gynecomastia, correct?

THE COURT: Do you need a hard copy? Why don't you give him a hard copy.

A No, no, that's --

Q I can shorten this up, Your Honor.

A That's incorrect.

Q I will withdraw the question, I will shorten it up. I want to give time. Let's take it down. We will move on. I am going to try to get this finished.

Sir, we talked briefly about this label?

A Is it the 2006 label?

Q Yeah. By the way, 2006 label, when autism was changed, just to be clear, was not in effect when the drug was being used off-label for doctors in 2002 to 2006, correct?

A That is correct.

Q And by the way, sir, do you know of any effort Janssen took -- it's just a simple you know or you don't -- any effort Janssen took to send a Dear Doctor letter to doctors prescribing off-label, any time between 2002 and 2006, about this prolactin issue?

A No. We would not be even allowed to do so.

Q That's a different story, sir.

A Yeah.

Q Do you know -- it's just a do-you-know question -- do you know what the former Commissioner of the FDA told us about that?

A No, I was not here.

Q Yeah. And, sir, the label itself, the 2006 label, first of all, let's go to the proposal. This was with -- you did this with Ms. Sullivan, Exhibit 60(D). This would be JJRP00824752.

MR. GOMEZ: D-62.

Q Do you remember you were talking about the label markup?

A Yes.

Q This was in front of the jury earlier, it's D-234.23, it's D-60-D. It's a document previously marked, a defense Exhibit. I am told it's D-62.

Remember discussing it with counsel for the Janssen companies?

A What is the question? I am sorry.

Q Do you recall it, I want to put it in perspective so that I can ask you a few questions and hopefully sit down?

A Is this --

Q The label markup with the FDA?

A That the FDA sent us?

Q Yeah.

A Okay.

Q Because you see the first sentence, "As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels." Do you see that?

A Yes.

Q That was the language that Janssen suggested and it was crossed off by the FDA?

A No, no, this was the language that has been in since 1993.

Q Oh, and that's why it's crossed off. Got it. Okay, sir.

MR. KLINE: Nothing further right now, Your Honor. I want to be done today with our 15/15.

THE COURT: I guess this would be redirect.

MS. SULLIVAN: Thank you, Your Honor.

- - -

REDIRECT EXAMINATION

- - -

BY MS. SULLIVAN:

Q Good afternoon, everyone. Good afternoon, Dr. Caers. Dr. Caers, I want to start by asking you about those events in the prepubertal kids that Mr. Kline was asking you about from the data tables? And I will get out the document and show you.

MS. SULLIVAN: If we could get Dr. Caers and Mr. Kline a copy of what's been marked as Dr. Caers' Exhibit 63, and that's where these tables that Mr. Kline was talking about came from.

Q Dr. Caers, Mr. Kline showed you -- if I could have the elmo -- showed you this table, and Dr. Caers, these are kids that are under the age of ten, right?

A The boys with gynecomastia, yes.

Q Yes. And one of the things that Mr. Kline didn't talk to you about was the fact that the company --

MR. KLINE: Objection to the form.

THE COURT: Sustained.

Q Was there also an analysis in this package that looked at whether or not these events were

related to Risperdal, were related to prolactin?
A Yes.
Q And so when he was talking about the little girls with amenorrhea or lactation, and the boys with gynecomastia, there was actually an analysis to see whether or not these events were related to Risperdal or prolactin, right?
A Yes.
Q And let's look at that analysis. And that would be Table 20, Dr. Caers?
A Yes.
Q And can you talk to our jurors about what Table 20 is and what it looked at?
A Table 20 looked at the potential relationship of the SHAP(B) adverse events with the prolactin levels throughout the study.
Q And SHAP(B) were the boys under ten who weren't in puberty, and girls who might have had pubertal events? The kids under ten.
A They were the SHAPs as defined in SHAP(B), which was gynecomastia in boys, only the boys who had gynecomastia below the age of ten, yeah.
Q And can you tell our jurors what Table 20 showed in terms of whether these events were related

to Risperdal or prolactin elevation?
A They were not.
Q They were not, and can you explain that?
MR. KLINE: Your Honor, this was covered on direct.
THE COURT: No, overruled.
A I can explain. The analysis fails in showing and proving that there is a relationship between the SHAP(B) adverse events and the prolactin levels in these patients.
Q Can you tell our jurors whether there was any difference statistically between people who had events at normal prolactin levels and people who had events with higher prolactin levels on Risperdal?
A No difference.
Q No difference. So what did the company and the outside scientists conclude on the issue of whether these events Mr. Kline talked to you about in the younger children were even related to Risperdal?
MR. KLINE: Objection to the hearsay, objection to the outside people.
THE COURT: As to the FDA, yeah, that's sustained.

