has helped so many kids with serious psychiatric problems. And 20 years later, it's been on the market 20 years, still helping kids today, still the most widely prescribed medicine, as you heard from Dr. Robb, for kids with serious psychiatric problems.

And so you saw then that when Mr. Pledger started using Risperdal, both his parents and his doctor said it was really helping him. It helped him be more tolerant of his environment, last pinching, no tantrums. He went from having eight a day, screaming, head banging. No tantrums.

"Mom and Dad are very pleased. Continue the Risperdal."

"Austin is doing very well. Mom is very pleased with the school year. The medications appear to be effective without any notable side effects."

And they go on and on, and for five years Dr. Mathisen and his mother keep him on it because it's really helping him. He is doing much better in school, he is doing well,

he is controlling his weight, and we will talk about the weight gain, but he was able to lose and gain weight on Risperdal. And again, the comments about how well he is doing in school. And his teachers at school also noticed the difference.

And so this is after he started on Risperdal in 2002. And they are talking about how he is doing better. He's improved his attention and behaviors, "it's felt that the summer program, in addition to his new medicine, has been very beneficial to Austin." It really helped this child.

And this is grade four for the entire year report: "Austin had a very good year, his behavior was way more consistent." Not perfect. He had four or five days over the whole year that was difficult, but a very good year for Mr. Pledger.

That's why they kept him on it, it really helped him, and it's helped thousands of kids like Mr. Pledger. In fact, they didn't bring a single witness in here to tell you that Mr. Pledger shouldn't have been on

this medicine. There is nobody who said -- think about all the witnesses they brought, and they talk about how horrible this medicine is, unsafe, they didn't bring in one witness who said he shouldn't have been prescribed this medicine.

Even Dr. Mathisen, he said, Well, if I, you know, well, maybe, I would have talked to the mother more. But not that he wouldn't have prescribed it. Because the evidence was obvious, he should have been on this medicine. It helped him.

And you also heard -- I am going to talk about the weight gain briefly. Ms. Brown, Slide six.

And I think you heard the weight gain information was a side effect mentioned in the label from the very beginning, there is really no dispute about that, and Dr. Mathisen testified that he knew about it, and Mrs. Pledger said that was the only risk he actually did tell her about. And you saw that this clinical study data talked about the mean increase was about 7.5 kilograms, and if you

subtract the growth amount, how much you are going to grow from that, it ends up to be about seven to 10 pounds, as Dr. Vaughan told you. That's what you generally see in terms of the mean, seven to 10 pounds. And you saw that Mr. Pledger -- if we could put up the weight chart, Slide seven -- and both Dr. Vaughan and Dr. Mathisen testified that he was obese before he started. He suffered from obesity before he started taking Risperdal, back when he was only six years old. And then he did gain weight on Risperdal, and he also was able to lose some. And you saw from the records and from the fact that autistic kids are often fixated on fattening foods, you saw that he didn't have the best diet in terms of french fries and Little Debbie cakes and Tang and things like that. And you heard from Dr. Vaughan, because the clinical trials show seven to 10 pounds weight gain and because of his diet and inactivity, most of his weight gain was from his diet and inactivity and not from the medicine, and in part because when he ate better and exercised he lost weight on

Risperdal. But then we saw he gained a lot more weight after stopping Risperdal on these other medicines, Geodon and Abilify, and Prozac. He gained like a 127 pounds, that put him in the morbidly obese category. And he was able to lose some weight, to his credit and his mom's credit, and he is still in the obese category.

Why is that important. We will talk a little bit more about it, but it's important because people who are obese, as Dr. Vaughan told you about men, and especially when you are in the morbidly obese category, he said it would be really unusual if you were morbidly obese and didn't have pseudogynecomastia, didn't have enlarged breasts from fat. And even if you have lost weight and you are still obese and you have sagging skin, it's going to make your breasts enlarged whether or not you have gynecomastia.

But the weight gain was something that Mr. Pledger had problems with before, during, and even after Risperdal.

And then there is going to be another

question on the verdict sheet -- and, Ms. Brown, if we could put up Slide eight -- take it down for one second.

So the second question you are going to be asked to answer is: Do you find that Janssen's negligent failure to provide an adequate warning was the cause of Austin Pledger's gynecomastia?

And there is a couple of parts to that the Judge is going to charge you. One part is would a different Warning have made a difference to Dr. Mathisen. And I am going to show you that it wouldn't. Would a different Warning have changed his decision to prescribe.

