IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: RISPERDAL® LITIGATION March Term, 2010, No. 296	:	
PHILLIP PLEDGER, by BENITA PLEDGER, as Guardian of his Person and Conservator of his Estate, Plaintiffs,	:	APRIL TERM 2012
v.	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, and Janssen Pharmaceutical Research and Development, L.L.C. Defendants	:	NO. 01997

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WEDNESDAY, JANUARY 28, 2015

VOLUME III
MORNING SESSION

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COURTROOM 425
CITY HALL
PHILADELPHIA, PENNSYLVANIA

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B E F O R E: THE HONORABLE RAMI I. DJERASSI, J.,
and a Jury

- - -

REPORTED BY:
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(Pledger v Janssen, et al.)

I N D E X

(Pledger v Janssen, et al.)

(Hearing is reconvened at 9:45 a.m. with all parties present.)

THE COURT: Good morning, everybody. We had a nice slow day yesterday, real slow.

We are still waiting for one of the jurors, so I thought that I would like to go over now the evidentiary procedure -- is Dr. Kessler testifying today?

MR. KLINE: Yes.

THE COURT: I would like to go over the evidentiary procedure and any evidentiary issues that may arise that we may address now rather than delay the actual testimony.

MS. SULLIVAN: Yes, Your Honor, thank you. Actually, two issues, Your Honor. One relates to the end of the day testimony on Friday. Dr. Mathisen talked about the fact when he saw the 2006 label it didn't have a black box, that's why he really didn't pay attention to it. And I would ask the Court for instructions on that for two reasons.

One, it's clear, and I think even the plaintiffs would stipulate, a manufacturer cannot add a black box, only the FDA can.

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Also, Mr. Kline made clear at the beginning of this case, black box is not part of this case.

And second, Your Honor, it raises the issue of the citizen's petition, where the FDA concluded that a black box is not appropriate here.

So I would ask the Court to give the jurors an instruction that they should disregard Dr. Mathisen's testimony about any black box, a manufacturer cannot voluntarily add a black box warning.

THE COURT: I am not going to do that, counsel, that's a matter of evidence. You put on the evidence through the cross examination of Dr. Kessler or through your own witnesses, and the issue of what should have been or what should have not been on a black box will be in evidence. At that point you proved the point and we can look at what kind of jury instructions are necessary at that time.

MS. SULLIVAN: Fair enough, Your Honor. The second relates to the exhibits we got last night on Dr. Kessler. There are two categories, Judge, and one category we do not

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have an issue with. Dr. Kessler is a regulatory expert, so the things that the FDA would have seen in terms of clinical study reports, documents regarding adverse events, study data internally that maybe the FDA didn't get, but study data, the kind of things that a regulatory expert can opine on as it relates to the regulations, we don't have a problem with.

What we do have a problem with is the Plaintiff using Dr. Kessler as a mouthpiece for all the company E-mails, business plans, other documents that have nothing to do with a regulatory expert's opinions. They have company witnesses they can use to get some of this in.

Also, there is a lot of stuff in here about drafts of manuscripts of the Findling article. This doctor, the testimony is clear he has never seen the Findling article, there is no evidence he has ever seen the Findling article. I don't mind him showing Dr. Kessler the data from the Findling article, but all these E-mails about draft manuscripts that the

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testifying prescriber never saw. And Dr. Kessler is not an expert in manuscript drafting or what should be in articles, he is a regulatory expert.

So I have no problems with the study data, I do have a problem with all this internal E-mail, draft manuscripts, that are untethered, Your Honor, in this case, not tied to the prescriber.

Also, Your Honor, again, the core of Dr. Kessler's warning opinion is that the Regulations require that any serious hazard be in the Warnings section of the label, and, Your Honor, again, that is a matter governed by FDA, and the FDA has concluded that Dr. Kessler is wrong on that issue. And I would like, if the Court is not going to exclude that opinion, and we have a brief coming to the Court on that issue, I would like to be able to cross-examine him on the FDA's conclusion that gynecomastia does not constitute a serious adverse event under the Regulatory definitions in this case. I think that's fair cross if he is going to come in

and say it, that the FDA disagrees with him.

THE COURT: Well, before we have a response, let me just, so we can address it to what the concerns are that I have. We have ruled preliminarily that many of the documents that the doctor might have relied on are inadmissible to be admitted just because they were relied on by the doctor. However, obviously, they are admissible for other purposes if they are admissible.

So the procedure that I want to go through now is exactly what are the documents that are going to be admitted through other witnesses in this case that properly can, in the interest of judicial economy, be used, rather than having Dr. Kessler called back if necessary.

So I really need to straighten out those evidentiary issues. That's the first thing.

The second thing is in order to understand these evidentiary issues, I really do need to understand what exactly is Dr. Kessler's opinion.

I have looked at the report, it's not clear to me exactly what is the core opinion of Dr. Kessler as relevant to the issues in this case.

So why don't we address that first issue first, and then all the other types of evidentiary issues are going to be related to that core opinion.

MR. KLINE: I am pleased to do so, Your Honor, good morning.

THE COURT: Good morning.

MR. KLINE: I haven't had a chance to say anything, but that's my official good morning.

Your Honor, I have, knowing the Court's rulings, knowing the pretrial rulings of Judge New, and knowing the restriction of this case as a failure-to-warn case -- Your Honor, I can explain this very directly, I believe.

The case is limited to a failure to warn case. By the way, nearly everything Ms. Sullivan says, nearly always, is some adversarial position, not kind of a neutral statement.

MS. SULLIVAN: Your Honor, that's not necessary.

THE COURT: Counsel, we are going to be in here for a long haul, it looks like. Obviously, I respect both of you, I trust at this point you are respecting each other. So let's not get into all of that. We don't need the personal back and forth.

MR. KLINE: It wasn't personal, it was a statement, it was an observation, respectfully.

And what we have here, and what I have been saying ever since I walked in the courtroom is that I intend to try a very simple, direct case, in the most efficient possible manner. If I am allowed to just do it, put in the documents that I am going to tell the Court about, put them in through Dr. Kessler -- and by the way, not those marketing documents, I know what you said about them -- but documents he reviewed. Then I will be able to put him on, I will be able to put my causation expert on, I am be able to put my mom on, I will be able to call their sales

rep, and but for some pieces here and there, I will be able to rest my case.

Alternatively, we have an alternative which they invite, which is a free-for-all, and the free-for-all is I am not allowed to simply put on the direct expert, like we have been doing in cases forever, with experts that review documents, render opinions and are cross-examined.

Now in this case, she tries to put the rabbit in the hat. There is always something that is just not the case. And this is what's not the case: He is not a "regulatory expert." Yes, he is an expert in regulation, yes, he is that, but for purposes of this case, he is an expert in pharmaceuticals, in the overall pharmaceutical industry as it relates to prescription drugs. Therefore, he is here and his report says so.

While his report, Your Honor, says many other things which were in the case before Judge New's rulings -- which, by the way, we are going to take up on appeal and we will see if some day we are able to litigate those

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issues. But for now, in front of Your Honor, what we have is a failure to warn case.

He rendered an opinion in his report which I am going to ask him, frankly, I plan to ask him up front, like I almost always do with an expert, and then get all of his opinions: Do you have an opinion with reasonable certainty as to whether they failed to warn.

That's the case.

MS. SULLIVAN: That's an ultimate opinion. It's not proper.

MR. KLINE: See, there we go. Your Honor, we are allowed -- if I may finish, if I may finish my presentation.

THE COURT: Yes. We are in no hurry, the juror is not even here yet. We don't expect a snowstorm, a false report on a snowstorm any time soon, hopefully.

MR. KLINE: Next time we will have 20 inches and they will open the place.

Of course, he can render an ultimate opinion because that's the purpose of an expert, to guide the jury on whether -- with

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his enormous background, they don't like him but that's not the issue.

MS. SULLIVAN: Never met him.

MR. KLINE: Well, the things you said to the jury were, frankly, outrageous, and we are going to cover those, because she says all kinds of things which are not true. Like yesterday --

MS. SULLIVAN: Your Honor, here we go, the snide comments, the personal attacks.

MR. KLINE: Yesterday with the doctor getting "extra warnings", she said to the jury, the doctor got "extra warnings."

THE COURT: Let me tell how saw I see the case, because honestly --

MR. KLINE: May I please tell the Court what I plan to do?

THE COURT: Absolutely.

MR. KLINE: I plan to ask Dr. Kessler, either in the beginning or the end, probably up front, here is the basis of his opinion: Have you reviewed -- there are literally, I was told last night, how many millions of documents that were produced? Three million

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documents I was told were produced. This thing has been culled down. He reviewed thousands and thousands of documents of which they include internal E-mails, they include study reports, they included published medical literature, they include everything.

There is a story that he now knows. I am going to ask him, Your Honor, I am going to go through with him. I have hopefully become -- meticulously may be an overstatement, but I am very prepared. I have a tabbed binder, by the way, it has 30 tabs of documents, some are full and I am going to refer to one page. I plan to efficiently go through the documents, many of which they don't like because they are very, very unkind to this company. And I am going to ask him has he reviewed the documents. Here is what he is going to tell us in a nutshell:

I reviewed the study reports, I reviewed the internal E-mails of the company, I reviewed the drafts of the key data that shows that there is gynecomastia, and, frankly, Your Honor is going to learn a story

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which is flabbergasting, now they knew that it increased the risk of gynecomastia and how they tried to write it out of a study, how they tried to massage the language and the data. And that was negligent failure to warn, because they didn't tell this doctor 20 times.

THE COURT: Mr. Kline, I am going to tell you, I do understand your theory of the case, I am going to put it on the record, all of it, I understand your theory --

MR. KLINE: In terms of what I am going to do, I will simply march through documents upon which he relied to form his ultimate opinion.

THE COURT: Well, that's the question. That's the question, is whether you need to march through documents and what documents of those are admissible. Because the Rules of Evidence, as both of you well know, is, you know, one can offer an opinion based on inadmissible evidence and that's okay. So a lot of it has to do with, okay, study reports, E-mails, you know, what's admissible, let's go over it, and we will all know ahead of time

what the game is.

Because from my point of view, if the E-mails, for example, are ultimately admissible, then they are going to get in ultimately anyway or I will order Dr. Kessler to come back.

So it doesn't really matter to me, it really has to do with what's admissible and what's not, and from that point of view, well, the chips fall where they fall. And again, ultimately, because none of us are rookies here, Ms. Sullivan, you went to University of Pennsylvania law. The Rules of Evidence says an opinion is not objectionable just because it embraces an ultimate issue. So I don't really need to hear all of this side flack.

MS. SULLIVAN: Your Honor, the issue is Dr. Kessler instructing the jury on the law.

THE COURT: Well, I say to you that I am going to determine the law, and we have got the books in front of us, and I have experience myself. I just don't need that kind of side flack on what the law is. Okay? And, you know, kind of bickering and

snippering about stuff that is well settled.

What's well settled is the basis of an opinion for an expert can be based even if the stuff is inadmissible. However, if it's admissible, it can be shown to the jury or read into the record during the witness' testimony. We all know that.

So therefore, the issue is what specific documents are objectionable because they are inadmissible and should not be raised or referred to by Mr. Kline in his direct examination of Dr. Kessler.

MS. SULLIVAN: And, Your Honor, here is the issue. Some of them are the business plans that Your Honor has already ruled on.

THE COURT: Let's see them.

MR. KLINE: I don't plan to use the business plans.

THE COURT: We are already determined that the business plans -- I only saw -- where are those documents so the record is clear? We had marked those. They are all subject to review. So let's have those things marked once and for all.

MS. SULLIVAN: Your Honor, this morning from the plaintiffs we got a more limited set of documents and it included all of these business plans. So Mr. Kline says he is not using them but he told us this morning he was. So I am raising it.

THE COURT: They don't need to be marked, if they are going to be marked we are going to follow old-school procedure with this witness and if necessary we will go through document by document. I am trying to save time for all of us by narrowing the objections before the jury comes out.

MS. SULLIVAN: I appreciate that, Your Honor. The other relates to internal company E-mails, which shouldn't come in through this witness, and actually, there is case law specifically relating to Dr. Kessler, that he shouldn't be able to give plaintiff's closing argument where they just dump in every piece of evidence in the case, whether he has ever seen it before, he was hired by the plaintiffs, whether it's proper foundation for an expert. So what they want to do is put in

all the company E-mails through Dr. Kessler.

THE COURT: Are they admissible or not? In other words, is Mr. Kline able to have these things admitted as a business record or as some other exception out there or through direct testimony? If they are admissible, they are going to come in, Ms. Sullivan, it's as simple as that.

MS. SULLIVAN: Your Honor, many should not be admissible.

THE COURT: Let's see them.

MS. SULLIVAN: So here is the issue, Your Honor. There is two issues related to the Findling study. One is the data. No problem, that should be in the case.

The other relates to drafts of this manuscript relating to a study the prescribing doctor never saw. And I submit they can't tie that to this prescriber in any way.

THE COURT: That's not E-mails.

MS. SULLIVAN: It's E-mails talking about the manuscripts.

MR. KLINE: Your Honor, that doesn't have to do with this physician.

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THE COURT: Why don't we do it this way. Do you have specific documents that you know you intend to show?

MR. KLINE: Sure.

THE COURT: Let's see them. Let's go through them one by one.

MS. SULLIVAN: Your Honor, there should be some foundation.

THE COURT: We are going to see what these documents are, because I think it will be saving time ultimately if we don't have to do these one by one in front of the jury.

MR. KLINE: Your Honor, respectfully, number one, you will get better context. Number two, I think we can go through it in ten minutes.

THE COURT: Let me tell you about the context. I think I understand the theory of the case and I am going to state it on the record.

As I understand the case now after opening arguments and first witness, the theory of the Plaintiff's case is that there was a knowledge that was known to the drug

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company about the proclivity to cause gynecomastia that was known since 2002, or sometime before the 2006 label, and that that particular knowledge was not made known to prescribing doctors, off-label prescribing doctors, that they should have known that and they should have been told, and as a result, the doctors were not in a position to properly counsel treating parents of patients, and as a result, the treating patient was unable to make an informed decision, in fact, an informed consent decision. And as a result of that, there was some damage caused.

Did I get it right?

MR. KLINE: Your Honor, I should go home.

THE COURT: Exactly. So I understand what your theory is. I just need to see the documents ahead of time.