Q Dr. Caers, what were the scientific conclusions as to whether these events were even related to Risperdal based on the data?
MR. KLINE: No objection as to Janssen's conclusions.
THE COURT: Well, as to his conclusions or Janssen's, correct.
MR. KLINE: Actually his. I object to other than his. He is the witness.
THE COURT: Janssen or him.
Q What do the data show, Dr. Caers?
A The data show that there is no significant correlation between the occurrence of these type of adverse events and prolactin levels as seen during Risperdal treatment.
Q And what was the reason that the data showed that?
A The reason?
Q Yeah, what was the basis?
A The reason is that there is no correlation, obviously.
Q In terms of the elevation of prolactin and these events?
A Yes.

Q And, Dr. Caers, you were also asked a lot of questions about math, and I want to go back briefly to some of this math, if I could.
Dr. Caers, Mr. Kline went through this math issue with you pretty quickly and he was trying to suggest that there were --
MR. KLINE: Objection, Your Honor. Once again, it's improper.
THE COURT: That's sustained. Right now, just again, Mrs. Sullivan, where are you?
MS. SULLIVAN: This is Plaintiff's 28.
THE COURT: All right, thank you.
MS. SULLIVAN: And if we could put on the board as we look at this --
THE COURT: I mean, you can say it was suggested to you, but to personalize this all the time.
MS. SULLIVAN: Sure.
Q And, Dr. Caers, it was suggested to you that there were fewer patients in the long-term studies by Mr. Kline in his questioning, right?
A There were less than the 1885 that had long-term exposure.
Q Yeah, but we are going to look at the math,

Dr. Caers. If we can put up Defense Exhibit 58, it's been up before, a demonstrative. And I have another copy for you.

MR. KLINE: Thank you, it's much appreciated.

Q Dr. Caers, this 1885 that's in the 2006 label, was this all the kids on Risperdal, all the children on Risperdal?

A Yes, indeed.

MS. SULLIVAN: And if we could put this up, Ken.

Q Dr. Caers, why don't you tell us, when Mr. Kline was doing his math he included the placebo, the kids on the dummy pill in these numbers, didn't he?

A That?

Q If you look at NED-9, the actual number of patients on Risperdal is --

MR. KLINE: Your Honor, objection. Your Honor, this is just leading.

THE COURT: I don't know. What's the question?

Q Dr. Caers, the actual number of patients on Risperdal in NED-9 was 19?

A Yeah.

Q But Mr. Kline put 38 there, right?

A Yeah, apparently, yes.

Q That's wrong. That includes the placebo numbers, right?

A Yes.

Q And the same thing, he has inflated all of these numbers by including the placebo numbers, right?

A Yes, it looks like.

Q Yeah. So this is misleading and wrong math?

A Well, it's definitely not correct.

Q Not correct. Not correct. In fact, if you do the math correctly, you have a lot more patients on Risperdal in the long-term studies, correct?

A Yes.

Q If you do --

THE COURT: Excuse me, was there an objection?

MR. KLINE: You don't know it's wrong. How dare you?

MS. SULLIVAN: Take a look at the studies.

MR. KLINE: That's a chart. That's in

front of the jury.

MS. SULLIVAN: But it's misleading and it's wrong.

MR. KLINE: So you say. My word.

MS. SULLIVAN: My word.

THE COURT: (Gavel) Counsel, right now, what is the document that is up there?

MS. SULLIVAN: There is Plaintiff 28.

THE COURT: Plaintiff's 28? I thought it was 58.

MS. SULLIVAN: No Defense Exhibit 58 is on the screen, Your Honor.

THE COURT: This is P-28?

MS. SULLIVAN: Yes.

THE COURT: All right.

Q So, Dr. Caers, if --

THE COURT: I am going to caution you about leading. There was a leading question in there.

MS. SULLIVAN: Okay, I will rephrase it, Your Honor.

Q And, Dr. Caers, can we go through these numbers and accurately report, if we look at this table, the number of patients on Risperdal?

A Those are not the number of patients on Risperdal.

Q Right. These include the patients on Risperdal and the patients on placebo, right?

A They must be. Otherwise the figures should fit.

Q And if you do the math correctly, you end up with --

MR. KLINE: What is the math?

THE COURT: Is there an objection?

MR. KLINE: Yes. I made a mistake, then let's hear it.

THE COURT: I guess we will get to that, and then you can explain it for 15 minutes afterwards, but that's where we are right now.