And then the second part of that is whether or not, medically, Risperdal caused his gynecomastia. And I am going to submit to you the evidence, as you already heard, would indicate no. And we will talk about it because the label in 2006 -- and that's Slide eight -- so the label in 2006, Mr. Kline, the Plaintiffs hold up as the, you know, the adequate, this is the one we should have been

saying all along, but we were able to say it in 2006 because the FDA approved Risperdal for kids just like Mr. Pledger.

So in 2006, the FDA said yes, this medicine works, and it's effective, and if used as prescribed, safe for kids like Mr. Pledger.

And so in 2006, the label was changed to reflect the pediatric data, and it talked about prolactin elevations and that Risperdal elevates prolactin more than others. And you heard Dr. Vaughan and Dr. Robb talk about the fact that there has been no correlation between prolactin elevations and side effects. It's not like blood pressure and cholesterol, where we know higher causes side effects. It's like some of us have different levels of vitamins in our body and it may not have any clinical effect, and prolactin, the studies have shown, is like that. So whether it's higher or lower than others on prolactin doesn't relate to side effects in the studies.

But we did have the 2.3 percent data on pediatric studies in terms of the rates of

gynecomastia, and Dr. Mathisen had -- and this is on the seconds question, really important -- Dr. Mathisen had that information. He had the 2006 label in his hand, and how do we know that.

Well, first, he testified he did. But this is a call-note that Mr. Kline talked to Dr. Mathisen about, where he was visited by a Janssen sales rep. So after the autism approval, Janssen goes to see Dr. Mathisen, thanks him and gives him the new autism information. And what is the new autism information.

Well, it's this detail piece, and it's the label. And so it talks about the fact that, Visit our website, please see the important safety information and box warnings. And it has, sort of the first line of -- it has some of the major side effects in it, and it has the first line, and I think Mr. Kline likes this first line because it says, Risperdal elevates prolactin levels like other drugs and it persists during chronic administration. But that's what the label

said, and even in 2006 that was the first line of the label -- they are pulling out the first line of everything -- and Dr. Mathisen had all the rest, too, had the rest that Risperdal elevated it more, and he had the 2.3 percent information as well, in 2006. And if we could put up Slide eight briefly -- it had the 2.3 percent information.

And why is that important to the second question you are going to have to answer? Because Dr. Mathisen was asked, in terms of the evidence that you heard, the question:

"Q And when you met with the Janssen reps after the autism approval, they gave you the new label for Risperdal as related to children and adolescents?

"A I am sure they did.

"Q Dr. Mathisen, you knew in 2006 that the rate was 2.3 percent in terms of gynecomastia seen in clinical trials with children?

"A Well, obviously. The package insert indicated that. But I may not have personally looked into the package insert and picked out

that specific number.

"Q But you had it?

"A But I had it in my hand.

"Q You had the package insert?

"A Yes."

And we know -- Slide nine -- and we know that after Dr. Mathisen has what they say is the adequate label, Mrs. Pledger calls him. And maybe you folks remember, when I put this call message up on the screen during Dr. Mathisen's exam, the courtroom kind of went crazy. Dr. Mathisen started talking before I asked him a question, Mr. Kline started objecting. Because they know what it means in terms of their case.

Dr. Mathisen got a call from Mrs. Pledger on January 19, 2007, after he had what they claim is the adequate warning, after he had all the information, he had the information about the 2.3 percent rate in kids, he had the information about elevated prolactin in Risperdal higher than other antipsychotics. And what does he do? He calls in a new prescription.

We talked to him about the fact that's the number for the Wal-Mart pharmacy in Clayton, Alabama, and he calls in a prescription and five refills.

And then we have the Wal-Mart record, December 11, and we see that in January of 2007, months after Dr. Mathisen has what they claim is the adequate label, it doesn't change his prescribing decision at all. He continues to prescribe.

And Mr. Kline I think said, Oh, it's a refill. It doesn't matter if it's a refill or not, but it's clearly not a refill if you look at the record. It says Refill, zero, it's a new prescription, and it has refill one, refill two.

He continued to prescribe and Mr. Pledger continued to get Risperdal for months after Dr. Mathisen had what they claim is the adequate label.

And so if you look at his testimony, he was asked:

"Q Doctor, in January of 2007, Mrs. Pledger calls you about getting more

Risperdal?

"A Yes.

"Q And this was after the sales rep had given you the 2006 label that showed more rates of gynecomastia in children, right?