MR. KLINE: I have a binder of documents that go right to that, and I am going to hand them to the Court. It's what I am going to prepare with him, as you would expect.

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THE COURT: So all of these, you intend to show each one of these, and for the record, there are about a thousand pages here --

MR. KLINE: No, for context they are there. There are essentially 25 kind of modules, if you will. Some of those documents I have one page. I know that if I put one page in there, I know what's going to happen. Someone is going to say, you don't have the full document.

So I can go through -- I can walk you through my case. I shouldn't have to, by the way.

THE COURT: Let me find out, procedurally -- I mean if the way to go is to have other witnesses come in to authenticate these documents, if that's what you want, I can admit these conditionally to that particular proof.

MS. SULLIVAN: Your Honor, many of them, we submit, shouldn't come in through any witness, they are clearly objectionable, including the business plans Your Honor outlined and draft manuscripts --

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MR. KLINE: I don't have any business plans.

MS. SULLIVAN: -- and these draft E-mails on a study this prescriber never saw. Your Honor made clear this is a limited case, and they want to dump in all of this evidence that has nothing to do with this doctor. He made clear he didn't see the Findling article, so what do these draft manuscripts have to do with this case.

The data they can show, they knew the data, sure. But what they are saying about draft manuscripts of the study the prescriber never saw is prejudicial and has nothing to do with this case.

THE COURT: Let me ask you this. If Dr. Kessler were not testifying and you wanted to show circumstantially to the jury, this is a strong circumstantial case of covering up some information, how would you do that?

MR. KLINE: I would do one of a number of things. First of all, this is an interesting case. The CEO of the company, whose name is Gorsky, who by the way was

involved in all the issues down in the Federal courthouse about this drug, he has knowledge, and he is sitting in the jurisdiction. They have a lot of people up in Spring Mill in Pennsylvania, who we can bring down here. They have a lady in the court who is a current person. I can take another day or two. Get me a corporate representative and I will cross-examine her for two days.

THE COURT: That's the point. I think it's admissible because the witnesses are available.

MR. KLINE: Your Honor, the other thing is the development of the case involves reviewing E-mails. I will tell you right now. Everything I said to the jury is correct and everything is based on E-mails, including the words that I used. Of course, those E-mails are direct, they are authentic business documents.

And by the way, we examined these people, and if I wanted to play a boring case I could designate all of that deposition testimony, we would sit here and snooze for

two weeks listening to it. We would all snooze around and everybody would be happier.

THE COURT: I would not be.

MR. KLINE: I know that. And neither would I. And what I --

THE COURT: I don't think Ms. Sullivan would really be happy if we had to formally authenticate each one of these documents.

MR. KLINE: Just responding to Ms. Sullivan, as to this Findling article, it's very interesting. We discussed it previously, the Court ruled. There is no ruling that doesn't get like re-brought up ten times.

MS. SULLIVAN: This is a different issue here, this is drafts.

MR. KLINE: It's the same issue.

MS. SULLIVAN: It's a different issue.

MR. KLINE: Okay, it's the same issue. It's such a pleasure to be here today.

MS. SULLIVAN: Here he goes, with the snide comments.

MR. KLINE: I just said it's a pleasure to be here today. And here is the problem.

They had information, and it has nothing to do with whether it went to this doctor, it had to do with their knowledge in the company that they didn't tell this doctor. And they don't like it.

THE COURT: I understand it, I really do, but as far as your concerns are, if something is inadmissible ultimately it will be precluded. Give me an example of something you think should not be admitted during Dr. Kessler's testimony. Give me one document. Let's look at it.

MS. SULLIVAN: Sure, Your Honor. For example, and I think Your Honor has already ruled on the business plans. Dr. Kessler is not a mind-reading expert, so to put all these company E-mails in and have him say, I believe the company is saying this, knew this, and that's my opinion in this case, interpreting E-mails --

THE COURT: As far as I heard so far, the proffer is that he is going -- is Dr. Kessler in the room, by the way?

MR. KLINE: Yes, he is.

THE COURT: I am going to ask that he step out at this point.

MS. SULLIVAN: Your Honor, it also goes to the punitive issues --

THE COURT: One second, please.

(Dr. Kessler exits the courtroom.)

MS. SULLIVAN: And, Judge, we are just trying to make sure we get a fair trial here. There is no punitive claim, there is no fraud claim. He is going to get up there and say, they intended, they were motivated to hide, whatever; it has nothing to do with the issues in this case, notice and failure to warn.

He can say, I see this data and under the Regulations I believe they had a duty to warn, if Your Honor permits that legal opinion. But to say, this is what they intended and were motivated to hide, about draft transcripts and that the prescriber never saw the article, it's prejudicial, there is no punitive claim, there is no fraud claim. And Dr. Kessler has been known in other cases, and there is law on this, to just go hog wild about corporate intent and motivation. A

dangerous witness in a case where there is clear there is no punitives and fraud claim.

We are just trying to get a fair trial here, Your Honor, and have some basic evidentiary rules. He shouldn't be the E-mail reading expert.

MR. KLINE: Let's not start to talk about what other people have done in other courtrooms.

THE COURT: In this age in transparency, everybody's views with courts and others is well-known in the general literature. It doesn't really matter. We are in a new courtroom here. As far as I'm concerned, I am interested in a fair trial. I do understand your theory of the case. I also do know that fraud and intentional conduct is not in the case.

MR. KLINE: Your Honor, I said in the beginning in response, respectfully, to the Court, and I have just repeated to a barrage from my learned opponent, and the barrage has been, He is going to do this, he is going to do that, he is going to do the other thing.

Does the Court believe, knowing that I have been in this courthouse for 37 years, that I am going to come and I am going to elicit testimony that has to do with pejorative terminology about this.

I am going to ask him questions that relate to, for the proof that I have in the case, and she would like to just knock the documents out.

THE COURT: I understand all of that. I think all she is trying to do is get me alerted to any potential of that.

MR. KLINE: I would like to alert the Court to a potential, too.

THE COURT: All right.

MR. KLINE: This is the kind of thing that goes on. She is not an alertive potential, that I can tell you. Here is what is going on. She said in her opening speech -- this is something I have the documents for -- she said in her opening speech something about Dr. Kessler that's just not true, and that she can't prove. She can't previous it because under Pennsylvania law.

The case law says that she is allowed to cross-examine him, and I have the cases to give to the Court -- I have them tabbed for everybody because they are kind of basic -- and the case law says that he can be examined on the money that he has made from me and from, of course, Mr. Sheller. And she goes and she says he has made "millions of dollars from plaintiffs' lawyers". That is an ad hominem personal attack, the kind of which the Courts say does not go to pro-bias. What goes to pro-bias is how much money the man was paid by me, which by the way was a lot.

MS. SULLIVAN: That's not true.

MR. KLINE: But it has nothing to do with how much he has been paid by Mr. Lanier in the Botox cases, or in the Actos cases, or anything else.

THE COURT: I will referee that the best I can. Right now we are talking about, we are right now talking about the admissibility of documents during Dr. Kessler's direct examination. Anything that you try to cross-examine him on, obviously,

Ms. Sullivan, you open the door and it's gone. But we are not talking about -- you know, give me an example of a document that you think Dr. Kessler shuted not be able to read into the record or say something that he relied on. And mind you, I am not going to permit Dr. Kessler to read thousands of pages of documents into the record.

MS. SULLIVAN: And so, for example, Your Honor, and again this goes to the intent issue, there is an E-mail from and Gahan Pandina dated October 28, 2002, I can hand it up to the Court, it's sort of hearsay within hearsay. The folks from Helix, this is an outside consulting firm who are helping us --

THE COURT: What document is that? Let's take a look at it. I want to see an example of what you are talking about so that I have some idea of what your argument really is.

MS. SULLIVAN: This is Bates number 3884282 --

MR. KLINE: Let us just find it, please, so we can have it in front of us,

kindly?

MS. SULLIVAN: You gave it to us this morning.

THE COURT: It's clear that I am not going to be able to do it one on one, so I want to see what these are so we will be able to make quicker decisions at the time that they come up.

MS. SULLIVAN: Judge, there is a series of E-mails like this where they are going to have Dr. Kessler speculate as to what Mr. Pandina and others meant when they were writing that E-mail, and that is not proper testimony for this expert witness.

THE COURT: Let's mark this now. Do we have any exhibits that are called Court-1, have you started with those yet? This is the first Court document, Court-1.

(Court-1 is marked for identification.)

THE COURT: This appears to be a document from a Gahan Pandina, who I don't know who that is, sent to Olga Mittelman, and I don't know who that is, and it says, Are you here. What is this document and what is it

relevant to, Mr. Kline?

MR. KLINE: Sure. Number one, it is one of many documents that Dr. Kessler reviewed, and this is a document which is written October 22, 2002, it is from two of the key people involved in the development of the pediatric indication for the drug.

Gahan Pandina was a psychologist, I referred to him in my opening, he was running point and he said many different things in his E-mail. This is words of his that he used, this was his view, his interpretation of things.

If you notice, and of course, I want this in and they want it out, the man who is running point on the whole project -- look at line three. I mentioned it in my opening, line three -- and by the way, Pandina has been deposed, and by the way, if I had to prove this I simply would play Pandina or I'd subpoena him. And they have Pandina on the witness list.

THE COURT: I am well aware of that.

MR. KLINE: And here is what he says.

By the way, Dr. Kessler doesn't have to comment on what it is, I have to ask him did you see this document, did you take it into consideration.

THE COURT: And I assume you are going to publish it up there on the screen, correct?

MR. KLINE: I plan to, yes.

THE COURT: So again, this Gahan Pandina is a psychiatrist or psychologist for Johnson & Johnson.

MR. KLINE: Working for Janssen Pharmaceuticals.

THE COURT: And Olga Mittelman is who?

MR. KLINE: Olga Mittelman is a physician, she works on the prolactin project.

THE COURT: For Johnson & Johnson?

MR. KLINE: Yes.

THE COURT: So this is an internal document of Johnson & Johnson, an E-mail conversation between two members --

MR. KLINE: Two of the key people.

THE COURT: Let me just read it to myself, one second.

MR. KLINE: And right before they went

to a key advisory committee meeting. You will see what I am after. I am after the third sentence.

THE COURT: I know.

MR. KLINE: This is where they said we have to decide if we want to be transparent or translucent.

MS. SULLIVAN: What does that have to do with a regulatory opinion? This goes to punitive damages kind of issues, motive and intent, mind reading. It's not proper for this expert.

MR. KLINE: By the way, this is the lead-in, this is the transition in part of the story. He has reviewed documents which he believes are part of his understanding of what the company did and what they said. What they did and what they said is at issue here. Frankly, it's going to come in front of the jury. It's efficient to do it this way.

THE COURT: I think you are right, it would ultimately come before the jury, however, what is the fair way of doing it. This is a document that on its face would

invite some cross examination to explain what is meant by this particular document.

So if this comes in as a business record, it may or may not, I am not sure exactly under what theory this comes in on its own.

MR. KLINE: It's a business record, it's out of their files. It's between two of the key people. It's what the one said he was thinking. Not what Dr. Kessler was thinking.

THE COURT: I haven't reviewed the question of whether confidential E-mails between each other are business records in the classic sense.

MR. KLINE: There is no confidentially here, Judge. This is a business E-mail between two business colleagues on a business computer.

THE COURT: I would have to review that. It hasn't been presented to me in the context of a pretrial motion as to whether that comes in as a simple business record. It seems to me that a statement, an out-of-court statement is different at a particular

occasion is not a regular business kind of procedure that would normally qualify under a business record.

So to me, this is the kind of document, if I were you, Mr. Kline, I would bring in one of those witnesses to get that information in.

So that is something I would not permit to be published to the jury. It's certainly a basis for an opinion, and if she wants to open the door and challenge the opinion, then maybe this thing would come in in some way. But just to publish it and have the jury read this particular document on the screen without the ability to essentially cross-examine this individual who made the statement or something, I don't think that is fair. I don't see that as a permitted use of this kind of document. It's not really a business record.

MS. SULLIVAN: Thank you, Your Honor.

MR. KLINE: I will bring in every individual, Your Honor, they are all between here and New Jersey. We will have 20 more it's witnesses.

THE COURT: That's fine. I don't see this as a business record. I don't want to be reversed on business records ground. This is not really a business record, this is not custodial. This is a conversation between two parties, an out-of-court statement, not subject to cross examination with available witnesses. It's not something that I am going to stick the whole case on.

MS. SULLIVAN: Thank you, Your Honor. And, Your Honor, there is a stack of --

MR. KLINE: Is that to say, because this changes the whole way, if I may get some --

THE COURT: I have warned you, I told you ahead of time that this is not going to come in I said that, I said that at pretrial, with Dr. Kessler. If I were you I would have Dr. Kessler come in to clean up the mess at the end rather than at the beginning. That's what I would have done, but you are the trial lawyer here.

MR. KLINE: Well, I thought that records -- first of all, almost every one of

these documents was talked about in a deposition -- please indulge me for a moment -- and there is no doubt as to this Pandina having been examined about this and Ms. Mittelman having been examined. And I can represent to the Court, and maybe the way I can do this is a different way, which was allowed yesterday.

If I may, I would like to ask Dr. Kessler, as I did with the other doctor -- I am not here to fight with your ruling but I would like to find a way that I can try my case efficiently. And what I would like to do is simply ask him, Dr. Kessler, I would like you to assume that the evidence will show that there is a E-mail saying this -- hear me out -- and then I would like to say to him -- by the way, that seems to me to be a fair way to do it -- and I would then like to say to him, Is that something you took into consideration in the formulation of your opinion.

Nothing more. Nothing more. Because it is part of the basis of his opinion. And

(Pledger v Janssen, et al.)

so to strip it out of his opinion doesn't seem to be fair when I can represent to the Court, and I will represent to the Court, and my colleague Mr. Gomez, who knows this case better than I think anyone in the country, has been working on it for years, will tell you that every one of these documents, the author or the recipient has been deposed.

It's the same thing with those business plans that Your Honor said you can't put them in through Kessler but I might let them in through something else.

So we are going to be busy between now and the weekend cutting up a whole bunch of deposition stuff, which I wasn't planning to do, but if that's the way I am told to try the case, okay.

But I can tell Your Honor, I can represent to the Court when I tell him, Assuming the evidence will show that, I can also tell you that the E-mails all have been the subject of deposition testimony.