Q So Dr. Caers --

MR. KLINE: It's always about somebody but Janssen, always.

THE COURT: Right now I am going to permit this as a redirect right now, and as long as we are not using leading questions, we are at P-28.

MS. SULLIVAN: Judge, I am just trying

to get the accurate math.

THE COURT: I don't know about accurate. That's your characterization. You have to get whatever you want from your witness and that's evidence.

Q Dr. Caers, the data is what it is, the numbers are what they are, right?

A That's usually the case, yes.

Q And so the total number of kids in the label were 1885, right?

A Something like that, yeah.

Q And if you add up the number of patients in the short-term studies, which you define as ten weeks or less, you minus 726?

MR. KLINE: Your Honor, this is all leading, for someone on direct.

THE COURT: Well, again, counsel, we are trying to get to the gist of the arithmetic argument in this case. I have no problem with re-writing it tomorrow.

Q Dr. Caers, if we do that, we get 1159 patients that were in long-term studies, no these low numbers, right?

A Yes, that sounds reasonable.

Q And if you do the math correctly, you got a lot more Risperdal patients that were in the long-term studies?

A Yes.

Q And then I want to talk briefly about the manuscripts that you were asked about?

A By the way, there is another add on of your chart, that's on the duration of the double-blind period in the INT-79. It's six months other than nine months, by the way. The double-blind period in INT-79, you said that is nine months. The duration of the total study is nine months, but the double-blind duration is up to six months. Just to let you know.

MR. KLINE: Okay, thank you.

Q Dr. Caers, I want to ask you about these manuscripts. Remember you were talking to Mr. Kline about these manuscripts related to the Findling study? And you had been saying earlier, you were talking about the fact that the Findling study was an exploratory study?

A And explorative analysis, yes.

Q And did you actually see that referred to in the manuscripts that were put up?

A Yes.

Q And I think it was suggested that in the manuscript you were copied on there was no reference to this SHAP(B) analysis. Remember?

A Not in the second version.

Q But let's take a look at that -- and can you just remind our jurors the reason the SHAP(B) analysis was done by Janssen?

A Because the pediatric endocrinologists, as I said earlier, advised us to do the differentiation because there were certain adverse events in SHAP(A) that they did not see to be related to prolactin and consequently should not be defined as a potentially prolactin-related adverse event.

Q And I am going to show you again, and I don't know if you have it up there, Dr. Caers, Plaintiff's Exhibit 38. You got it, okay. And I am going to show you -- and this was the manuscript you were copied on?

A Yes.

Q And if we turn to --

MR. KLINE: Do you have another copy?

MS. SULLIVAN: I don't have one that's not marked up. Ms. Brown has it.

Q Dr. Caers, do you have 38?

A I have 38, yes.

Q And, Dr. Caers, in the draft manuscript that you were provided, if we could turn to, on the bottom is 177, the Bates number?

A Okay.

Q And let's just put it up. You were copied on it, and this is the draft of the Pooled Prolactin Manuscript, which ultimately became the Findling article?

A Yes.

Q And if we turn to 177?

A Yes.

Q It talks about, The objective of this post-hoc analysis, and what is a post-hoc analysis?

A Once again, it's an analysis after the study has been completed and fully analyzed, but yet you do additional analysis, explorative to learn more from the data from the studies.

Q And there is a reference to this SHAP(B) issue in this section of the paper?

A (No response.)

Q Where it talks about --

A Your question is?

(Caers - Redirect)

Q Does it discuss the issue of puberty --

MR. KLINE: Your Honor, objection. She just wants to tell him something that's not in the paper, and to get his interpretation.

THE COURT: I don't really know. Isn't this the second page of P-38?

MR. KLINE: Yes. It says nothing about SHAP(B).

A Okay, okay, but conceptually, yes, because that's exactly what is written here in the last sentence. Because many of those children would have been going through puberty and symptoms associated with hyperprolactinemia, such as gynecomastia and menstrual disturbances, can also be seen with puberty. Possible associations with age and gender were also explored."

So that's exactly the whole SHAP(B) concept.

Q And if we could, Dr. Caers, also look at page 182, the Bates number, and this is the draft manuscript you were given?

A 118?

Q Yes, the Bates number ends in 182?

A Okay.

(Caers - Redirect)

Q And do you see where it says, "Upon consultation with pediatric endocrinologists," and who were they?

A Daneman and Moshang.

Q And it goes on to say, "Any adverse events under the following preferred terms were not included," and it goes onto list them, and it includes at the end, "Patients with less than one week of amenorrhea and males eight years of age or older and females with less than 31 days of gynecomastia were also excluded." And can you tell our jurors what that section is addressing?