"A That's for sure.

"Q And so in January 2007 -- and we can look at the prescription records from Wal-Mart -- you called in another prescription for Risperdal and some refills?

"A Yes.

"Q So after you got the 2006 label from the sales rep that said elevated prolactin is worse with Risperdal, that you knew the incidence in children was higher, you continued to prescribe it to Mr. Pledger here?

"A Yes, I agree with it.

"Q Well, doctor, I am sorry, I didn't mean to interrupt. Doctor, had you read this label, had you read this label, you knew that there was a new issue?

"A You can argue that I didn't do my responsibility in terms of reading every word in that label and saying, ah-hah, there is a

2 percent or 3 percent risk with that drug, and any time a patient calls in for a refill I have to say, no way, we are not going to treat you anymore because of a small risk."

He had it, and he said maybe I didn't do my responsibility because I didn't call her about a small risk, but he had what they claim is the adequate label and he continued to prescribe. And he continues to prescribe Risperdal to patients to this day, he told you.

And so when you are asked, Did you find Janssen's negligent failure to provide an adequate warning was the cause of Austin Pledger's gynecomastia, well, when we provided what they claim was the adequate Warning, it didn't make a darn bit of difference. Dr. Mathisen had all the information and again made the decision to continue to prescribe Risperdal to Mr. Pledger. And Mrs. Pledger said he didn't tell her even then about the elevated risk of prolactin or the risk of gynecomastia. But that's not on Janssen. They gave him the new label. He said he had

it in his hand.

And then Mrs. Pledger claims -- and, you know, you can't blame a mom, a mom would say, yeah, if I had known something I wouldn't have subjected my kid to a risk, but you have to test that against the evidence. She claims had she known about any risk of gynecomastia, was her testimony, she wouldn't have allowed her son to be on this drug. Well, Dr. Mathisen didn't tell her, but the truth is, she has got her son on another drug now that has far worse risks, according to Dr. Mathisen and Dr. Robb, the expert psychiatrist. Geodon is the medicine that Mr. Pledger has been on since about 2007, 2008. And Dr. Mathisen said he didn't prescribe it back then because it had a very significant heart risk, it causes fatal skin diseases, and it's still even to this day not approved by the FDA at all for autism.

So while Mrs. Pledger says she wouldn't have let him take Risperdal had she known about the risk of gynecomastia, I am not sure that it adds up when you hear that she has him

on medicine that even Dr. Mathisen said is worse in terms of the side effect profile on heart risk, fatal skin risk, and it also has in its label elevates prolactin and can cause gynecomastia, in terms of a potential risk.

If we can put up Slide ten. And so here is the chart I think you guys saw yesterday in terms of the medicine Mr. Pledger was on. He was on Risperdal until about mid-April of 2007. And they did try Abilify on him, but you heard it didn't work. They had to take him off it, his behavior problems got worse and he got a hand tremor, if you remember Dr. Mathisen saying. So since then they have had him on two medicines to try to control his serious behavior problems. Geodon, that we talked about that is not FDA approved in kids at all and has these heart and fatal skin disease risks, and he is also on Prozac to try to control his behavior problems. But the school records made clear and the medical records played clear that these other medicines, unfortunately, didn't work as well for Mr. Pledger.

So we saw that in mid-April he stopped taking Risperdal, and here is a record right after that. It says in April, "Austin was reported to be initiating interaction and being more verbal, however, after returning from spring break" -- after stopping Risperdal -- "his behavior had regressed. It was reported that his medications had changed and this could explain the difference in behavior."

So they noticed right away, when the second doctor, Dr. Paoletti, took him off of Risperdal because of concerns of weight gain, his behavior according to school records got significantly worse. Ms. Brown -- this is another school record that you saw from -- it talks about the fact that after Risperdal, "he is having significant behavioral difficulties that may cause harm to himself or others. It is recommended that all staff receive training in appropriate deescalation and restraint."

Because now he is a big kid. Now he is getting close to 207 pounds or over, he is 15 years old and he is acting up. We saw

evidence he was hitting teachers, hitting other kids, and they talk about the fact that after Risperdal he was having a lot more problems, biting himself, biting some of his teachers or teachers assistants, kicks, punches teachers, throwing objects like books, chairs, headbutts pavement, pinches his classmates, et cetera, et cetera, et cetera.