These are not a blank slate. This case is well developed, 50 depositions were taken

(Pledger v Janssen, et al.)

by the Sheller firm, a yeoman's job, and we are here talking about documents that we know what they say and what they mean. And what they would like to do is strip the heart out of it to begin with.

As to my strategy, I am putting him on and when I put him on, my word, I think I would want to lead off with my expert in this case and go through the documents and go through them serially.

There is no surprise here, there is no prejudice here. They know the documents, the documents have been the subject of cross examination. And to the extent Your Honor doesn't want them published, I would just ask him to assume so at least I can have context for the basis of his opinion, because when we get to the appellate courts they are going to challenge the basis of his opinion, and I at least need to have in the case the fact that he knows --

THE COURT: Your procedure sounds tempting if I knew ahead of time how many and which ones. But you presented me with a

(Pledger v Janssen, et al.)

binder of a thousand pages. So I am very vulnerable to that and I am not going to do it.

MR. KLINE: I didn't have a chance to explain.

THE COURT: If you told me which documents and you are going to prove it, you are going to call Pandina, you are going to call somebody and introduce the trial dep by stipulation, fine. But I am handed here a binder of a thousand pages, and I am taking your word for it that you are proving everything in this case. I am not going to keep a score card of what you proffered.

So in the end I would prefer that it either be done the usual way or you let me know ahead of time and counsel know ahead of time which documents you are going to use as a hypothetical as a basis for an opinion so we are all on the same page and we all know what's going on.

MR. KLINE: It would only be the E-mails.

THE COURT: How many are there?

(Pledger v Janssen, et al.)

MR. KLINE: Maybe a half a dozen. If there are a thousand pages in there, and, geez, I was trying to be inclusive. This is a few hours of testimony, not a few days, at least I hope. I think we could have had a quarter of it on already. And in there she has picked out a handful of E-mails. The handful of E-mails I will know how to handle.

THE COURT: Why don't you show us and counsel the handful of E-mails that you wish to use as a hypothetical for Dr. Kessler's opinion and we can go on our merry way. Otherwise, you are just not going to get it done by just cherry-picking, using a phrase that has been used here --

MR. KLINE: Red flag.

THE COURT: And then we are off in the dark. I would not rely on these as business records, and so therefore, they have to be admitted in some way, and for that to be done you need witnesses.

You want to put Dr. Kessler on first, fine. Give us a hypo, get his opinions and bring him back. Or get your hypos by advance

notice to all of us and we will look at it and you will get your hypo. But you can't have it in kind of a nebulous form ahead of time in a trial like this with the jury waiting.

MR. KLINE: So Your Honor knows, again, just so I hope I have some reliability on this, I don't know of a case that I have tried forever that I wasn't allowed to show an E-mail to a witness --

THE COURT: Show me the ones you intend to do ahead of time. Otherwise, we will have to be interrupted multiple times during the testimony of this case and I don't want that if it can be avoided.

MR. KLINE: I will show it to you, but I will tell you right now, it's going to be the same issue. You have already ruled globally that an E-mail isn't a reliable business record.

THE COURT: It depends on how it's going to be proven. If you are going to show me that later on you are going to prove this E-mail, fine. I don't want to have to keep a scoreboard of 14 different E-mails and whether

or not you have proven it and then I would be subject to reversal later on because a hypo didn't match up.

MS. SULLIVAN: Your Honor, just because the Plaintiff showed a document to a witness in a deposition doesn't make it admissible.

THE COURT: I believe so.

MR. KLINE: Every one of these E-mails -- Your Honor may or may not have picked this up by now, there have been a lot of names thrown around. Pandina is the point guy when it comes right down to it in this project.

THE COURT: Is he going to testify in this case?

MR. KLINE: He is on their witness list.

THE COURT: He is on yours. I read them both. I am really distressed that many of these matters have not been resolved between the parties themselves as to which witnesses are actually going to be used. I am assuming, and I read a hundred names, and I have said that, you know, we are prepared to try this case the old-fashioned way, so all of

them can be called. So I am just trying to narrow the issues down so we can avoid that. But if not, then, Hey, I got a panel of 15 and we will make it through.

MR. KLINE: Appropos of that, I have said now for days, I am willing to call the treating doctor, Dr. Kessler, the detail man, the mom, and the sales rep and rest my case.

THE COURT: I understand, but you want to do through Dr. Kessler three weeks' worth of testimony. I understand that, too.

MR. KLINE: All of which are business records.

THE COURT: I can't do it that way. If you want six E-mails, show me the six E-mails you are going to proffer as a hypo, we will look at them, make a ruling on them and you will all know ahead of time what's permitted or not permitted.

Other types of documents, you are going to have to get them in through the witnesses themselves or some other accepted way of evidentiary authentication, and you will also have your proof ultimately, I suppose.

MR. KLINE: So are you saying that this binder I am not going to be able to work through with Dr. Kessler?

THE COURT: I am saying you told me you got six E-mails that you want to use out of that binder, let's see them and use them.

MR. KLINE: What about the rest of the exhibits?

THE COURT: I don't know. What are they?

MR. KLINE: I have been told I can't put their studies in, I have been told I can't put in any of the documents --

THE COURT: Whose documents? They are business records.

MS. SULLIVAN: I don't have a problem with them.

MR. KLINE: She only has a problem with the stuff that she doesn't like.

THE COURT: She has a problem with the implicating E-mails, and I understand that. Let's see them.

MR. KLINE: They are really good, Your Honor, you are going to like them.

(Pledger v Janssen, et al.)

MS. SULLIVAN: They are not that good, Your Honor, and they are not proper, especially through this witness. Even the -- here is the problem even with the hypothetical, Your Honor. It's a witness who wasn't on the E-mail, he is speculating what it meant, and he is giving the jury his mind-reading opinion --

THE COURT: No, I am -- I just want to see the E-mails. Other than that, let's see what you are talking about. As to how an expert in the pharmaceutical industry, if he is qualified, interprets those particular documents, that's for the expert to determine. But I need to see what the basis is because that's what the Plaintiff wants to use to show to the jury and essentially save the Court and everyone else weeks of testimony.

MS. SULLIVAN: Your Honor, the problem is they should do it the right way.

MR. KLINE: Your Honor, I am not going to ask him to interpret them. She keeps saying that. She is not right about that.

MS. SULLIVAN: Of course, he is.

(Pledger v Janssen, et al.)

MR. KLINE: How do you know what I am going to ask him?

MS. SULLIVAN: Because he wrote an opinion based on them, so of course, you will.

THE COURT: Counsel, why don't you both sit down. Let's see the six E-mails that we have here, and, you know, it's interesting that we are bogged down on these kind of elementary aspects of evidentiary law.

Let's just see what the E-mails are because, frankly, it's for the convenience of Plaintiff that we are even having this discussion because otherwise I would have insisted that the documents be introduced the right way, through the right witnesses, and then have them used and published. But if you are telling me that you want it done this way and it also favors judicial economy, then let's look at the E-mails you wish to use right now with Dr. Kessler and see when they are going to be admitted at trial and we can go our merry way and have the jury come in.

MS. SULLIVAN: Your Honor, I am interested in judicial economy and doing

(Pledger v Janssen, et al.)

anything we can to expedite the trial but not at the price of a fair trial for Johnson & Johnson.

THE COURT: The record is being taken here, I think this Court has been very indulgent up to here, extremely indulgent.

MS. SULLIVAN: Your Honor, there is another class of E-mails that relate to these draft manuscripts of a study --

THE COURT: Right now I am still waiting for those E-mails so we can address those. And then draft manuscripts, if one of you shows me an example of a draft manuscript.

MS. SULLIVAN: Your Honor, there are a bunch of E-mails on the draft manuscripts. I will be happy to hand up.

MR. KLINE: Why don't we show the Court what we are going to proffer rather than --

THE COURT: I am waiting for the six E-mails. You want to -- the E-mails anyway you want to use as a hypo, essentially.

MR. KLINE: I would like Your Honor to reconsider. They are business records, they

(Pledger v Janssen, et al.)

are on a business computer, a business --

MS. SULLIVAN: They are not business records.

THE COURT: You want to use those as a basis of an opinion and offer it through as a hypothetical or --

MR. KLINE: If I had my druthers I would say, Have you reviewed this document, is it part of the materials you considered in reaching your opinion, sir.

THE COURT: And I would say to you that particular document, the contents can be given to the jury and even published if they are going to be admitted the right way at some future point at this trial. I need to know ahead of time when that's going to be done and by whom. And then we go.

MR. KLINE: We will also flag one of the draft documents -- actually, the page. For example, on one tab, it's this thick, what I do is I say, Doctor, is that Draft One. Yes. Would you turn to page 26 of it. Is the key information in that document?

Then I go to Draft Three. Is the key

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information missing.

THE COURT: I appreciate how that would be done, I just want to know basically what they are, who they will be admitted through and when in this trial. So I can keep score. Otherwise, you are going to put in a thousand different documents and I will never know which hypo has ever been proven and then get reversed at the end of the day.

MS. SULLIVAN: And, Your Honor, just looking at the E-mails that Mr. Gomez was kind enough to tab, first, they are not business records, they are random E-mails. They are not studies, they are not data, they are not books and records.

THE COURT: That's why we are going through this process.

MR. KLINE: Respectfully, they are business records. I think there is case law on it.

THE COURT: They are documents that were generated through the business affairs of Janssen. Whether they are evidentiary business records, I have preliminarily ruled

(Pledger v Janssen, et al.)

that they are not.

MR. KLINE: We might want to look at the case law to see whether an E-mail is a business record on a business computer.

THE COURT: It can be.

MR. KLINE: It has to be.

MS. SULLIVAN: The second issue there side comments by others -- can I speak for maybe a minute? Some of them are talking about comments doctors outside the company, and then it looks like the bulk of them go to this core issue, E-mails about these drafts of manuscripts about this Findling article that the prescribing doctor never saw.

And so, first, prejudicial, goes to motive and intent and has nothing to do with this case.

THE COURT: Again, I wish you would cease all that motive intent part because motive and intent is relevant in many circumstances to prove, let's say, in a receiving stolen property case, you know, that he should have known that it was stolen, and the motive can come in as something relevant

(Pledger v Janssen, et al.)

to what he should have known.

MS. SULLIVAN: They are trying to show the intent to hide data, which is the punitive and fraud claim.

THE COURT: It's not a matter of intent to hide data. It's a matter of should they have known it and should they have divulged it.

MS. SULLIVAN: They have the data, they can show that. What they can't show is drafts about a manuscript that the prescriber never saw.

THE COURT: I don't have an evidentiary question in front of me on that question, but I have already stated that the distinction that you are trying to make between a cause of action that's been dismissed for fraud is not the same situation as to probative proof for this failure to warn case. They are different issues. I don't agree with you that everything has to be thrown out as to whether or not there was an intention to hide versus a should have known. If there is an intention to hide, that implies that they knowingly --

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they should have known that something existed. One can prove the intentional act and still have enough evidence to show some kind of knowing act, like they should have known.

Just because you prove intention doesn't mean that it doesn't go to a lesser standard.

MS. SULLIVAN: But the way, Your Honor, to prove that is, Here is the data, I had notice, I should have warned, it was true. Not to show what they are saying internally in these E-mails about a data, about a manuscript that the prescriber never saw.

THE COURT: I am sorry, it's academic at this point without a question. But again, Ms. Sullivan, I know that you have argued this before, but think of it as a receiving stolen property situation. In that particular situation, if a person intends, he intended to take the stuff knowing that it was stolen, that's one element of proof. Another element of proof of the same crime is that he should have known that it was taken. The same evidence goes for both aspects of the case.

So in this particular situation, if the Plaintiff can show that there was an intention to hide, that also goes to whether they should have known.

MS. SULLIVAN: Your Honor, that's not an element. Respectfully, it may be an element, I defer to Your Honor on the criminal standards, but it's not an element of the claim here.

THE COURT: But it is probative, and that's the bottom line with this. It's probative. If they knew something and decided not to reveal it, it's probative to the question of whether or not they failed to warn in a negligence sense.

I rest on that. I am not going to worry about that particular issue, and I suggest that you stop on that, that just because the cause of action in this case for fraud and all of those have been dismissed by summary judgment does not mean that evidence of intentional conduct is inadmissible at this trial if it goes to the probative proof that they should have known that a particular type

of side effect existed.

MR. KLINE: She won't stop on it.

THE COURT: She might not, but I will clarify that once and for all and certainly in a jury instruction.

MS. SULLIVAN: Your Honor, respectfully, I think that injects punitive damages.

THE COURT: You made that particular argument ad nauseam, Ms. Sullivan. And by the way, the punitive action in this case is something that is not relevant here. And I will make that clear, if we ever get to jury instructions on damages in this case. I hope we get that far without a mistrial.

It's clear that this case is about pain and suffering and embarrassment and humiliation. It is not about punitive damages. I will certainly make that clear.

MS. SULLIVAN: And, Your Honor, so the issue for them is, and for us, is all of these E-mails, which is the bulk of what they want to show about a draft of a manuscript that the prescriber never saw, we object to it, first

on foundation for Dr. Kessler, on relevance, and on 403 grounds.

THE COURT: You have made your record. Do we have the documents that we are looking at? Let's see them.

I am looking at, first of all, a document, we are now going to mark this as Court-2.

(Court-2 is marked for identification.)

THE COURT: January 24, 2002 -- that's a different document. From Gahan Pandina to various members of the --

MR. KLINE: It's the E-mail below that we would likely focus on. This was prior to them having a meeting with all of their people -- it was actually afterwards. It's a summary. It's a classic business record, a summary of what happened at a meeting by a person that was there.

MS. SULLIVAN: Filled with hearsay.

MR. KLINE: Of course, it's filled with hearsay. It's somebody who was at a company meeting who took down everything that was there and their interpretation.

THE COURT: All things being equal, how would you produce this as far as a document that's admissible? Forget Dr. Kessler. How would this come in and it will be admitted?

MR. KLINE: I would say, Dr. Kessler, there was --

THE COURT: No, not to Dr. Kessler. I need to know how this document would come into evidence in this case without Dr. Kessler.

MR. KLINE: This document was the subject of examination in a discovery deposition by Caren Binder. I would need to have her de bene esse live in the courtroom to really cross-examine her.