A That is addressing the SHAP(B) definition where indeed this type of -- that type of events would be excluded.

Q And, Dr. Caers, the paper talks about that being done upon consultation with these outside endocrinologists?

A Yes.

Q And, Dr. Caers, in this draft manuscript you were given, can you tell us whether these outside endocrinologists wanted to include, at all, boys over eight?

MR. KLINE: Hearsay. Objection.

(Caers - Redirect)

THE COURT: As to their motive?

MR. KLINE: No, as to what they told him. They are not bringing them in. And they disavow the article.

MS. SULLIVAN: Objection, Your Honor, they did not.

MR. KLINE: They do, too. I have the documents.

MS. SULLIVAN: The running commentary from him is improper.

THE COURT: There is no time issue here. If this is going to be a very important area of this trial I have no problem with, you know, concluding this. I really need to have the evidence out.

MR. KLINE: We have a 15/15 agreement.

THE COURT: Fifteen is over.

MS. SULLIVAN: Your Honor, he went all day long.

THE COURT: Objection is overruled, go ahead.

Q Dr. Caers, can you answer the question?

A So those are the adverse events that were excluded from the SHAP(B) based on the advice of the

(Caers - Redirect)

endocrinologists.

Q And, Dr. Caers, can you tell us based on this manuscript and your involvement in this paper, whether the outside endocrinologists wanted to include the SHAP(A) events at all in terms of the boys over ten?

A They said SHAP(B) is the only real SHAP.

THE COURT: They said, they said. Is there an objection here?

MR. KLINE: Yes.

THE COURT: Sustained as to what "they said."

MR. KLINE: I just want it to be done.

THE COURT: I am not going to go into hearsay at this hour.

Q Dr. Caers, were you kept informed about this study, including being provided draft manuscripts?

A Well, I got at least the pre-final manuscript for approval, which eventually brings it to the final, because otherwise it would not have been submitted to a journal.

Q And, Dr. Caers, did you learn the position of these outside endocrinologists?

A Well, by reading such as this and the earlier

minutes of the meeting that we discussed earlier, yes. I knew about this position of the endocrinologists.

Q And, Dr. Caers, can you tell us whether the endocrinologists had final say as to what was in the paper?

A Oh, yes. Since they were authors, they all reviewed the final manuscript before it is submitted.

Q And, Dr. Caers, can you explain why these outside endocrinologists did not want to include boys over the age of eight?

MR. KLINE: Your Honor, objection. She just asked questions she knows are wrong.

THE COURT: It's sustained --

MR. KLINE: It's hearsay.

THE COURT: He can tell you why he acted the way he did.

MS. SULLIVAN: Fair enough.

Q Can you tell us, Dr. Cares, why Janssen did the SHAP(B) analysis excluding boys over the age of ten?

MR. KLINE: Objection, asked and answered four times.

THE COURT: Answer it again. You will have your chance in a couple of minutes.

A So that's because the endocrinologists advised us to do so.

MR. KLINE: Objection, hearsay.

THE COURT: All right. Anything further?

MS. SULLIVAN: Yes.

Q On Table 12 --

MR. KLINE: Contradicts the document.

THE COURT: I guess you will point that out then.

MR. KLINE: I did already.

THE COURT: Right now we are going to conclude.

MS. SULLIVAN: One more question, Your Honor.

BY MS. SULLIVAN:

Q On Table 21, that did include the boys over ten that Mr. Kline asked you about that showed that one 8- to 12-week finding. First, did that 8 to 12-week finding say anything about when the patients develop the SHAP --

THE COURT: Counsel, we are not going

that fast. What is the document we are looking at?

MS. SULLIVAN: It's going to be Table 21?

THE COURT: And where is that from? And also, while we are at it, that last document was P-38. What page was it that we were looking at?

MS. SULLIVAN: I am sorry, Your Honor's question was, the last page I was looking at, it ends in Bates number 182. And then Table 21, if I can find it, P-34(A).

Q Dr. Caers, you were asked about this Weeks 8 to 12 data, the one statistically significant finding after the many analysis run on this?

A Yes.

Q Does that 8 to 12-week data tell us anything about when the adverse event occurred, whether it occurred before the prolactin was elevated or after?

A No, it does not.

Q And why is that important in terms much how Janssen viewed the data?

MR. KLINE: Objection. He is not even a physician. And it's a opinion.

A That's basic --

THE COURT: Excuse me. Is this an expert? This goes back to what we discussed yesterday. Is this witness qualified as an expert in endocrinology?