So he was able to stay in school on Risperdal, and while it wasn't perfect he was in school, he was learning, he was out in the world. And after they took him took him off Risperdal, ultimately the school said -- they had to kick him out of school, because of their concern for safety of teachers and other students. And it's natural for the mother to blame the school, of course, but the records were pretty clear about the kind of behavior difficulties after Risperdal Mr. Pledger was having.

And that's why Dr. Robb, the psychiatrist, one of the world's leading psychiatrists said Risperdal is different, it's better for kids than these other, it

works better and its safety profile is better. It's not without side effects, but overall, this was the best medicine for Mr. Pledger, and nobody here has come in and said any differently. And you have heard now Mr. Pledger is essentially homebound. He watches TV, according to his mother, up to ten hours a day and isn't in school, isn't out in the world the way he was while he was on Risperdal.

So they claim that Risperdal caused -- and so another part of this verdict sheet is you have got to decide whether a different warning -- failure to provide an adequate warning was a cause, and there is two parts of that, as I mentioned. One is would a different warning have mattered. Clearly, Dr. Mathisen had what they claim was the adequate warning and continued to prescribe. And the second part of that is was Risperdal the medical cause of Mr. Pledger's enlarged breasts. And you heard yesterday from Dr. Vaughan -- now, we brought you Dr. Vaughan and Dr. Robb were our two experts. Neither

one of them has ever testified in a lawsuit before. They are real doctors, not part of the lawsuit game. Dr. Vaughan made $26,000 over an entire year, reading tons of records, et cetera. That's as much as they paid Dr. Solomon in a day. Dr. Robb never testifies in lawsuits at all, but she came here because she knows how important Risperdal is in treating kids with serious problems.

But they weren't polished and they didn't fight as much as Dr. Kessler and Dr. Solomon, their experts who do this, you know, part of the lawsuit game all the time. But they came in here and they told you the truth. Dr. Vaughan, and he was -- I think Mr. Kline asked him about ten times, You are not a pediatric endocrinologist. He is an endocrinologist, Board certified, who treats a lot of kids. They didn't bring in any endocrinologist. And Dr. Vaughan, at the major institution in Alabama, an endocrinologist, said, you know what, he has got gynecomastia but he has got the kind of gynecomastia I see all the time in kids caused

by puberty. And you saw the studies that showed, even Dr. Solomon's book, 65 percent of kids going through puberty get some degree of gynecomastia. Some worse than others, some moderate, some more severe. And Dr. Vaughan said he also had pseudogynecomastia.

And, you know, I think because Dr. Vaughan was the only endocrinologist who came here, Mr. Kline decided he really had to take him out. So he spent two days cross-examining him. And one thing Dr. Vaughan was solid on was that Risperdal did not cause Mr. Pledger's gynecomastia. And he told you about the fact that he sees obese patients in his practice, both adults and children, and obesity, especially the kind of morbid obesity that Mr. Pledger suffered for a time, can cause enlarged breasts as the pictures depict. And he gave you the analogy of a plate and a pillow, and Ms. Brown brought me a plate and it's about 10 centimeters -- it's actually about ten and a half, which is about the size of what Dr. Vaughan measured for Mr. Pledger. It's not a softball, it's

not a water bottle. This is the size, and picture it on a big man -- and Ms. Brown, since she has three kids under five, I guess doesn't wash dishes too much because this is a dirty plate -- but this is about the size of the gynecomastia. And to put it in perspective, most of it, as Dr. Vaughan told you, was from fat tissue, from obesity. And so this is the pubertal gynecomastia, and the rest was from the obesity.

And one thing he said was it's not physically possible, there is not a lick of scientific or medical literature across the world that says Risperdal can cause gynecomastia in someone prepuberty. Because the hormones aren't on yet. You don't have the estrogen to make the breast tissue. It doesn't make any sense.

And Dr. Solomon, their cosmetic, Botox, breast augmentation, penile enlargement surgeon, couldn't cite a single piece of literature at all or study to support his opinion. And you remember what he said, Dr. Solomon. He said, You know what, it's

kind of like pornography, I know it when I see it. And he said, I can diagnose gynecomastia based on a picture across the room, even though his textbook said no, you need a physical exam to do it. Remember he looked at that pool picture from a decade ago and said, yeah, I know like pornography, that's gynecomastia. And Dr. Vaughan and the textbooks say no, you got to do a physical exam. And it makes more sense, because it happens so often, 50 to 65 percent of the time during puberty, that puberty plus his obesity is the cause of his gynecomastia, rather than the scientifically and medically implausible event that they talked about.