THE COURT: So you would present it through Carin Binder. So you are on notice if there is an objection based on inadmissibility, Caren Binder needs to be available at this trial by Court order.

MS. SULLIVAN: Your Honor, they have deposed her, they can play her tape.

THE COURT: Play her tape then.

MR. KLINE: I would want her here.

MS. SULLIVAN: She doesn't work for us,

(Pledger v Janssen, et al.)

she is retired.

MR. KLINE: We will find her.

THE COURT: If that's the ground of inadmissibility, her unavailability, it comes in.

MS. SULLIVAN: Your Honor, there is a right way to put this evidence in --

THE COURT: We are going over what is the right way in this courtroom for this case, and what I am saying to you is if the objection is Carin Binder is unavailable, then it comes in. Either she is here and available --

MS. SULLIVAN: She is here, Your Honor, because she was deposed fully by them.

THE COURT: Fine, then her testimony is available. And the required statement comes in. It's admitted.

MS. SULLIVAN: No, Your Honor, here is the issue. Just because she was deposed on this, this is filled with comments from outside the company doctors. This goes to an advisory board that was filled with experts from outside the company. So it's filled with

(Pledger v Janssen, et al.)

hearsay comments by people that don't work for the company. This shouldn't come in under basic hearsay.

THE COURT: That's overruled. So we are clear.

MR. KLINE: Now, what I would ask --

THE COURT: I want to know how these things come in and we can go on our merry way.

MR. KLINE: It is probative of the --

THE COURT: No, I just want to know how you authenticate it.

MR. KLINE: The way it's authenticated is through Caren Binder, who was deposed on this document and who was asked questions about this document.

MS. SULLIVAN: Your Honor, why didn't they play with first and it comes in the proper way, with questions from us and questions from them, instead of having Dr. Kessler saying here is what it says, and we don't have anything from the witness to counter it.

THE COURT: You can call Carin Binder if you wish.

(Pledger v Janssen, et al.)

MR. KLINE: I am told she is in Canada.

THE COURT: We had a doctor come in from Boston, she can come in. Next.

MR. KLINE: But I have her deposition on this.

THE COURT: I am not persuaded by that, lack of sabotage, there is no sabotage here. Number two.

MR. KLINE: I am on Tab 15, I think. And I hope we tabbed them all.

THE COURT: I have another one here, January 6, 2003, Carin Binder. Is that the one you are talking about?

MR. KLINE: I was done with that one. I am on Tab 15, at the very top, and in Tab 15 there is a document which is forwarding the abstract, the draft, and the E-mail is from Pandina to Magali. And Pandina's deposition was taken and he was asked about this document -- he was not asked about this document. He is under their witness list, they will either have to call him or I will have to subpoena him and get him in here. But he is in the venue, he is in the jurisdiction.

(Pledger v Janssen, et al.)

THE COURT: Who is this?

MR. KLINE: Pandina.

MS. SULLIVAN: Here is the problem, Your Honor, it's a draft poster for a conference that the prescribing doctor here never saw. Again, it's internal E-mails that aren't business records, and they want Dr. Kessler to come in and say Here is what it means, without putting it in through the proper witness.

MR. KLINE: This is ridiculously crazy this morning.

THE COURT: Mr. Kline, I am going to ask that you allow Ms. Sullivan and yourself to finish your argument and then we will hear the other one.

MR. KLINE: I will wait for her to be done, and then I will explain to the Court what I was about to explain as to why I want to use this document.

THE COURT: Just for the record, we are looking at an E-mail from Gahan Pandina dated Wednesday, February 20, 2002 at 1:50 p.m. to Reyes Harde Magali and the subject was "AACAP

(Pledger v Janssen, et al.)

prolactin abstract".

Now I understand that this is a written internal document among the employees of Janssen Pharmaceuticals, correct?

MS. SULLIVAN: And, Your Honor, it sounds like we are getting back to dumping in all of these internal E-mails through a regulatory expert so he can tell the jury what was said and what was meant here.

THE COURT: We are right now, Ms. Sullivan, we are culling the record. For the record, I am looking at a binder that has about a thousand pages, and we are going through a number of E-mails that have been proffered by Mr. Kline as the only documents from this binder that relate to the E-mail communications that he intends to use as a basis of the opinion for his expert witness Dr. Kessler.

So that's what we are doing, Ms. Sullivan, and I don't need, please, for you to keep on referring to matters that are really -- they are argumentative.

MS. SULLIVAN: Then, Your Honor, we

(Pledger v Janssen, et al.)

would object because there is no foundation here through this witness, he is just speculating on intent, and it relates to an abstract that the prescribing doctor here never saw. It's not a business record --

THE COURT: On those grounds that is overruled, subject to, how is this going to be admitted?

MR. KLINE: Well, I can tell the Court that this is the only one of the documents that I believe that we have here that there was no deposition testimony about. I can tell you that. And we would need to have Pandina.

I understand that he is their witness -- and by the way, I have told them who my witnesses are. Can I find out who their witnesses are?

MS. SULLIVAN: Mr. Kline, you know we had only 24 hours --

MR. KLINE: Wait a minute. That would help me know, if I knew Pandina was going to be in this courtroom I could confidently either use this document or ask a hypothetical. I am entitled to know.

(Pledger v Janssen, et al.)

THE COURT: If I were you I would give up a single document and have it come in after the subpoena so you don't take any chances.

MR. KLINE: The reason this is an important document -- I will get it in with someone else -- so the Court knows --

THE COURT: You don't have the direct admissibility and you get into ruling on a hypothetical because you can't somehow get this witness in somehow, she has disappeared.

MR. KLINE: He is not disappearing. He is like the company man, capital M, capital A, capital N. He is the company MAN.

THE COURT: I would like you to get this document in in a different way at a different time.

MR. KLINE: He is the company man. Even the folks at Janssen like that, he is the company man.

The next thing I would like to do with this document, what they did is they had prolactin-related side effects, and they decided that doesn't sound so good, we are going to call it "symptoms associated with".

(Pledger v Janssen, et al.)

This is that document.

THE COURT: I understand the defense argument. I am just saying for our purposes, this particular document, if you don't have a direct method that you can assure me at this time it's inadmissible. I am not going to let you do it.

MR. KLINE: I am not going to play loosey goosey with that one.

THE COURT: We are not going to go there.

MR. KLINE: In Tab 16 -- I can probably speed this up -- in Tab 16 I have tabbed an E-mail, and at the bottom of the page the Court will see there is an E-mail from Binder to a bunch of people, a business E-mail stating what the key message is going to be. "Key message: Prolactin rise is transient and not related to side effects hypothetically attributed to prolactin EPS or efficacy response."

Anti-science, people making up the result before it. And this doctor, Dr. Kessler knows it when he sees it. Now, this

document -- as would anybody, by the way, including lots of people sitting in this room would understand that.

THE COURT: How is this going to be admitted?

MR. KLINE: I am going to have to play the Binder testimony, or Pandina.

THE COURT: As long as, you know, this is going to be covered it's admissible.

MR. KLINE: I will play the transcripts, or I will ask for Pandina to show up in this courtroom.

THE COURT: As long as you have something it's already in the can, so to speak, I am going to admit it.

MS. SULLIVAN: Just so we are clear, they gave us notice that they wanted us to bring Dr. Pandina to this trial, and they told us before the trial that they didn't want him.

THE COURT: Dr. Pandina is somebody, however, I read it out, Gahan Pandina I read it out, both of you had him as a potential witness. That's not an issue.

MS. SULLIVAN: He has a tape they could

have played.

THE COURT: Whatever. He was submitted as a potential witness by both of you.

MR. KLINE: I have the deposition transcript. No sense fighting over whether I can bring him now in or not.

MS. SULLIVAN: Here is the reason it shouldn't be in, I respectfully submit. This is the series of documents that go to this draft manuscript. They have E-mails about drafts and drafts of this manuscript about a study the prescribing doctor never saw it, it has nothing to do with this case.

THE COURT: Excuse me, I am just looking at these E-mails.

MS. SULLIVAN: The E-mails are about the draft manuscript.

THE COURT: The E-mails are about the draft manuscript, it refers to it, but the contents of the draft manuscript are not before me.

MS. SULLIVAN: It's attached as well, Your Honor.

THE COURT: At the moment we just --

MS. SULLIVAN: It talks about and attaches the draft manuscript.

MR. KLINE: It attaches the draft manuscript.

THE COURT: So what you want to do is use 16 -- was that an attachment as part of this E-mail?

MR. KLINE: I believe it was, yes. He says, here is the attached thing and says, here is what the results should be. And by the way, then the draft document comes in because it shows the knowledge of the company. And it's the company's document.

MS. SULLIVAN: No, Your Honor, the data that underlies this manuscript, I have no problem with them showing the expert that, this eight to 12-week data that's the centerpiece of their case. But what people are saying about the draft manuscript and the draft manuscript itself that the prescriber never saw has nothing to do with this case and it's prejudicial.

THE COURT: That's overruled. That comes in, the draft manuscript that was under

review by Janssen comes in.

MS. SULLIVAN: But it shouldn't come in through Dr. Kessler, Your Honor.

THE COURT: It comes in through Dr. Kessler as long as this particular document is admissible through -- who is it going to be, through the deposition you have?

MR. KLINE: Pandina and Binder testified about it.

THE COURT: It comes in through Dr. Kessler's testimony now.

MS. SULLIVAN: So is the Court going to permit Dr. Kessler to talk about what he thinks was meant by these documents?

THE COURT: Absolutely.

MS. SULLIVAN: We object.

THE COURT: He is going to give an opinion.

MS. SULLIVAN: He is a mind reader about --

THE COURT: I don't know what you mean -- he is going to give an opinion as to whether or not -- what is the opinion you are proffering in relation to these documents?

MR. KLINE: I am going to say, Doctor, you have a wealth of information including the FDA Chairman for six years, and did yo?u review this document. Is this document something that you considered in your opinion? What -- I am going to publish the document to the jury, I am going to say, Doctor, what is being said there as you understood?

THE COURT: I didn't ask you that, Mr. Kline, what is the opinion that this document is the basis of or contributing --

MR. KLINE: It's one document of this large number of documents.

THE COURT: Right, and what is the overall opinion?

MR. KLINE: His overall opinion, as I said in the very beginning, is that Janssen Pharmaceuticals provided an inadequate warning as to the risk of prolactin increase and as to gynecomastia in children.

THE COURT: That's it? That's the opinion?

MR. KLINE: That's the ultimate opinion.

THE COURT: So it's admissible. Certainly subject to the way this is used, but if it's probative to that particular opinion it's going to be admitted.

MS. SULLIVAN: Your Honor, he can give that opinion without using these hearsay documents that are untethered to this case.

THE COURT: If they are admissible, they are admissible.

MS. SULLIVAN: I understand the Court's ruling.

THE COURT: All right, thank you. Are there anymore of these?

MR. KLINE: They are all in the same category.

THE COURT: Right now we are going one by one and that's it. If something is not given to me now, it's can't be used as a hypo, it can't be shown.

MR. KLINE: I am going to show you.

THE COURT: Next one.

MR. KLINE: The next one is right under Tab 20 and then I flagged it with a big post-it. This is an E-mail of Binder to a

group of people regarding the prolactin manuscript.

THE COURT: That's from Carin Binder to Gahan Pandina and others. It's also a Janssen document on the subject of "latest prolactin manuscript". Is that the one you are talking about?

MR. KLINE: Yes. And she was deposed about this, she is the Director of Medical Affairs, although she is an MBA, but that's the title they gave her.

THE COURT: This is the one that says the revision now included a nauseating amount of info on SHAP?

MR. KLINE: No, she is not nauseated yet, she kind of gets there.

THE COURT: This one says, The revision now included a nauseating amount of info on SHAP, which is another name for some other kind of this condition?

MR. KLINE: Hold on a second. This is Tab 20th and it's the E-mail that says at the very bottom of page one, Bates number 170. It says, "Secondly, the U.S. group recommended

that the manuscript in all cases of gynecomastia specifically state whether the prolactin levels were normal or elevated, as well as state the new rates of gynecomastia as identified by the Endos. They feel applying the Endo position of gynecomastia in boys of puberty not being checked without listing all gynecomastia was -- are you ready for this one? -- "hiding data." And of course, they don't like that.

THE COURT: For the record, we are now looking at what is Tab 20. I misstated the document we were looking at, strike that. We are looking at a document from Gahan Pandina dated Monday, November 18, 2002 --

MR. KLINE: I am looking at the E-mail underneath that. The one that is from Binder --

THE COURT: Really the second one, from Carin Binder, November 8, 2002, 11:14 AM, to Vincente Nys, and that's 11:14 a.m. Is that the one you are talking about?

MR. KLINE: Yes. It's what we call it the "hiding data."

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THE COURT: How is that admitted?

MR. KLINE: Through the testimony of Binder. We will have to play the testimony of Ms. Binder, or Pandina. They were both questioned about it by us in their discovery depositions.

MS. SULLIVAN: And, Your Honor, in addition to the reasons that have already been stated on the record related to this draft manuscript that the prescriber never saw, this is a hearsay statement from people outside the company, the advisory board outside the company. So it's not a business record. The hiding data is a statement not from Janssen but from somebody outside the company, highly prejudicial --

THE COURT: I understand that. That's overruled. This goes toward the probative nature of what they should have known or did know and what they did with the information. Next one.

MR. KLINE: The next one is the nauseating -- the E-mail, it's the nauseating E-mail. It's at Tab 21. It is from Binder to

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Pandina. Mr. Gomez, were they both asked about it when you deposed them? Yes, they were asked by one of the lawyers from the Plaintiffs.

THE COURT: That's the one I read earlier, for the record, again, from Carin Binder, dated Thursday, November 21st, 2002, at 10:01 PM, to Gahan Pandina and others. That's the one it has in the second sentence, "The revision how includes a nauseating amount of info on SHAP, specifically gynecomastia, etc. That's admitted. If you can admit it through Binder that will be admissible.

MS. SULLIVAN: Your Honor, just because it's admitted through a proper witness doesn't mean this expert -- experts rely on data. This guy is going to come in and tell the jury this is what their E-mails mean, and that's completely improper.

THE COURT: He is going to be able to testify that he based his opinion that Janssen did not meet its duty to give an adequate warning and he is using this as a basis for an opinion. That's admissible. And I don't have

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a problem with it. What's the next one?