MS. SULLIVAN: Your Honor, he has been talking about these tables for two days.

THE COURT: No, you asked him a question that involves a medical opinion, therefore, the question is sustained.

Q Dr. Caers, can you tell our jury why Table 21 wasn't given to FDA?

A Well, because obviously, this is not an analysis that was intended for the FDA because this is an explorative analysis, and the FDA had all those data available in the submission and even in the database and could do similar analysis.

But this analysis doesn't make sense for reasons I already described yesterday. I can repeat that but it probably doesn't make sense.

Q Dr. Caers, do you know that the FDA --

MR. KLINE: Objection. What does he know about the FDA.

MS. SULLIVAN: He objected before I

even asked the question.

THE COURT: Counsel, right now there is an objection, and the objection is actually sustained. You are bringing in a new name now. You are in overtime, maybe double overtime anyway.

Q Dr. Caers, you were asked a question about the issue of whether the company could warn about an off-label risk before it was FDA approved. Can you explain the reason the company didn't do that?

MR. KLINE: Your Honor, they had a day to explain that.

THE COURT: She has a couple more questions, so why don't you nail it down, and then we will give you 20 minutes.

MR. KLINE: She is just running out the clock.

MS. SULLIVAN: He is the one, I am not trying to. I am done.

THE COURT: We are coming in late tomorrow. We are coming in late.

MS. SULLIVAN: I am done. If you can just explain to our jurors.

A Because that would be seen as an attempt of

off-label promotion. Because if you inform physicians on whatever aspect of use of the product in a population for which the product is not approved, they just see it as off-label promotion, because you suggest that this might be an appropriate population to use this compound in.

Q And, Dr. Caers, is there any way the FDA would have permitted you to do that?

A I am pretty sure --

MR. KLINE: Objection. How would he know.

MS. SULLIVAN: I have nothing further, thank you, Dr. Caers.

MR. KLINE: I do. I have a bunch.

THE COURT: You have 20 minutes.

MR. KLINE: That's great.

- - -

RECROSS-EXAMINATION

BY MR. KLINE:

Q Stir, Table 21 was not given to the FDA?

A That's correct.

Q Wow.

MS. SULLIVAN: Your Honor, I object to

the commentary.

THE COURT: That's true.

MR. KLINE: We have requests for admissions that they wouldn't --

THE COURT: Counsel, Table 21 was not given.

MR. KLINE: Okay, I will behave myself. Your Honor, and members of the jury, I apologize for being so frustrated. I hope, I hope, that I didn't overstate my bounds and my welcome, I am sorry.

Q I have some questions, sir, for you. Some serious questions for you.

The FDA is supposed to get all the data, and you are not supposed to decide what they get and what they don't get?

MS. SULLIVAN: Objection, Your Honor, there is no reason for the yelling.

A They have had all those data.

Q They did not get Table 21, correct?

A This Table 21 is not data. That's an analysis.

Q Sir, that's your interpretation. It's up to the FDA, who gets all the data, to make that

interpretation?

A All the data, all the data we have been discussing, are and have been with the FDA since we submitted this as an NDA, and all those data on an annual basis were shared with the FDA in the annual safety update, which is a requirement still ongoing today.

Q To this day, sitting here today, you did not submit Table 21 to the FDA, yes or no?

A That is correct.

Q Now, sir, what you told the FDA -- I need a document, it's going to take me a minute.

MR. KLINE: Let's show DG10-8 in the meantime. Can we display DG6-3.

Q Sir, short-term studies, first of all, when I examined you as a witness, and if I put up the placebos and the others I didn't intend to do so, neither you nor I caught that at the time. Correct?

A I don't know but --

Q These figures were sitting in front of you as well as me, correct?

A Say again?

Q Those figures were up in front of the jury at the time we were doing our chart?

even asked the question.

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Q These figures were sitting in front of you as well as me, correct?

A Say again?

Q Those figures were up in front of the jury at the time we were doing our chart?

(Caers - Recross)

A That, I am not sure.

MS. SULLIVAN: Objection, it's a different chart.

THE COURT: All right, let's get to it, though, counsel, please.

Q I would like to try to figure out with you, quickly if we can, if we can, the long-term and the short-term studies, let's take the time with the math. If I made a mistake, I am human.

It seems to me that what we have is in short-term versus long-term, that's all I was trying to get to, the number of short-term and long-term. Do you have a calculator?

Of the 1885, how many were in short-term, how many were in long-term? That's all I was trying to do. Do you know?

A I am sorry?

Q Of the 1885, how many were short-term, how many were long-term?

A I would need to calculate that.