And the only proof we have in this case is that when he was on -- their whole case is that Risperdal elevated prolactin and caused gynecomastia in Mr. Pledger. Well, the only proof we have about what his prolactin levels are while he was on Risperdal show that after five years on Risperdal, still on Risperdal in April 2007, his prolactin levels are completely normal. It's the opposite of what

they argued. So the prolactin levels were not elevated at all by Risperdal.

And if we could have Slide 11 now.

And you saw in the studies, 49 percent of the folks had elevated prolactin, kids like Austin Pledger, 51 percent didn't. And then it showed that only -- so it's a better than 50 percent chance that Austin Pledger's prolactin was never elevated, and the measurement we have shows that it wasn't. Again, more likely that it was from puberty and this obesity issue.

And so the science just doesn't support what they are arguing here, and that's probably why they couldn't find a single endocrinologist anywhere in the country to come in and support their case. They had to have a $20,000-a-day cosmetic surgeon, who admitted he doesn't know anything about hormones, doesn't do any research in hormones, and testified, yeah, like pornography, I know it when I see it.

And you also saw -- I am going to briefly talk about this accusation and this --

so their whole case is built on this Findling paper, this 8 to 12-week analysis. And I submit to you it's the height of cherrypicking. And so this is the analysis, this Table 21, that showed for every single data point there was no association between Risperdal and gynecomastia, but they want to cherrypick out one data point that included all the boys in puberty to say that that was a real finding. And an analogy is sort of like, I know there are probably Eagles fans in the box, so picture if there's a wide receiver -- he doesn't play here anymore, but DeSean Jackson, and you see him drop a pass. And you say, He is terrible, he must be a terrible receiver. But that's only one data point. But if you look at the whole season or his whole career, he was a pretty good receiver.

And that's why one data point can be misleading, that you don't base your conclusions on one data point. As Dr. Robb told you, you have to look at all of the data. And when you look at all of the data -- and by the way, they keep saying, didn't give it to

the FDA, you didn't give it to the FDA. The FDA had it, and even Dr. Kessler admitted they had every single event, all of the raw data, all of the clinical study reports. The FDA knows exactly what to look for, believe me, it's really hard to get a medicine approved. They had all of the gynecomastia events from the studies, and they run their own analysis.

Think about all the data analyses that companies across the world do on medicines. They run statistical tables, they run all kinds of tables. The FDA doesn't want all of your junk, they don't want all of your spin, good, bad, or indifferent, piles and piles of data. They want the actual events. Tell me how many events of gynecomastia are in your study. Tell me what the efficacy data looks like. We will run our own analysis. They know exactly what to look for. And Dr. Robb told you one data point, 8 to 12 weeks, where it's inconsistent with all of the other studies, that's not clinically significant at all. The FDA wouldn't want that data, it's meaningless.

And another piece of evidence that proves that it's meaningless is that the government did a study that found, in 2007, on Risperdal, not Janssen, government-funded study including government investigators and these outside autism researchers, 22 months, a long-term study, Risperdal in autistic kids, they found the exact same thing Janssen did. The prolactin elevations didn't correlate with gynecomastia.

We are ten, 12 years after the Findling study. There has been no evidence in any other study that what they are saying is true, that Risperdal causes gynecomastia. The government study found it doesn't. Same thing as ours, in 2007.

And they like to talk about "hiding data", and I think Mr. Kline showed you -- he didn't show you any evidence in his closing but during the trial he showed you this Janssen E-mail about hiding data, and he suggested this means Janssen was hiding data. But if you read the whole E-mail it's the opposite of what he was suggesting it was.

It says, Gahan -- that's the doctor at Janssen, Gahan Pandina -- and the U.S. Group convened a children and adolescent advisory board, and here is what they say: "The U.S. group recommended that the manuscript list all cases of gynecomastia in males" -- that's Janssen, the U.S. group. We say let's list them all, both kids over ten and under ten, let's list them all, and state whether prolactin levels are normal or elevated. This U.S. group of Janssen, they felt that applying the endos' position of gynecomastia in boys in puberty not being SHAP without listing all the gynecomastia was hiding data.