MR. KLINE: For the record, footnote: He also reviewed the deposition testimony of these people.

THE COURT: I understand that, also.

MR. KLINE: So it's not a raw --

THE COURT: I understand that. The defense needs to make a record and they are. Next one.

MS. SULLIVAN: Your Honor, one of the things I would object, so if you are going to permit Mr. Kline over objection to publish these E-mails that he didn't write, he wasn't on, he shouldn't be able to say what he thinks they mean or what they mean. I mean, you know, the words are there, they will be up there, but he shouldn't be able to say, And what they are saying here is. He has no idea, he didn't write them.

THE COURT: That's why we have cross-examination and able counsel will be able to contradict what he says. Able counsel should be able to do that. Next.

MR. KLINE: The next one is an E-mail

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in Tab 22, and it is December -- it's the top E-mail, December 3, 2002, and once again, it is from Pandina. I am assured by Mr. Gomez -- notice the way that I am looking to put him into this -- that the E-mail was the subject of deposition testimony and he is saying that's correct. And that E-mail is the one that says, among other things, the issue of prolactin and SHAP is obviously a charged one.

THE COURT: So we are looking at an original message from Gahan Pandina, sent on Thursday, December 13, 2002, to Carin Binder and others, Subject: Latest prolactin manuscript. It says, "Dear Carin and Team," and it has the phrase, "The issue of prolactin and SHAP is obviously a charged one." Is that it?

MR. KLINE: Yes.

THE COURT: How is this going to be admitted?

MR. KLINE: This, again, like all of the others, was the subject of inquiry by Plaintiff's counsel to both Carin Binder as well as I believe Pandina, so we would pick

one or the other at deposition at which both parties are represented.

THE COURT: If it is not introduced properly, the whole case can fall down on that little point.

MR. KLINE: When you say admitted properly, I plan to play those segments of the deposition where they were asked about that in those depositions.

THE COURT: That's fine, as long as the jury gets to hear that these documents aren't pulled out of thin air, that's fine with me.

MS. SULLIVAN: Your Honor, this is a Regulatory expert, not someone who is supposed to interpreting E-mails. This had been precluded by other courts, as Dr. Kessler just giving a closing argument for Plaintiffs, instead of talking about data, talking about intent and E-mails, and we object.

THE COURT: I do understand the objection. But we are -- we have one more document?

I, of course, do reserve for the Court the discretion on exactly what the commentary

would be by the witness ultimately. It may be preferable for all concerned that only the contents of this document be shown and read by the witness and not commented on. That may be a point well taken.

MR. KLINE: There is one more, and the one more is an E-mail dated --

THE COURT: What's the other one?

MR. KLINE: It's another E-mail, you know, they have the study they don't like by Findling. And they talk about the author. It says, "Findling is okay, but I find he doesn't stand up firmly for his convictions and tends to be swayed. On the other hand -- they are saying internally -- "he will do/say whatever you want him to. Your choice, Pam."

That's when they are picking the author. And that's going to be part of the case because it demonstrates their negligent failure to warn.

THE COURT: I will hear argument on this. It sounds to me like it's kind of a backdoor expert argument about a learned treatise.

MR. KLINE: No, it doesn't have to do with a learned treaties. Here is what it has to do with. We believe it's a pivotal document in the case, if I need to call Pandina I will question him about it. What they have is a study that they published, that they massaged five different drafts. They never warned what they knew about and they took out and essentially hid the key finding.

Along the way, they needed to get the blessing of the guy who they chose to be the key author. This is their conduct, their view.

MS. SULLIVAN: This is the bad conduct case, Your Honor, this is exactly what they want to do with this witness. This is what they want to do with this witness, the bad conduct case.

MR. KLINE: Can I have the Bates number so we have a record?

MS. SULLIVAN: It has nothing to do with --

THE COURT: Wait. Now you are talking --

MR. KLINE: Hello?

THE COURT: Mr. Kline, sit down for one second. Let me get this for the record. Is this the one from Pamela Rasmussen, is that what we are talking about? January 23, 2003 to Carin Binder?

MR. KLINE: Yes.

THE COURT: What is the line you want?

MR. KLINE: I -- of course, I am interested in a couple of things, but the thing that is astounding is that the people who are writing this Janssen article and trying to not warn rather than warn about a key finding, say that the key author is a go-along. And we question --

THE COURT: I am not going -- that one, Mr. Kline, sorry, but that one you need to get through the author of this. This is sort of like an opinion about somebody else's opinion, and I just don't want to get into that world except through direct testimony.

MS. SULLIVAN: And it's not relevant, Your Honor.

THE COURT: Its relevance also is a

little bit of a stretch. So if you want it, it has to come in through its author.

MS. SULLIVAN: And even then, Your Honor, it has no relevance to the claims in this case.

THE COURT: It's not coming in through Dr. Kessler so we don't have to worry about it right now.

MR. KLINE: But the issue will be before the Court again when we do the deposition cuts for binder. We will argue it then.

THE COURT: We will look at it then. But for Dr. Kessler, that is like getting into an opinion of an opinion.

MR. KLINE: It's a pretty amazing document, though, sir.

THE COURT: It could be, I don't know.

MR. KLINE: I think --

THE COURT: Marianne, before we bring the jury out, I need to have these documents in hand. Ask Mr. Gomez to give us those documents.

MR. KLINE: Those documents?

THE COURT: I didn't destroy your binder. I would like to have those particular documents here.

MR. KLINE: That's your binder now.

THE COURT: I know, but the documents we are relying on as potentially admitted evidence are those documents that we have just gone through. Tabs one, 15, 16, 21, 22, I probably missed one. I want to make sure that I have them before we start Dr. Kessler's testimony, and we are limited to that. Anything beyond that is going to be inadmissible now through Dr. Kessler, because we have a jury waiting, it's ten after 11 and I do want to get started with his testimony.

Mr. Gomez, tab them for me again, that will be easiest.

MR. GOMEZ: 16, 20 --

THE COURT: Wait. 15, then we have 16?

MR. GOMEZ: 16, 20, 21.

THE COURT: There are two E-mails on that. The one we are admitting is November 16, 2002 at 11:14 a.m., Prolactin Manuscript. That's the one we are talking

about, right?

MS. SULLIVAN: Yes, Your Honor.

MR. GOMEZ: Is that the Carin Binder E-mail, Your Honor?

THE COURT: Carin Binder to Vincent Nys.

MR. GOMEZ: Your Honor, that was Tab 20.

THE COURT: It says Tab 20, but there are two E-mails on there, I want to make sure we are talking about the same one.

MR. GOMEZ: We are, Your Honor, the bottom one.

THE COURT: The bottom half, okay?

MR. GOMEZ: Okay. Tab 21.

THE COURT CRIER: Can I have the Bates number?

MR. GOMEZ: JJ RE-14088063. Carin Binder to Gahan Pandina.

Tab 22, Gahan Pandina to Caren Binder, December 3rd, 2002, at 2:13.

THE COURT: That is December 3rd, 2002? At 2:13 p.m.

MR. GOMEZ: Do you need a Bates number?

THE COURT: All right, and that -- which is the one that includes the draft manuscript?

MR. GOMEZ: That was Tab 16.

THE COURT: All right, to be clear, the admission of 16 would include the draft manuscript. And these all, of course, are subject to their proper introduction. They are used -- Plaintiff would be in trouble if they do not admit those documents through what we discussed and proffered to me. But they can be used now.

The rules would be that, to be very clear about this, these documents can be shown to the jury or read to the jury on the screen, and then questions about those documents are permitted but they are subject to an evidentiary consideration. And if it calls for speculation on the mindset of an individual, I will sustain the objection. Because I think that ultimately, you know, the point is that they are the basis of an opinion and the jury has the basis right in front of them.

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Any commentary about what was going on in the minds of other people that is speculative is subject to a potential ruling adverse to Plaintiffs.

So keep that in mind. If you have a document that you need, I am not sure what you really need.

MR. KLINE: I hear you. One point of clarification, Your Honor. I understand everything. Famous last words.

I want to make sure I understand, please indulge me. I have deposition testimony, and the deposition testimony from all of these documents is from Binder or Pandina, saying that this is the document, this is what I wrote, and that's what it is. It's basically authentication.

THE COURT: That's fine. The main evidentiary concern is that the jury understands that there is a source for these documents, that it came from a certain location or a certain company, and that it was in fact generated within the company, and that was a document that was relied upon by the

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expert witness in forming his opinion. That's all this is.

Mr. Murphy?

MR. MURPHY: Mr. Gomez identified these various exhibits, Your Honor, and he began with Tab 15. I just want to make sure that we are all clear that as to the document behind Tab 15, you said it's out.

THE COURT: That is out.

MR. KLINE: Just a very short comfort break before we start?

THE COURT: Yes. We will take a recess now and then we will have the jury finally come in.

MR. KLINE: Should I get Dr. Kessler back in the room?

THE COURT: Yes.

(A brief recess is taken.)

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(The following transpired in open court:)

THE COURT: Before we bring in the jury, I would ask the journalists in the courtroom, make yourself known to Marianne

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Mari so we know you are here. And the chief rule that I am concerned about is it is ordered that nobody shall make realtime verbatim transcripts available to the general public.

MR. KLINE: Your Honor, as to realtime, the Court had --

THE COURT: I mean verbatim transcripts.

MR. KLINE: Yes. As to realtime, we had a discussion and the Court ruled that they could send it to their war room and that we would be told the names of the people. I have the specific colloquy. I asked Mr. Murphy and I was given back an answer essentially that tells me that they have all their lawyers in both firms, which, by the way, are 2,000 and some, and I would simply like, perfect the Court's ruling, to know who has access at any time to this.

The answer back to me I did not think satisfied the Court's instruction, which was to tell both me, and I would hope the Court, given all the interest in this trial, who is

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actually getting realtime that's not in City Hall. I think that's fair.

THE COURT: Right, well, okay --

MR. KLINE: Not to tell me that they have thousands of lawyers.

THE COURT: I understand it. As I said, for the journalists, the order of this Court is no one may transmit realtime verbatim transcripts to the general public.

Now regarding realtime verbatim transcripts to members of the parties' attorneys, yes, there is a point well taken. It was not my intention that these documents be made generally available to a large law firm, because it's not within this Court's control, nor probably, Mr. Murphy, your control as to what an associate does with realtime transcripts on his own.

MR. MURPHY: Understood. And as I made clear to Mr. Kline and Mr. Gomez, only the lawyers who are working on this litigation, lawyers who are working on this case, are the ones who get this. Different people are called in to do different things at different

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times.

MR. KLINE: That's the problem.

MR. MURPHY: Well, within the team, if you will. So what Mr. Kline is asking for, is a list of people who get this.

MR. KLINE: Yes.

MR. MURPHY: So someone may be looking at it on a Monday, a different person may be involved on Tuesday for a different issue. So if what is requested an after-the-fact record of the people who got it, no problem. But what I can't do at this time is determine who may be working on it next week. But the point of the matter is --

THE COURT: I don't have a problem, I don't really think it's our business who particularly within a law firm is working on a particular case at a particular moment. What I think is important, though, is that the transmission of these transcripts are in someone's responsibility that is known to the Court and to opposing counsel, and that it is not put out as a generally available transmission to your firm, let's say, all the

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attorneys at Dechert. I mean there are hundreds of attorneys here who have nothing to do with this case.

MR. MURPHY: Understood, and only the attorneys at Drinker, Biddle & Reath working on this litigation are the ones who have access to it.

THE COURT: So it's not going out at Drinker as a --

MR. MURPHY: Absolutely not. It's not a broadcast that anyone can tune into at any time.

THE COURT: Do you have an objection to that?

MR. KLINE: Yes. I respectfully request, given all of the interest and all of the issues that are involved here, that we simply be told, and the Court simply know, what lawyers in the Weil firm, and what lawyers in the Drinker firm have access to the realtime feed.

That is not an overreaching or overburdening request. The Court should not have, in my respectful opinion, and this is a

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matter given the change of technology that probably the Rules Committee and the Supreme Court will have to take up, but the defense should not have phantom people who are not under the control of the Court. One last point. I raised this issue, here was the answer I got back.

Your Honor said the other day that, when we allowed this, it was asked and answered. I said, "And I want to know the lawyers involved, I assume" and the Court said "Yes."

And then what happened was, I said, Who are the lawyers? And listen if you would, please, Your Honor -- this if from Mr. Murphy -- "As you are aware, Drinker Biddle and Reath is a national counsel. Attorneys and paralegals from various of Drinker Biddle offices have worked on this litigation and continue to do so. Certain of them have been involved in the instant case and may be called to assist. Thus, live feed is available to them as needed."

Now I don't know who they are or where

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they are.

"And the list of those called to assist is not constant." I don't know who they are, neither do you, Your Honor.

"This is the same true for the Weil firm."

By the way, I look at their website. They both combined have over 2,000 lawyers.

MS. SULLIVAN: I can make it easy for Weil. Every Weil lawyer is in the courtroom.

THE COURT: We can take this up at another moment. I really want to move forward. The rules for the journalists are clear.

As far as -- I think that I would be satisfied if at the end of the week of this litigation we are given a list of names of attorneys or paralegals who have shared in this information so we have some accountability. Obviously, if there are leaks, shall we say, we will then address that in terms of some kind of sanctions or contempt hearing, and that would be a separate proceeding from this trial.

So everyone is on notice that I do consider this to be an important matter. We have raised this issue among the Judges of the Court of Common Pleas, we are aware of changes in court reporter status come this summer. In the meantime, as far as this trial is concerned, I respectfully am asking counsel to have the names of the individuals who have shared in these transcripts available to Mr. Kline and the Court at the end of each week.

MR. MURPHY: Fair enough, Your Honor.

MR. KLINE: The other thing, Your Honor, is I don't know if you instructed the jury about publicity. You might want to tell them earlier rather than later that there may be things written in the newspaper and they should not read the paper.

THE COURT: We will certainly tell them that.

MS. SULLIVAN: Your Honor, I appreciate the instruction about not reading the paper. I object to telling the jury there may be something in the press like this is a big, big case. I know Mr. Sheller has done a lot to

trump it up, but I would respectfully object to the Court telling the jury that this may be a case that is worthy of the newspapers.

THE COURT: I never got involved with that. We have we have had high profile criminal cases and --

MS. SULLIVAN: I understand it's a standard instruction.