Q It's addition, sir.

THE COURT: He said he would need a calculator.

MR. KLINE: I have a calculator.

(Caers - Recross)

THE COURT: It was ten weeks or less, something like that.

THE WITNESS: That doesn't make sense.

MR. KLINE: Pardon me?

Q What do I need to know, sir, other than the numbers? And we eliminated BIM-301, 302, and USA-231 and 234, correct?

A Yes.

Q Maybe we can have an agreement, so everybody doesn't have to stand and watch us, is add the ones that are over ten weeks and those will be long-term, and the ones under will be short-term? Correct? Would that be correct conceptually?

A (No response.)

Q Okay, here. INT-41 is 504. The next one down is 97, it's 107. That's 611. The next one is one year at 77. The next one is the two-year one, the Hungary study, it's 35. The next one is the INT-70, it's 48. Although I think you told -- well, you don't count them double, it all gets confusing.

And the incident INT-84 is 232. That's it. 1,003 long-term.

So my new chart, and I do apologize for getting something wrong, you got 1885 minus 1003.

(Caers - Recross)

Do you see anything I have done wrong, sir? If you have, please tell me.

THE COURT: Do you have a calculator? I know it's basic arithmetic, this is sixth grade for me.

A You are never going to be able to reconstitute this 1885 patients based on this table because this gives the total number of patients that were studied in each individual study and doesn't correct for double counting.

Q Right, so we can't --

A I am just making the calculation. Also, in the final review for the autism approval, the INT-84 was included so I counted it out at 2004. So that's a double calculation. You will never succeed in identifying from this table.

But the most important thing is the FDA asked for 100 patients, at least 100 patients for a year, and they ask for at least 350 patients for six months, and they asked for 1500 patients in total. We overdid this number largely on all the three requirements.

Q Sir, the thing that's important, correct me if I am wrong, is in the label it says 1885 and we were

(Caers - Recross)

having a discussion -- hear me out, it's very late, and nothing to do with what you just said, respectfully -- 1885 patients, there were 1885 patients, and all I was trying to figure out was how many were long-term and how many were short-term. And here is what I would like to ask you the question, rather than a treatise, here is what I would like as an answer: Can you give us a ballpark, if not maybe I can reach a stipulation with counsel, as to how many of the 1885 were long-term or short-term? That's all I want to try to do, ballpark.

A I cannot do that, base --

Q Okay, then we will not do it today. I will move on. I have one or two more things.

A It wouldn't be right.

Q So based on whether I am right or you are right or that table is wrong, you can't do it sitting here today, correct?

A Not based on this table, that's correct.

Q Now, Table 20 -- I have one more point -- Table 20, sir. In Table 20, if we put it up real quickly, Table 20 -- I promise everybody I will be done.

I just want to have an understanding of what that this means, sir, not a discussion of statistically significance, nothing anything else, I just want to know what this means statistically.

When you have nine versus, which is 3.5 percent, versus three at 1.2 percent, nine with elevated prolactin, three with not elevated prolactin. And they say that it's a statistically significant finding or not. Let's not talk about statistical significance. Let's only talk about what the number .0992 means.

Now as I understand it, sir -- and we can be done if we agree on this -- as I understand it, that means that you are 90 percent, actually 90.1 percent, confident that the answer that is up there is not by chance. That's what it means?

I don't need a treatise on the other stuff, I just need to know if that's what it means?

A I would say it a little bit different, but that's what it means.

Q Yes, you might say it different, but you can agree it's close enough from a layperson?

A That is correct.

Q Yes. So we know that as to this finding, we

are 90 percent certain, it may not be 98 percent, or 95 percent, but we are 90 percent certain of this particular association. Correct?

A The likelihood that this is correct is 90 percent.

Q That's my question, thank you, sir, I am done.

THE COURT: Okay. Dr. Caers, you are excused. I don't know whether you are going back to Belgium today or tomorrow or any time soon, but safe travels.

THE WITNESS: Thank you.

(The witness is excused.)

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THE COURT: All right, ladies and gentlemen, we are going to adjourn now until tomorrow at 10 o'clock. I think there are some legal issues that we may have to address either now or early morning tomorrow. So we will call it 10 o'clock tomorrow.

As I understand it, we are going to have a videotape presentation by the defense, and I think that we are going to try to make the 3 o'clock so one of our jurors can attend something involved with her school.

So that's the plan as we speak now. So please come in so we can start around 10 o'clock. I appreciate it.

Wear the yellow badges, make sure you do not discuss it with each other, please keep an open mind, and do not conduct any investigation or ignore any accounts of this case, if there are any, in any media, social media, newspapers, radio, TV, you name it, ignore it. Okay? All right, thank you.