And who were the endos? The endos were these world-renown -- Mr. Kline and I don't agree on a lot but we agree that the outside endocrinologists that Janssen used that were co-authors on this Findling paper were some of the best endocrinologists in the world. And what do they say to Janssen? They say don't include SHAP(A), don't include boys over ten in your study because you are going to get too many gynecomastias from puberty, so you are

not going to be able to tell whether the drug is associated with gynecomastia or whether it's puberty. And so the outside endos, these world-renown experts, Dr. Moshang and Dr. Daneman, they say don't put it in. And Janssen is saying, the endos' position of gynecomastia in boys in puberty not being a SHAP -- so these world-renown experts, outside scientists are saying to Janssen, it's not a SHAP related to prolactin if you are including boys in puberty, so they are saying don't include the boys in puberty. That's why we did SHAP(B), nothing sinister. The world-renown experts are saying you can't include boys with puberty, it will mess up your study because so many of them have gynecomastia. They say don't include them, and Janssen says, well, we might be accused of hiding data if we listen to these outside endos, so let's put it all in.

And remember when Dr. Kessler and Mr. Kline were on the stand, they never turned the page to this E-mail. They never showed you the second page, and then I showed it to you

and Dr. Kessler when he was on the stand, and what Carin Binder from Janssen says: "I have no problem adding the boys over ten, and keeping the pediatric endo analysis -- that's the experts. This is how SHAP(A) and SHAP(B) was done, Janssen said let's put it all in. The outside endos said just look at SHAP(B) because the boys in puberty are going to mess up your study. It was the opposite of hiding data. Janssen was transparent in showing data.

And if I could have the SHAP(A) and SHAP(B) -- actually, if you could start with 61, and then we will go to 65.

And you see even in the Findling publication, the outside authors, Dr. Moshang and Dr. Daneman, these are these world-famous endocrinologists, they are the ones who are saying exclude the first analysis, SHAP(A), use the more inclusive definition as to kids over ten, and the second analysis SHAP(B) excluded additional symptoms that the pediatric endocrinologists, Dr. Moshang and Daneman attributed to puberty. They are the

ones that told us don't even do SHAP(A), but Janssen in the paper: Transparent. Let's include all kids so we are not accused of hiding data. They put all 25 gynecomastia events right in the paper, and then they do what the outside endos believe is the more appropriate and scientifically reliable analysis, SHAP(B), when you exclude kids in puberty.

And then the government finds the same thing Janssen did in their 22-month study, no correlation between prolactin elevations and side effects.

And I think Mr. Kline likes to talk about this, I think he likes the word "nauseating" amount of information. He keeps saying nauseating amount of gynecomastia, but the E-mail actually says nauseating amount of information. Probably not the best word, but what she is saying here is we have so much information because we cut this data so many different ways, "there is nothing to find, people!" There is no association between prolactin elevations and gynecomastia. The

opposite of what he suggests, not a nauseating amount of gynecomastia. There is nothing to find, there is no association.

And when you look at the SHAP(B) analysis, which is what these world-renown experts told us to do, you exclude the boys over ten, even if you include the boys over ten, you only saw one data point, the eight to 12-week, with any association. None of the others, even if you included all the boys in puberty there was no association. But when you did the analysis, the outside experts said was the right thing to do, the one that Mr. Pledger fit in, SHAP(B), these are the boys under ten, and they claim he got it when he was eight, there is no association, none, between prolactin and side effects.

And he keeps putting up that Table about 7-year old, 5-year old, but when you look at the data, the prolactin elevations weren't high enough, according to these outside authors, to cause gynecomastia. And when you actually do the analysis to see if there is any relationship between prolactin

elevation and gynecomastia, there wasn't any. The science doesn't support their case.

And Dr. Vaughan explained why you can't cherrypick from one data point. And Dr. Robb does more clinical trials on antipsychotics, the child psychiatrist from Washington DC, than just about any psychiatrist in the world. Because she said she is trying to find new medicines, better medicines to help her patients. And she knows how to interpret clinical data. In fact, they have her on all of these data safety monitoring boards to see if there is any safety problem in a study she can stop it. And she was asked, speaking about this eight to 12-week statistical finding in the Findling study, can you talk about how you interpret that data in the grand scheme of all the data. "It's one data point. It's mostly an open label data. So we don't have a comparative placebo group." There was no placebo group, remember, in the INT-41 study that had almost all the events in Findling.

"Q Doctor Robb, is it important to look

at a finding in the context of all the other findings?

"A Absolutely, because one data point doesn't tell a story.

"Q Why is it important to look at all the data?

"A Because what you really want to see is a big trend in elevations and that being associated with the findings at the end of the study. So one data point doesn't do it."

And she went on to talk about the fact that other studies concluded the same thing as the Findling investigators, that there was no association between elevated prolactin and gynecomastia.