MR. KLINE: That's all I ask for was a standard instruction.

MS. SULLIVAN: And for the Court's information, we have filed and I will hand up a courtesy copy, the motion to exclude Dr. Kessler on the serious adverse event pre-emption issue.

THE COURT: I am not going into that right now.

MR. KLINE: I do not intend to ask Dr. Kessler as to a serious adverse event to give the Court a review.

MS. SULLIVAN: The problem with that on the pre-emption front is that's the only thing that gives rise to a duty to put it in the Warning label.

THE COURT: Ultimately that's a legal decision that the Court will make and I will make it when the time comes. Pursuant to this motion or pursuant to a jury instruction, I have, as you know, read the CFRs involved here. I do think, having not read your brief, I would rather not peg myself on this, but it would seem to me that any type of injury that we require some kind of medical procedure in order to repair would come under a severe adverse impact definition.

MS. SULLIVAN: That's the point, Your Honor. This doesn't require that, it's elective.

THE COURT: I believe ultimately that's going to be a factual issue for the jury to decide. If we have testimony eventually in this case about what can be done to repair any damage that may exist, that would be, I think, a factual question for the jury to decide.

So I understand your point, but I am letting you know ahead of time before Dr. Kessler's testimony that that is likely the Court's view, because I have read the CFRs on

this issue.

MS. SULLIVAN: Your Honor, the point with Dr. Kessler, his whole opinion goes to the duty to warn based, even if he doesn't say it, so you can only put in your Warning what's a serious adverse event.

THE COURT: I am sure you are not honing your whole defense based on this issue. We wouldn't be here otherwise. Let's have the jury come in.

MR. KLINE: Your Honor, I believe I handed up to the Court the couple of cases that deal with what I believe is going to be their attempt to cross examination on money.

MS. SULLIVAN: Your Honor --

THE COURT: Right now, we have had a lot of pre-witness -- let's just rumble now and see what happens as far as rulings during the actual course of the testimony. We have given enough framework, I think, to guide you.

(At this time the jury enters the courtroom.)

THE COURT: Good morning, members of the jury, we are still saying good morning.

All right, did everybody have a nice snow day yesterday? Whatever. I am glad I am not a meteorologist in this city.

But we are here now. We have had some discussion about some law involved with this next witness, which I believe, hopefully, will have saved us a lot of time. So we will find out.

So what we are going to do now is we are going to begin the testimony of a new witness, and we are going to go for a full hour until about quarter of one and take our break then.

So, Mr. Kline, your next witness, please.

MR. KLINE: Your Honor, thank you very much. The Plaintiff calls David Kessler.

(DAVID A. KESSLER, MD is duly sworn.)

MR. KLINE: Proceed, Your Honor? Is my mic on, Judy? Good morning, all.

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DIRECT EXAMINATION (QUALIFICATIONS)

- - -

BY MR. KLINE:

Q Good morning, Dr. Kessler.

A Good morning, Mr. Kline.

Q Dr. Kessler, you have been marooned in Philadelphia for a number of days; is that correct?

A Yes. It's been a pleasure.

Q Between our three-day jury selection and our delays, you are now prepared to testify, sir?

A I am.

Q You held a position with the Government of the United States for a period of six years. What was that position, sir?

A I was Commissioner of the United States Food and Drug Administration.

Q And which President appointed you, sir?

A George Bush, the father.

Q And in what year were you appointed as the Commissioner of the FDA?

A 1990.

Q And then when the Administration changed, did President Clinton keep you on?

A Yes.

Q And did you serve as the Commissioner of the FDA during the first term of President Clinton?

A Yes.

Q And what were your years of service to the United States Government and people as the Commissioner of the FDA?

A End of 1990 to the beginning of 1997.

Q A period of roughly six years?

A Yes.

Q Six-plus years. Sir, what is the FDA and -- by the way, is that a cabinet level position but not confirmed by the United States Senate?

A Just the opposite, it is not cabinet level but it is confirmed by the United States Senate.

Q I see. And what date were you appointed, approximately? What month and year were you appointed and then confirmed?

A It was in the Fall of 1990.

Q During your tenure at the FDA, did you have a number of achievements which are important to the American public as we sit here today?

MS. SULLIVAN: Objection, Your Honor, as to what's important to the American public.

THE COURT: That's sustained.

Q Did you have a number of achievements, sir, as Commissioner of the Food and Drug Administration?

A Certainly things that I am proud of.

Q What are they, sir?

A 1990, when I became Commissioner, there was only one drug for HIV and it didn't work very well. By the time I left, there were 17 drugs available. It was a historic period of drug development, people worked very hard, and while not a cure, none of those drugs are a cure, it changed the course of that disease. So it was a historic period of drug development.

Q Were there other significant accomplishments during your tenure as Commissioner of the FDA?

A I think so, yes.

Q I am sure you can't list them all but can you give us some idea what happened in that period? I know it's 20-some years ago.

A So pick up any packaged food, you pick up a pack of M&Ms and see those nutrition facts? How much fat, how much cholesterol, how much salt? We did the nutrition facts while I was at FDA.

And probably one of the other most significant things we did was the regulation to protect children and young people from tobacco. That was also one of the other big things we did.

Q And what has your role been in that regard? What has your role been with respect to tobacco regulation, briefly?
A Well, while I was at FDA, sir?
Q FDA, and then afterwards?

MS. SULLIVAN: And I am just going to object, Your Honor, I am not sure what tobacco regulation has to do with pharmaceutical regulation in terms of qualifying him.

THE COURT: If you can explain the relevance, go ahead.

BY MR. KLINE:
Q Can you explain the relevance, sir, to your background and experience in terms of knowledge of regulation of food substances and pharmaceuticals?
A Well, the specific question we looked at was whether nicotin was a drug under the Federal Food, Drug and Cosmetic Act, and I led that investigation.
Q And what did that investigation result in?
A It took 15, 20 years, a major investigation into the tobacco industry, a lot of court cases. Ultimately, the Congress passed legislation that the President signed in 2009 to give FDA the authority to regulate and protect young people, children and

adolescents.
Q And by the way, sir, you are not here speaking for the FDA?
A Absolutely not.
Q The opinions that you will be asked to render here today, are those the opinions of David A. Kessler, MD?
A Exactly.
Q And are you a medical doctor?
A I am.
Q I hear you are also a lawyer?
A I never took a bar exam. I went to med school, I also went to law school. I never sat for the bar.
Q So you never practiced law?
A That's exactly correct.
Q Let's talk about your background briefly and try to get through this, but I do need some underpinnings, especially as they relate to this case.

First of all, you went to medical school and you went to college. Where did you go to college?
A Amherst College.

Q And that's located where?
A Weston, Massachusetts.
Q After you graduated from Amherst, did you attend medical school directly after that?
A I did.
Q And by the way, you graduated from college in 1973?
A Yes, sir.
Q By the way, just for background, you grew up where?
A I grew up in New York.
Q And you went to Amherst to college, graduated in 1973. Where did you then go to medical school?
A Harvard.
Q Harvard Medical School. And how long were you at Harvard, sir? For four years? Until 1979?
A Well, it was a little more than four years because I went off to law school in the middle of med school. So it took me a little longer than four years. It took me six years.
Q I see. According to your curriculum vitae, which, by the way, is marked for identification purposes during this trial under Tab One, Bates numbers 001 through -- Kess CV 001 through 025.

You got a degree from Harvard Medical School in 1979, is that correct, that was your medical degree?
A That's correct.
Q In between you got a law degree from the University of Chicago?
A Yes.
Q And then you went on to get from NYU in 1986, it appears, some additional certification in management; is that correct?
A In business training, yes. I was running a hospital.
Q What kind of doctor are you, sir?
A I am a pediatrician. I was trained as a pediatrician.
Q Are you a practicing pediatrician today?
A Not really. I have tapered off.
Q Do you see patients today?
A Occasionally, but it's not what I do. I am a professor of pediatrics.
Q And let's explain that in a moment. Before getting to be a professor of pediatrics today, let me talk about your training, education and background. The jury already has seen one medical

expert so they know kind of the drill on this.

After medical school what did you do in your medical training?

A Johns Hopkins Hospital. I did my pediatric internship and residency in Baltimore.

Q I see. Did you then become Board certified?

A Yes, I did.

Q So you were a Board certified pediatrician in that period?

A Right. I was Board certified for some 30 years. I need to take my recertification, I haven't done that. But I have been Board certified for 30 years.

Q You have taught at a number of institutions, correct?

A Yes.

Q And it looks like at some point you taught at Columbia University?

A I taught Food and Drug Regulation and Law at Columbia Law School.

Q And that was right before you became the Commissioner of the FDA?

A Exactly.

Q And then after you were the Commissioner of

the FDA, seeing that you were the Commissioner of the FDA 1990 to 1997, you then went to the Yale University School of Medicine?

A I did.

Q What did you become there?

A I was Dean there. I was also professor of pediatrics, epidemiology, public health.

Q So you were the Dean of the School of Medicine at Yale University; is that correct?

A Yes.

Q Following your stint as the United States Food and Drug Administration Commissioner?

A Yes.

Q You then, today, let's go to today -- and that lasted from 1997 to 2003?

A Approximately, yes.

Q So to put your, kind of later career in perspective, 1990 to 1997 you were Commissioner of the FDA, 1997 to 2003 you were the Dean, that's the chief academic officer of the Yale University school of medicine?

A Of the medical school, yes.

Q And then you then moved to the University of California; is that correct?

A At San Francisco, yes.

Q And since 2003, what have you been doing at University of California San Francisco, sir?

A Among other things, I am currently a professor of pediatrics, professor of epidemiology, professor of biostatistics.

Q Tell the members of the jury, the field of epidemiology, because we are going to hear something about studies here today and I want to make sure that they understand it, what you might know about them?

A So a physician who takes care of patients takes care of one patient in front of them or a family, or a number of patients every day. Epidemiologists look at diseases in population, in certain groups of people, and use certain methods to study epidemiology which is diseases in populations.

Q And when you say diseases in populations, does that mean things that can arise that are studied, like symptoms that result from a drug, would that be included in epidemiology?

A Sure. Epidemiology looks at a lot of those kinds of questions; is this drug associated with this side effect, does this drug work.

So those methods to answer those questions that we used at the Food and Drug Administration while I was there were epidemiological methods.

Q Is that one of the things that qualified you to be the Commissioner of the FDA?

A There are a lot of things, I think, they would look to. I certainly had a wide understanding. I had written extensively in the area before I was nominated by the President.

Q I know you have written extensively in the medical literature. You have published articles as well as books; correct?

A Yes.

Q In fact, you wrote a *New York Times* bestseller -- my copy says this is due back in the library 2-11-15 -- but it's entitled, The End Of Overeating: Taking Control of the Insatiable American Appetite, by David Kessler MD, correct?

A Thanks for the pitch for the book, Mr. Kline, I appreciate it.

Q I am sure we will all run and get it. But it is available on Amazon dot com -- only kidding.

But the book is one of your

contributions to the overall understanding of this particular problem?

A Well, that book dealt with the obesity question and why we have such difficulty controlling what we eat and the question of overeating, and it was really the study of that.

I have written many professional articles in journals on Food and Drug regulation.

Q In your curriculum vitae, and I don't plan on burden us with this, also, there is a long list of articles and publications that you have contributed to the medical literature; is that correct?

A Yes.

Q And you mentioned epidemiology. I just want to hit the highlights here in qualifying you, my job being here to qualify you as an expert witness and ask the Court to so qualify you, that's why we are doing this, as you know.

I would like to ask you, you mentioned that you have both taught and have advanced training in biostatistics, correct?

A And even a more narrow field call pharmacoepidemiology, but also, I am a professor of biostatistics.

Q First of all, let's take the word apart. Pharmacoepidemiology, you already told me epidemiology being the study of human population?

A And pharmaco being drugs, so it's the study of drugs in populations. So it's not just when one person takes the drug but what happens when many people take the drug.

Q All right. And you are an expert in that field?

A I think that would be fair, yeah.

Q And you are also an expert in epidemiology as well?

A Yes.

Q And, also, you mentioned biostatistics, and we are going to hear here in this case about a particular finding that was statistically significant, so I want the jury to know your expertise there.

A So I understand especially biostatistics as it relates to the study of drugs. That's my real area of expertise. There may be -- there are mathematicians that are much smarter statisticians than I am, but I understand it as it relates to drug studies.

Q Sir, in addition to the degrees that you have been given that are what are called earned degrees, degrees in which you did the course work for and then got your degrees, like your medical degree from Harvard, do you also hold a number of honorary degrees that institutions have recognized you for your service and generally for your work?

A Yes.

Q And for example, is one of those Drexel University?

A Yes. I was honored to give the commencement speech and they also gave me a doctorate.

Q I think an honorary doctorate, if I am not mistaken?

A Yes.

Q Now, I know that you are at the University of California San Francisco. You also do significant consulting work, sir?

A Yes. I am on the boards of several companies, for example.

Q I want to talk about that. I will get back to that in a moment. Are you also in the process of writing and publishing another book?

A I am, and I have a deadline on Friday.

Q So while you were here in Philadelphia did you spend considerable time working on that?

A I have been working nonstop, actually, for several years.

Q What's the tentative title and who is the publisher?

A The publisher is Harper. It really follows on my books on tobacco and overeating and how certain things make us feel sometimes that we lose control.

Q What is it tentative entitled?

A It's called, Capture.

Q And consulting work, you told us, sir, briefly, first of all, are you involved on the boards of a number of companies?

A I am, sir.

Q Are these hedge funds or something like that?

A These companies are -- I have been on the company boards, one is a device company, it does things to protect people on the safety of the blood supply. Another is a small start-up company that's working on a prostate cancer drug for advanced prostate cancer. And I was on the board of a company that did drugs primarily in the GI area, but I am no longer on that board, that company was sold.

Q GI meaning gastrointestinal?
A I am sorry, yes, sir.
Q And have you consulted with pharmaceutical companies?
A Yes.
Q How about a pharmaceutical company called Johnson & Johnson?
A Yes, I have been asked and have consulted with them.
Q Okay, and what issues have you consulted with them on that you can recall?
A I don't have an exact recollection. I think I was asked questions about obesity drugs, to the best of my knowledge.
Q Were you ever asked about ethics by them as well?
A I have a recollection that I did -- it's a little vague in my head -- that I did a speech for the company, for the company lawyers. But again, my recollection isn't perfect on that.
Q Okay, now, the jury heard about you in both my opening statement and Ms. Sullivan's. She told the jury that you are going to come in here and dump all over Janssen. Is that what you are here to do?