(The jury is excused at 5:05 p.m. and the following transpired in open court:)

THE COURT: I just want to know what is the nature of what -- what we need to do in order to clear the way for an unobstructed viewing of the depositions. Will I might be able to do that tomorrow morning or what? I am involved in a Inn of Court meeting today which has begun. So I just want to know what exactly we have to do.

MS. SULLIVAN: I think you can do it in the morning, Your Honor. We have two treater depositions, which I think there are some objections to, but I don't think it should be

a big issue. And then we would like to play a short clip from Dr. Mathisen on this off-label issue that we talked about yesterday, and we would like to read one or two questions and answers from Mrs. Pledger's deposition.

THE COURT: I do recall now that the issue of Dr. Mathisen was one of some dispute. I want to know whether we have reached an agreement on that?

MR. KLINE: No, Your Honor. The issue, the way I see it, is Dr. Mathisen was here in the courtroom, the Court made rulings as to what's admissible and what's not admissible. Ms. Sullivan's view of the world is that if she gets another crack at it she may get another ruling. Whatever the Court said was admissible or not admissible at the time is what the ruling was. They had every right to fully cross-examine Dr. Mathisen, which they did. Now they want to introduce deposition testimony, that would require counter designation, because they only want to play a snippet --

THE COURT: When you say counter

designation, what do you mean? Like another part of the deposition?

MR. KLINE: Yes.

THE COURT: Is that a real burden?

MR. KLINE: Is it a real burden? In my view it is. And furthermore, there is no reason why -- her argument, as I understand it, is the Court wouldn't allow me to ask a question of Dr. Mathisen so --

THE COURT: Let's go on the record what the question is. I think I remember. The question has to do with whether it was marketed and I am going to put on the record why the objection was sustained.

The reason the objection was sustained, if you recall, and I probably explained it on the record though I haven't checked it myself, but the reason that objection was sustained was because of the vague nature of the term "marketing," coming from a doctor of pediatric neurology, and his characterization of marketing was in fact a vague and potentially confusing statement in correlation with all the very precise terminology we are nuancing

in this case. And that is the reason why the question about marketing at trial was sustained.

MS. SULLIVAN: And, Your Honor, I can hand up the question and answer. It actually didn't have the word "marketing" in it. It was clear from the testimony that Dr. Mathisen knew the difference between FDA-approved uses and off-label uses, and the question I wanted to ask is:

"Q And you know when they met with you they followed the rules in terms of not talking to you about off-label uses?"

There was an objection and Your Honor sustained it?

MR. KLINE: How would he know? How would he possibly know what they knew?

THE COURT: It's in the similar vein. That gets into the question of what are the FDA rules and whether a clinical neurologist who is qualified for something else is, you know, able to give that answer. How does he really know what the FDA -- you have that, as far as I can remember, repeatedly from

Mr. Gilbreath.

MS. SULLIVAN: Your Honor, the testimony didn't relate to FDA rules. It's just did they talk to you about off-label uses. That was the only question. Did the sales rep talk to you about off-label uses. That was the only question.

THE COURT: I am sure there is a counter designation to that.

MR. KLINE: That is not the question that she wants to read. The question is, you knew they were following the rules.

THE COURT: Counsel, I have to go to Inn of Courts today. What day was this, and I will get the transcript and look at it.

MS. SULLIVAN: Your Honor, this is Dr. Mathisen's testimony, and the date is the -- Your Honor, I can hand this up. The reason it was so important, Your Honor --

MS. BROWN: Was January 26, Your Honor.

MS. SULLIVAN: The reason this is so important is because after Dr. Mathisen left the stand they made a big deal with the sales rep about not discussing with the doctor the

risks in children and that we pushed samples, and this concept of off-label promotion. And so it's directly relevant that the prescriber will say I was not talked to, I was not promoted to off-label.

I think that's fair defense evidence, Judge, and it doesn't get into regulations, it's just did they talk to you about off-label uses, and the doctor says no.

MR. KLINE: Here is the problem with it. That would require a knowledge base of a physician, a pediatric neurologist in Alabama to know what off-label marketing was.

THE COURT: Let me just see, where is this whole area here? Where is this?

MR. KLINE: 153, line 18. To 154, line 23. Including the question, "So Austin's prescription was for an off-label use." Well, how in the world would he know.

MS. SULLIVAN: That's not the question, counsel, the question I am referring to the Court to is on page 107, line 13 through 17.

THE COURT: What is this, 107?

MR. KLINE: That's not even among your

designations.