And if you look at all of the data -- if we can put up Slide 14 -- so these are all the 18 pediatric studies. These are just the Janssen studies, they don't include some of those done by outside investigators. So Dr. Robb is saying you can't look at one data point for one four-week period, you have got to look at it in the context of all the data and all the analysis, and in the context of

all the analysis there was no association between Risperdal and gynecomastia.

And if we put up Slide 12 -- and even the FDA, in the 2006 label, the FDA you heard that if they think your medicine causes a problem they can make you say "cause" on your label. But what they say here, "It's important to emphasize that although the events reported occurred during treatment with Risperdal, they were not necessarily caused by it."

So gynecomastia was reported in 2.3 percent. That doesn't mean cause. That includes any gynecomastia from puberty, from obesity, from any cause, you have to report it. As Dr. Robb said, if somebody gets a headache on your medicine, that goes into the incidence rate whether the medicine is causing the headache or not. So the 2.3 percent doesn't mean cause, it means all events, even if they are caused by puberty or obesity or some other reason.

So that leaves us back to what they brought to you in terms of the causation

picture in this case. And so we saw that Mr. Pledger -- if we could put up Slide 16 -- we saw that Mr. Pledger had enlarged breasts, this is when he was 11, in 2005-2006, and his doctors said consistent with his weight gain it was proportional in those pictures.

And if we can look at slide -- can we get it so we have a full view -- and we see Mr. Pledger, and to Mrs. Pledger's credit, he looks like a happy guy there. But you see he is a big kid, he still suffers from obesity, and his chest proportions are consistent with that.

So who did they bring you on the causation issue. Well, first Ms. Brown, if we can go to 87.

And again, I submit to you, think about this. Is this kind of part of a show, is this kind of too cute. So they bring Dr. Solomon in here, who says miraculously, oh, yeah, Mr. Pledger got gynecomastia within eight to 12 weeks. Why do they say that. Here is the one data point. I know it's eight to 12 weeks, even though there is no photo back from

when he first started Risperdal, and even though Mrs. Pledger told Dr. Solomon and Dr. Vaughan his breast growth started immediately, consistent with weight gain.

And then Dr. Solomon is like, oh, no, within two months? Okay. And then he wrote his report and it went from two months to two to three months. They got to get that eight to 12 weeks, you know, make it fit just right.

And actually, even Dr. Solomon's opinion was incredible to their Regulatory guy Dr. Kessler, because remember he criticized us for doing short-term studies. He said you wouldn't expect to see gynecomastia in six weeks. You would have to look at it over a year. But Dr. Solomon comes in here and says, Oh, yeah, it's got to be eight to 12 weeks.

But if you look at Dr. Solomon's website, if we could -- Slide 17 -- he came in here and he said a lot of things that were dramatically inconsistent from what he actually says in the real world.

First he said in many cases of gynecomastia -- under Causes of Gynecomastia.

He says, and this is Dr. Solomon, their expert's website: "In many cases of gynecomastia the cause is unknown. Some men get the condition during puberty." And then he goes on to say on top of that -- here we go, you got it.

So remember, you heard Dr. Solomon, he didn't measure the fat in the breast at all. He measured the bra size. Dr. Vaughan says there is no medical reason you would ever do that, unless you want to put on a show. Come in here and say he got 46 double D. Why would you measure for bra size? Real doctors don't do that. And he talks about the fact that -- even though he knows that gynecomastia is largely fat, he doesn't measure Mr. Pledger for it at all.

And then his website also says -- even though they say, even though they come in here and say, well, pubertal gynecomastia goes away, their expert on his website, he says, "In men with gynecomastia, the condition persists well into adulthood." Exactly what Dr. Vaughan said, up to 20 percent of boys who

get pubertal are gynecomastia, it can persist well into adulthood, like it did here.

And you also saw -- if we can put up the fee schedule -- you also saw that Dr. Solomon charges $20,000 a day. The weekend before he met with the Plaintiff's lawyers in this courtroom, it must have been $60,000 for three days of work. $20,000 a day, no refunds. If you reschedule you still got to pay him. Raise his hand, says, oh, yeah, like pornography, I know he has gynecomastia, I can tell across the room. And by the way, if it helps your case, I'll say it happened within eight to 12 weeks, too, even though it's medically and scientifically impossible, and they don't cite any literature at all to support it.