A I am here to answer your questions and Ms. Sullivan's questions and try to educate the Court or explain to the Court the basis of how drug regulation works. That's my goal here.
Q And it was also represented here that you charge $1,000 an hour; is that correct?
A That is correct.
Q And, sir, do you charge $1,000 an hour whether the person paying the bill is a plaintiff's lawyer or whether it's a pharmaceutical company?
A That's correct.
Q And, sir, have you done work with pharmaceutical companies in litigation where you come to a court for a pharmaceutical company and testify?
A I have.
Q We also heard it stated that -- and by the way, you have been hired by a number of law firms, my law firm being one of them, and another firm that was introduced to the jury being Sheller, PC, to do work in this litigation. Have you done work in the litigation?
A I have.
Q And have you reviewed -- we can tell you, I

know because I asked last night and I represent, that there is something like three million documents that were produced in Risperdal litigation involving children and adolescents. Have you reviewed thousands of documents, would it be fair to say?
A Those boxes are full of documents that I have reviewed. So, yes, the answer is I have reviewed thousands of documents.
Q Did that take many, many hours to review?
A An enormous amount of hours, yes.
Q And have you indeed been paid to review those?
A Yes.
Q At your hourly rate, by lawyers who are representing children in Risperdal litigation?
A Your firm, the Sheller firm, yes, I have.
Q And, sir, to date, how much have you been paid, approximately?
A 275 hours, approximately, which translates into about $275,000.
Q And, sir, in addition to this -- and by the way, would the same thing be true if you were hired by a pharmaceutical company?
A I would do the same kind of thorough work that I tried to do here.

Q And actually, at your rate of $1,000 an hour do you turn work away?
A Oh, yeah. I mean, I get called all the time. I don't go out and seek this. I get called and --
Q You are not going to raise your rate on me while we are here, are you?
A No, I will not.
Q Now, let me say this. You were asked questions -- I want to make sure that the jury knows everything I can get out about you. We were told that "every couple of weeks" -- a couple being two in my universe -- "every couple of weeks" you come in and you testify against some pharma company. Have you and I sat down and figured out the number of times that you have testified in a courtroom, sir?
A We did the math, yes.
Q I want to go through it with you, rather than have this be --
MS. SULLIVAN: I am just going to object. Are you talking about just the courtroom or depositions there is testimony, too, Mr. Kline?
MR. KLINE: Of course, we are going to

do both, Ms. Sullivan.

MS. SULLIVAN: Good.

THE COURT: Is this part of his qualifications as an expert, Mr. Kline?

MR. KLINE: Yes, it's his professional work, and I am sure Ms. Sullivan would be asking about it and I want to put it out on the table.

Q First of all, you are in this courtroom here today. Have you been doing consulting work very long? How many years have you been doing consulting work in litigation?

A From about 2010.

Q So that's a period of about five years, okay?

A Yes.

Q And it was told to the jury that you come in and every case you come in you say somebody "failed to warn." Is that correct?

MS. SULLIVAN: He is misquoting the opening, I said everytime he comes to court --

THE COURT: Is there an objection, Ms. Sullivan?

MS. SULLIVAN: Yes, Your Honor. He should actually read it.

THE COURT: Objection is overruled. It's up to the jury to determine or remember what was said during opening argument and compare it to what's actually proven in court.

MS. SULLIVAN: Thank you, Your Honor.

MR. KLINE: I will rephrase the question:

Q "Every single case he comes in, every single case he comes in, Bayer failed to warn, Merck failed to warn, GSK failed to warn, Pfizer failed to warn, Allergen failed to warn."

Now I want to go through some of your past cases and who they were actually for.

First of all, sir, in a period of time --

MS. SULLIVAN: I am sorry, I hate to interrupt, Mr. Kline, but I thought we were doing qualifications so I can voir dire on --

THE COURT: If there is a an objection --

MS. SULLIVAN: I object. This is not qualifications.

MR. KLINE: If this is not going to be cross-examined on qualifications I will get

back to it.

MS. SULLIVAN: Oh, it's going to be cross-examined on.

THE COURT: I need to give the leeway to get everything out, and then there will be cross examination on it, and that again will depend on timing. Are you ready to proffer your witness as an expert?

MR. KLINE: Not yet.

THE COURT: Then let's get to it so we can then have this back and forth.

MR. KLINE: I will get to it. I know it's a big issue and I want to get it out on the table because she said it in her opening, and I want to get through this real quickly.

BY MR. KLINE:

Q Sir, have you counted up in five years the numbers of trials that you have been in, first of all?

A Yes, from 2010 through to the end of 2014, in that five-year period.

Q In that five-year period, how many times have you testified in a courtroom prior to today?

A I count seven. You can always give me a

little room, but my counting said seven.

Q Seven cases in five years; is that correct?

A At trial, yes.

Q And by my calculation, the jury was told that you were here every couple of weeks against some pharma company. That would mean you would be in the courtroom once every 260 days. Is that the math?

MS. SULLIVAN: Objection, Your Honor, again, he is misstating. I said he testifies, meaning at depositions and trials, misleading.

MR. KLINE: We will get there. I know she wants to do it.

THE COURT: Excuse me. The objection is overruled.

BY MR. KLINE:

Q Is that correct, sir? We did this math very quickly?

A Yes.

Q In the past five years, you have been in a courtroom on trial once every 260 days, correct?

A Approximately.

Q I understand. I went through the list with you to save time, correct?

A Yes.

Q Now, I want to just go through this quickly, then I want to get back to talking about your work at the FDA and qualify you.

The next thing, sir, is in that five-year period you did 22 depositions, correct?

A 22, 23, yes.

Q And two of them were in the Risperdal litigation?

A Correct.

Q Because they deposed you twice, correct?

A Yes.

Q A lawyer just like Ms. Sullivan asked you questions, correct?

A Yes.

Q And if you divide 1826 days that way, you were giving a deposition once every 65 days, right, approximately.

A Yes.

Q I want the jury to have a sense of your involvement. If you do the math, sir, is it something like 1 percent of your days are devoted to this kind of thing?

A This kind of testimony, yes.

Q Either in deposition or trial if you do the

math?

A I think we did 1.5 percent.

Q 1.5 percent of your days are spent in some kind of testimony, correct?

A Yes.

Q Now, very briefly, and then I will be finished, it was told to the jury that you testified that Merck failed to warn. Did that case involved an individual plaintiff like the young man I represent?

A No.

Q Tell me who was bringing claim in that case?

A There were three states. So it was the state of Louisiana --

MS. SULLIVAN: Objection, Your Honor, this goes beyond --

THE COURT: Objection sustained.

Q Sir, in the case where she said you came to court and said Pfizer failed to warn. Did that involve a case on behalf of a major healthcare plan, not plaintiffs?

A It was the Kaiser Healthcare Plan, yes.

Q And of the seven cases that you have set foot in courtroom -- and then I will be done with this,

because I want to get it out -- in the seven cases that you set foot in the courtroom, sir, how many of them have been for a plaintiff, a plaintiff, suing a pharmaceutical company, an individual plaintiff suing a pharmaceutical company in a courtroom like you are here today?

A I count three out of the seven.

Q So this is the fourth time in the five years you have been doing it, and the fourth time in your lifetime, correct?

A Yes.

Q All right, and I am sorry for taking so long on that.

Now, the -- did I miss anything, sir? I took a little too long on that stuff, but I knew that it was raised in the opening statement about you, I wanted you to know it and the jury to know it. Anything else?

MS. SULLIVAN: Your Honor, I object to Mr. Kline sort of running commentary. He can ask questions and the witness can answer.

MR. KLINE: Anything else that you have, sir?

THE COURT: That's sustained. Just a

caution on that. Go ahead.

MR. KLINE: I got it.

Q Anything, sir?

A I chair for those companies I have been on the board, I chair what's called, for the one company, a compliance committee. Another company I chair the quality committee. So those are dealing with the conduct of those -- how those companies should, because they sell drugs, they sell biologics and products, so I deal with sort of the rules that those companies should operate on with regard to those products.

Q Sir, are you familiar, as of the period 2002 to 2006, are you familiar first of all with pharmaceutical companies', their manufacture and their distribution and their marketing as well as their sales, as well as the safety and as well as indications in prescription pharmaceutical drugs?

A The answer is yes, both from my experience at FDA, and serving, you know, with these companies, and other experiences.

Q And I am specifically talking about the period 2002 to 2006, your answer to that was yes, correct?

A Yes.

Q And are you also familiar with the drug Risperdal, also known by it's name risperidone?
A Yes.
Q By the way, when the drug was approved in 1993 --

THE COURT: Counsel, I want to know where are we starting with -- are we starting with expert testimony?

MR. KLINE: Still qualifications. It will be done in about three questions.

Q In 1993, sir, as far as your knowledge goes of this drug, in 1993 when it was approved, what was your job?
A I was responsible for the FDA at that time.
Q You were the Commissioner?
A I was.
Q And are you prepared to express opinions, sir, here today which are based on your experience, background, and expertise as just outlined to the jury as to your knowledge as you have described?
A Yes.

MR. KLINE: I have nothing further on qualifications.

THE COURT: I do want to know what is

the field that you qualifying this witness in?

MR. KLINE: Yes. I have moving to qualify Dr. Kessler in the field of prescription pharmaceutical medications and their labeling -- I have to ask him that question.

BY MR. KLINE:
Q You are familiar with the labeling of drugs as Commissioner of the FDA?
A I studied it for over 30 years, yes.
Q And you are also familiar in terms of both warnings and precautions that a drug company would give to a physician as part of the prescription drug medication, are you, sir?
A Very much so.

MR. KLINE: I move to qualify Dr. Kessler as an expert in the field of labeling, warning, precautions, as well as regulation of prescription pharmaceutical medications, and in fields which relate to his background and experience and qualifications which I just outlined, sir.

MS. SULLIVAN: What fields would those be, Your Honor?

MR. KLINE: Those fields would be biostatistics, those fields would be epidemiology, those fields would be pharmacoepidemiology, those fields would be regulation of prescription drug products, those specifically, and as an expert in warnings as they should go to physicians outside of the label.

THE COURT: All right, well, we will get to the fields. Are there any objections -- first of all, I just want to know where we stand. Are there objections to the specifics of the subject matter of the fields?

MS. SULLIVAN: Yes, Your Honor, may I briefly voir dire?

THE COURT: Why don't you go voir dire and we will get to that.

MS. SULLIVAN: Thank you.

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CROSS-EXAMINATION (Qualifications)

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BY MS. SULLIVAN:
Q Good afternoon, everyone. Good afternoon, Dr.

Kessler, a couple of questions. You talked about how you used to work for the FDA, but you are not here speaking for the FDA?
A Absolutely not.
Q And, in fact, Dr. Kessler, you are not authorized to speak for the FDA?
A No one who is an expert who doesn't work there should be.
Q And so your opinions, Dr. Kessler, are your own and Mr. Kline's, they are not those of the FDA?
A I am sorry?
Q Your opinions here are your own and Mr. Kline's, they are not the opinions of the FDA?
A My opinions are Mr. Kline's?
Q Your opinions are your own, Dr. Kessler, not the FDA's?
A Yes.
Q And, Dr. Kessler, you haven't worked for the FDA in almost 20 years?
A I left as Commissioner in February of 1997, yes.
Q And, Dr. Kessler, you know that this case involves a prescription antipsychotic, right?
A Yes.

Q And you are not a psychiatrist, not Board certified in the area of psychiatry?
A I am not, but I understand --
Q Could you just answer that, and I am sure Mr. Kline will go back, but could you just answer my question. You are not a psychiatrist or Board certified in psychiatry?
A That's correct.
Q And you have never described an antipsychotic?
A I have to go back and review. Probably not.
Q And you don't have any clinical experience with Risperdal, in terms of patients, prescribing it?
A I would have to go back and review. I have taken care of a lot of patients over the years so I don't want to represent, but I have no clinical experience --
Q None that you recall?
A I am not a psychiatrist, it's not within my traditional wheelhouse.
Q And, doctor, you have not written or published any articles on the use of antipsychotic medicines like Risperdal, right?
A My current book is coming close to that. But

to date, I have not.
Q And you know, Dr. Kessler, that this case involves the injury or condition gynecomastia?
A Yes.
Q You are not an endocrinologist or Board certified in endocrinology, the specialty that treats that condition?
A I am not an endocrinologist, but pediatricians treat gynecomastia, too.
Q But you are not Board certified in endocrinology?
A Exactly.
Q And you have not written any publications or done any clinical research on the issue of gynecomastia or prolactin?
A That would be fair, yes.
Q And, doctor, you actually don't currently practice medicine at all, right, sir?
A I am licensed in the State of California. If you collapse here in the courtroom I will come over, I promise you, if you want. Someone on a plane, recently, those kind --
Q But in terms of active medical practice, you don't practice medicine anymore?

A I am licensed to practice, but I don't have a shingle out, I don't have an office. But I spend a lot of time on medical issues.
Q And you are not here, Dr. Kessler, to tell the jury whether Risperdal causes gynecomastia, you are not a causation expert?
A I am not a causation expert. I am happy to answer your questions that you ask me.
Q And, Dr. Kessler, you know this case is about Mr. Pledger?
A Yes.
Q You are not here to talk to the jury about this patient, Mr. Pledger?
A I reviewed the medical records, I have read the deposition of his treating doc. Again, I will answer your questions, Ms. Sullivan.
Q And, Dr. Kessler, you told us at your deposition that you hadn't been provided all of the medical records in this case?
A I had a binder, I am sure -- I made no representation that it is complete at all.
Q And it's true, Dr. Kessler, that other than when you issued your expert opinions in this case, your report, other than Dr. Mathisen's deposition,

the Plaintiff's lawyers hadn't given you the testimony of any of the other treating doctors, right?
A For this --
Q Yes.
A I think that's correct.
Q And you talked a little bit, Mr. Kline and you talked a little bit about clinical trial research and clinical trials. You have never been a principal investigator on a clinical trial?
A I have been a principal investigator at Yale and UCSF clinical research center that does multiple clinical trials. So I have been a PI of the center that does those clinical trials. I am not the one who carries them out, I think would be fair to say.
Q Fair enough. In other words, Dr. Kessler, you personally have never done clinical trial research?
A I don't think that would be -- I have not carried them out, but obviously, I have reviewed clinical trials, clinical trial research as relates to FDA.
Q But you haven't done -- in other words, and just so the jury knows, when we talk about clinical trials we are talking about where doctors in the

pharmaceutical context review a medicine to patients, sometimes hopefully controlled studies and watch what happens, follows them, collect the information, analyze them, you have not conducted clinical trials?