MS. SULLIVAN: No, this is at trial.

THE COURT: Mr. Kline, we will resolve this one way or the other.

MS. SULLIVAN: This is from the trial. And this is the deposition, the Q and A we want to play.

MR. KLINE: It's just the Q and A they want to play. They never told me even what it is.

MS. SULLIVAN: We gave it to you.

THE COURT: I have to see whether or not I precluded incorrectly a question that is relevant. And I want to check that. And we will proceed accordingly. Page 107, line 13.

MR. KLINE: May I, Your Honor? Listen to this question: "And you know," she says to a doctor, "when they met with you that they followed the rules in terms of not talking to you about off-label use?"

Well, how would he know that they followed the rules or didn't. The truth is they didn't. But it says here -- the Judge said sustained.

THE COURT: I don't see any error there. I just don't.

MS. SULLIVAN: And, Your Honor, if you would look at the deposition cut we want to play, it just talks about what the sales reps talked to him about.

MR. KLINE: No, it's much more malignant than that.

THE COURT: The deposition?

MS. SULLIVAN: Yes, and I just handed it up, Your Honor, it's on page 157, line four to 157, line 17.

MR. KLINE: Right, none of which they were precluded from asking had they wanted to ask him.

MS. SULLIVAN: And that's directly relevant, Your Honor, I would submit, in this case that the doctor was never talked to off-label, given the inference that Mr. Kline tried to draw from the sales rep that we were promoting to him off-label.

And it's also our case, Your Honor, it's a witness out of our control, out of the subpoena power.

THE COURT: We are not going to get there. You did have the opportunity to ask all of those questions there on page 153, for strategic reasons, obviously, you chose not to. I am not going to allow that at this point. The choices were made. The particular question that was asked that you were reviewing, I stand by that. "And you know when they met with you they followed the rules in terms of not talking to you about off-label uses?" How does he know. He is not an expert, he doesn't know what the rules are. As far as I am concerned, the point was made, though, through Dr. Mathisen, you have plenty to argue, that he knew it was an off-label drug. That's for sure. He testified to that for sure.

Anything else? I mean, after all, if you wanted all of that information, Ms. Sullivan, we are all trial lawyers here, you would have asked that stuff, because after all, he was the largest administrator of Risperdal in Alabama, he said.

MS. SULLIVAN: Well, Your Honor, I

tried to and there was an objection and it was sustained.

THE COURT: I stand by that particular ruling. Anything else?

MR. MURPHY: Your Honor, we have the cuts from the depositions of Dr. Paoletti and Dr. Dy that we can hand up to you for Your Honor's review. I think they include both what we propose to play and what Plaintiff proposes to play and the counters.

THE COURT: Is there any dispute about any of this?

MR. KLINE: Of course, there is. There is a dispute on nearly everything. As I understand it -- there is a easy one to start, I know you are trying to get out of here, Your Honor, there is a easy one to start, which is as I understand it, or I overheard in the hallway and I just would like it resolved. We have counter designations, we would except their designations and our counter designations to be played. We have been told no -- oh, now they agree. Now that we are in front of the Judge. So we don't have that.

(Caers - Recross)

THE COURT: So you will play them?

MR. MURPHY: Yes, we will play them. The only issue is there are some objections.

THE COURT: How many of them are there? How many of the objections are there? We may as well resolve it and make life easier for the videographer. Do you want to do that?

MR. KLINE: We both have objections on both sides.

MR. MURPHY: Your Honor, what we could do to make it simple for you, we can hand this up to you. I think this reflects what our points of departure are, and we can address them in the morning.

THE COURT: How many are there?

MR. MURPHY: There are not many.

THE COURT: Then let's go through them. I wasn't going to have a cocktail anyway, so that's okay. I probably need one.

MR. MURPHY: Your Honor, we are going to have to raise this with you tomorrow.

THE COURT: All right, let's be here at 9:30 and we will get it done. As long as I understand from the technical point of view,

(Caers - Recross)

any corrections can be made by the technical staff before we run these tapes tomorrow.

MR. MURPHY: That's correct, it's just the cutting.

THE COURT: We can do that?

MR. MURPHY: Correct.

THE COURT: All right, have a good night.

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(Hearing is adjourned at 5:20 p.m.)

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(Caers - Recross)

I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN THE NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE CAUSE, AND THAT THIS COPY IS A CORRECT TRANSCRIPT OF THE SAME.

JUDITH ANN ROMANO, RPR-CM-CRR
OFFICIAL COURT REPORTER
COURT OF COMMON PLEAS
PHILADELPHIA COUNTY