And then you learn more about what Dr. Solomon's specialties were. Not an endocrinologist, not a specialist in hormones, a specialist in cosmetics surgery. His website talks about hair transplants, Botox, tummy tucks, liposuctions, facelifts. And you also heard about his real specialty. If you

go on a website and do WWW penile enlargement surgery dot com, Dr. Solomon pops up. "Most men are good candidates". Who knew. "It's not unusual for men to feel disappointed with the size of their penis." If they really had a medical and scientific case, would they be reduced to bring in this guy? $20,000 a day, and I will say it, even though my real specialty is penile enlargement surgery.

They had a ruler here yesterday, they were criticizing Dr. Vaughan, and it was my fault, I should have given him a ruler when he was drawing gynecomastia, but it seems like Dr. Solomon has the corner on rulers because if you look at his website there are a lot of rulers and a lot of things going on there. And he came in here and he actually justified to you, remember, he was on the stand, and he justified his $20,000 a day. He said, That's a pittance for me. I am like an NFL quarterback. Yeah, he is like the Tom Brady of penile enlargement surgery. He actually said it's a pittance. That's what they are reduced to.

What does your common sense tell you? That's the expert they brought? Do they have a medical and scientific case?

We brought in Dr. Robb, the world's leading child psychiatrist. We brought in an endocrinologist from one of the major medical centers in Alabama. They brought the lawsuit experts. Because they are putting on a show. And they got Mrs. Pledger sucked in, 1-800-Call and we'll sue. Don't have to meet them, don't even have to have scientific support, can bring in highly-paid lawsuit experts, Dr. Kessler $1,000 an hour, this guy $4,000 a hour.

It's not a game to Janssen, it's not show to Janssen. They have made medicines that have helped a lot of people and they do it right. They take it seriously. They know patients depend on them.

And the FDA did it right. They do their jobs. The FDA rigorously studied this medicine, rigorously studied the events, and Dr. Kessler acknowledged the FDA disagrees with him here. He was asked the question, Dr.

Kessler -- and again, I would rather rely on the real FDA. Janssen would rely on the real FDA rather than a hired gun. Dr. Kessler was asked:

"Q Dr. Kessler, it's true that the FDA has never concluded in 20-plus years that Janssen failed to adequately warn about a safety risk?

"A I think that's probably correct."

The FDA disagrees with their hired gun.

Now I ask you again, you have a hard job, but you have got common sense and you folks have struggled to pay attention, we are all boring and we appreciate it. And when you go back there and you debate the verdict sheet, and sometimes it's easy to say let's give him a little money or let's give him money and get out of here, but if you don't believe the Plaintiffs have proved their case, stand your ground. Do justice. Put them to the proof. Don't be swayed by the crowd, stand on principle. And use your common sense. If Risperdal really caused Mr. Pledger's gynecomastia, why is the first

person to tell them that a lawyer, not a doctor? And if Risperdal really caused Plaintiff's gynecomastia, why do they get WWW-dot-whatever, Dr. Solomon as the only expert? Not an endocrinologist. $20,000 a day to support that. And if Janssen failed to adequately warn, why did the FDA never conclude that? And why did Dr. Mathisen testify he knew about the risk of prolactin elevation and gynecomastia and decided not to tell Mrs. Pledger? And why did he continue to prescribe Risperdal if we failed to adequately warn when he had the new information in his hands? Let your common sense light the way.

On behalf of the folks at Janssen, Dr. Coppola, Dr. Caers, Mr. Murphy, Ms. Brown, we appreciate your service, and I wish you the best in deliberations. Thank you.

THE COURT: All right, thank you, Ms. Sullivan. There are two ways of going about it, jury, we can have lunch now or we can take a break for about five or ten minutes, hear out the rebuttal, and then have lunch and then we will take awhile to get

ready. It's up to you.

I think we are going to take break then for about five minutes right here and then we will hear the rebuttal.

(The jury is excused and the following transpired in open court:)

THE COURT: Counsel, if there are any exceptions, or whatever, we will address them after the rebuttal.

MR. KLINE: There are multiple, Your Honor.

THE COURT: I am sure there are, but right now we have to do the rebuttal and get the jury lunch.

(Jury enters the room at 1:19 p.m.)

THE COURT: All right, please be seated, everybody. First of all, I want to thank the jury now for your own -- what's the word -- endurance at this point, but I do think it's better for all of us to have the rebuttal completed and then give us a chance to relax and then I will give you the jury instructions after some leisure time at lunch, okay? I think it is better. Thank you.