A You used the word "analyze them." I have certainly been on the analysis side because that's what FDA does. But usually the data is given me. Is that a fair --

Q Yeah. You are not the doctor that actually prescribes the medicine, treats the patients, and provides the data?

A Actually, you know, just going back and thinking, during my training I have been involved in clinical trials in prescribing the drugs. But it's not really -- I mean most of the time the data is given me and then I review that data. But sitting here now, I have recollections that I participated in clinical trials.

Q And, Dr. Kessler, you know in this case that the FDA -- well, I will reserve that, Dr. Kessler, and we will get to it later.

MS. SULLIVAN: Your Honor, on Dr. Kessler, I have no objection on the regulatory

issues. I do have an objection of Dr. Kessler going beyond his expertise in the regulatory area, thank you, Your Honor.

MR. KLINE: Redirect on qualifications.

THE COURT: I don't know what you mean by regulatory. So far, I have the proffer for Dr. Kessler as an expert in pharmaceutical prescriptions and medications, labeling of pharmaceuticals, their warnings, their precautions and their regulations, and also an expert in the field of biostatistics, epidemiology and pharmaco-statistics. Any objection to though specific qualifications?

MS. SULLIVAN: Your Honor, on the issue so Dr. Kessler has acknowledged he has never prescribed antipsychotics, so I would object to warnings as interpreted by prescribing doctors.

I don't have a problem with Dr. Kessler talking about the FDA, his opinion on the FDA's standards in terms of labeling, but he is not a prescriber. So as to what something would mean to a prescriber, how doctors --

THE COURT: I am going to permit the

qualifications as I have just read it. The question of what Dr. Kessler, if he were in the position of a prescribing doctor, that, I understand is not the proffer of the opinion testimony in this case; is that correct? It does not go to causation.

MR. KLINE: That's correct, Your Honor, yes. We do not intend to ask him --

THE COURT: So therefore, he is permitted to testify as an expert witness in the fields of pharmaceutical prescription, pharmaceutical medication, the labeling of pharmaceuticals, their warnings and precautions and their regulations as related to the FDA, and also in the fields of biostatistics, epidemiology, and pharmacoepidemiology.

THE WITNESS: I will take the Judge's also.

THE COURT: Pharmaco-statistics. I am comfortable with qualifying Dr. Kessler in those fields. I am going to tell you this. This is for the jury, we are going to get into about 15 minutes of the actual testimony on

these issues and we will adjourn for lunch, so we will get started.

What I want to tell you about expert witnesses at this point is that an expert witness is qualified to give an opinion that you or I as laypeople could not give based on the scientific experience, their experience in those fields. All right?

Now, I will tell you more about an expert witness' testimony during jury instructions. The thing to remember is that expert witnesses are like any other witnesses in the sense that you do not have to accept their opinions. You can, you cannot, it's up to you, and their credibility is up to you. So in other words, they are subject to the same kind of credibility decision making that you would make for any other witness.

What they are allowed to do, however, is to give you an expert opinion for you to consider. All right?

So, Mr. Kline, you may proceed now with your witness.

MR. KLINE: Your Honor, thank you.

Thank you again.

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DIRECT EXAMINATION

- - -

BY MR. KLINE:

Q Dr. Kessler, as part of the, I believe you said 274 hours that you spent on this, did a report result from that, that you actually had two depositions taken about. Did you issue a report?

A Yes.

Q And I have marked as KESS Report 001 through KESS Report 126, Bates number -- and for the Court we will have all of these documents, of course -- I have before me, with your CV it's a hundred and some pages. It's a 92-page report. Is that correct, sir?

A Yes.

Q And in that report did you review a lot of materials, synthesize it, and state both your findings and opinions?

A Exactly.

Q And are you, sir, prepared to go through some of the findings and opinions that I direct you to here in the courtroom?

A Yes.

Q And the next thing is, and that was a report that was dated -- see if I can find the date on it.

A If I may give it to you, it's September 17, 2012.

Q And that's another thing. You were asked to work on this matter and provide testimony if needed way back in 2012, correct?

A Yes. It's been several years.

Q And by the way, is this the first time you have come into a courtroom regarding Risperdal to express an opinion?

A Yes.

Q There was a supplemental report, which is marked as KESS report 127 through KESS report 143, and that supplemental report is dated -- I don't see the date on it.

A March 14, 2014.

Q March of last year?

A Yeah.

Q And again, does that report contain opinions that you have expressed and a discussion of information which you reviewed?

A Yes.

Q Dr. Kessler, I know you stated earlier that you reviewed boxes and boxes of materials. Were some supplied to you in paper form, some supplied electronically, I assume?

A Exactly, and others I have instructed people to search a computer database to look for documents.

Q And truly, in a prescription drug like Risperdal are there, we now know, millions of documents?

A There are vast, vast number of documents.

Q In this case were there numerous clinical trials on the drug as it pertained to children and adolescents as we go forward and outline this for the jury?

A Yes.

Q And did you review all of those trials?

A Yes. It's important, Mr. Kline, just to put a footnote, when you are talking about trials, trials are done for a drug for a specific use. So, for example, trials were done in children for conduct disorder, or autism, or bipolar. And I reviewed those, certainly the long-term trials, the safety trials for those indications, yes.

Q I think in the few minutes I have left, rather

than going through the label which we will do after lunch, the 2002 label and the 2006 label, I will just ask you this: Was Risperdal approved for use by the FDA in children with autism at any time prior to October 2006?

A No. It was approved on October 6, 2006.

Q October 6, 2006, was the date it was approved?

A Yes.

Q And prior to that date, was it an approved drug for use in children and adolescents?

A No, it was not.

Q In the period of 2002 to 2006, did Janssen Pharmaceuticals have information in their files that related to the safety of this drug?

A Yes.

Q And did they have information in their files in particular relating to both increase in prolactin levels as well as gynecomastia?

A Yes.

Q And are you prepared after our break to discuss that with the jury?

A Yes.

Q And we will put these documents up, but in 2006, did the label as approved for autism say that

the risk of gynecomastia in children and adolescents was 2.3 in 100?
A 2.3 percent, yes.
Q 2.3 percent?
A Yes, exactly.
Q And, sir, in terms of side effects, the way they are classified by the FDA, is that -- how is that categorized?
A So anything that is greater than one in a hundred would be classified as frequent.
Q So prior to 2006 when the label was approved by the FDA for the use of this drug for children and autism, was it known to Janssen Pharmaceuticals that the risk was 2.3 or greater during the entire period of time from 2002 to 2006?
A Yes, there was such data.
Q Now, we will put the exact language up, but the 2006 label on the drug, when it was finally approved by the FDA for autism, made a statement, and that statement -- we will have it up after lunch -- said that this drug as it pertained to raising prolactin levels was worse than the other drugs, worse than the other antipsychotics?
A Greater elevation, I believe.

Q Greater elevation than the other antipsychotics, and the other antipsychotics would be, like we heard yesterday, like Abilify, correct?
A Yes.
Q And the period 2002 through 2006, did Janssen Pharmaceuticals know that exact information, that fact?
A Yes.
Q And in that period of time, sir, in 2002 and 2006, as to both things that Janssen Pharmaceuticals put in their label and told people when it was approved, did they tell physicians those two pieces of information at any time before October of 2006?
A I have no -- I have seen no information that they had communicated that, no.
Q I am going to ask you a lot of questions after lunch, sir, you but the one I want to start with is your overall opinion. Do you have an opinion, sir, with a reasonable degree of certainty, based on all of the fields in which you are qualified by the Court, as to whether Janssen Pharmaceuticals failed to adequately warn of the risks of gynecomastia and increased prolactin in children and adults in the period from 2002 through 2006, do you have an

opinion?

MS. SULLIVAN: And I am going to object, Your Honor, because that's the issue for the jury to decide.

MR. KLINE: We discussed this at length.

THE COURT: That's overruled. The doctor is allowed to make this opinion, but I am asking you to qualify. Failure to actively warn who?

MR. KLINE: Physicians. Physicians. Thank you, Your Honor.

THE COURT: With that caveat, that question is permitted.

Q You can answer the question.
A Yes.
Q And, sir, is the basis of your opinion stated in the reports which I have put in front of us which we will discuss after the lunch hour?
A Yes.
Q And are they also stated in documents which you and I have discussed, so we can hopefully be organized this afternoon with the jury, are they contained in the documents which you are well

familiar with?
A Yes.

MR. KLINE: Your Honor, we are not at the exact point but it would be --

THE COURT: All right, we will take a recess right here, ladies and gentlemen. We are going to recess, and we want to start Court again around quarter of two. It's around 12:45 now, at 1:45 we will return.

Please wear the yellow badges. As I said before, please do not discuss the case with yourselves or anyone else during lunch. And as I will say all the time, please keep an open mind, this case has a way to go and it's important that you keep the case to evidence that we are hearing here and not outside of this courtroom.

So that's our instructions right now, we will see you at 1:45.

(The jury exits the courtroom.)

THE COURT: All right, then we are in recess until 1:45.

(A luncheon recess is taken.)

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(Pledger v Janssen, et al.)

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

(Pledger v Janssen, et al.)

(Hearing is reconvened at 9:45 a.m. with all parties present.)

THE COURT: We are waiting for two jurors. Everyone be seated, please. So we are at the mercy of our jurors. Is there anything to discuss at this point while we wait for the jurors?

MR. GOMEZ: Your Honor, I wanted to hand up to the Court a binder of documents which would make it a little easier for you to follow along today. That's it for now, Your Honor.

(Pause.)

THE COURT: All right, we have our jury and we are ready to proceed.

THE COURT: I want to remind everyone again, the rules of the use of computers in this courtroom is I permit it, however, for those who are reporting it, I do not permit verbatim transcripts to be published out of this courtroom. So please do not do that, otherwise there will be sanctions. But otherwise, if you want to make a writing from here, that's okay, just as long as it's not a

(Kessler - Direct)

verbatim transcript of the actual testimony.

(The jury enters the courtroom at 9:58 a.m.)

THE COURT: All right, good morning, everybody, please be seated. All right, members of the jury, we are now resuming the direct testimony of Dr. Kessler, and when Mr. Kline is ready he may proceed.

(DAVID A. KESSLER, MD, having been previously sworn, resumes the witness stand.)

MR. KLINE: Your Honor, good morning, nice to be here.

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DIRECT EXAMINATION (Continuing)

\- - -

BY MR. KLINE:

Q Good morning, Dr. Kessler.

A Good morning, Mr. Kline.

Q I am prepared to continue. We left off yesterday with RIS, Risperdal International 41 Study, which we and they have labeled RIS 41, and I moved my chart that I have been doing over here.

We had discussed the interim results and we had discussed the topline results and we had

(Kessler - Direct)

discussed the final results, and where we left off was the 16 of the 419, that would be 3.8 percent, were Very Likely or Probably had gynecomastia, the boys in the study had gynecomastia, the boys five to 14. I believe that's where we were, correct?

A Yes, sir.

Q Let's pick up from there and hopefully work to completion and then have cross examination.

I would like to return to Exhibit 20, and the pages we were on were Bates numbers JJRE08344195. So it's the Bates number ending 195 and 196. And this is the table of patients with prolactin-related adverse events. You had told us they also in their company files used the term PRAE. Correct?

A Yes.

Q And we were discussing this table and what it represented. There are a few terms which I would like to simply focus on which were included. The jury has had the definition of gynecomastia. I would like you to tell us briefly the definition of amenorrhea.

A Amenorrhea is the absence of menses, the absence of menstruation. The absence of having your

(Kessler - Direct)

period.

Q I would like to display 195, that would be page 81 in the study, and I would simply like to go to, if you would kindly go across. Among the findings was a 14-year old girl who had amenorrhea that is listed in this report as Very Likely associated with the drug. Correct?

A Yes.

Q And the next thing that I would like you to point out -- if we can pull that down, and I just want to get another one. If I can get the 13-year old, non-puerperal lactation, galactorrhea. And what is galactorrhea?

A Galactorrhea is milk from the breasts. So it's a case where, in this case this 13-year old is lactating or producing milk.

Q Thirteen-year old girl in the study that is lactating milk, correct?

A Yes, and just to be exact, it says non-puerperal. So it's not associated with puberty.

Q And I see, by the way, that the investigator said in there "drug relationship doubtful", correct?

A Yes.

Q But nevertheless, it's included among the

adverse events, correct?
A It's one of those things that are within the constellation definition that the company used of prolactin-related adverse events.
Q And I would like to go to on the next page, I don't want to go through all 33, but let's look at the very top one.
You have a 14-year old with gynecomastia -- this is on page 196 -- 14-year old boy, gynecomastia, the severity is Moderate and the drug relationship is Probable, correct?
A Yes.
Q And the next one is a 12-year old boy, gynecomastia, and the result is Possible, correct?
A It is both Possible, and the way I interpret it, it is also Very Likely. There are two different doses. So it's both Possibly and Very Likely.
Q At the one dose, it's Very Likely, correct?
A Yes, and in the other one it's Possibly, yes.
Q And this is the chart from which you counted up all of your numbers to get to where you are, correct, these numbers?
A That's correct.
Q And these weren't fancy statistics you did, it

was just simple arithmetic?
A And many of these numbers are in the texts, too, the absolute numbers.
Q And then moving down to get a sampling, and this is the final report of RIS 41, which I believe you showed yesterday was the study that paid special attention to this symptom?
A That's correct, that's what the study said.
Q And it says here, I am looking at 3365, the 13-year old.
MR. KLINE: I am taking your advice, Your Honor, and going a little slower rather than rushing. I was rushing too much yesterday.
Q It says here 13-year old, gynecomastia, and the investigators say Very Likely. Correct?
A Yes.
Q And then if I can go down, we have a 11-year old, just two down, the one in between is a 12-year old, Doubtful; and the next one is an 11-year old boy who has gynecomastia, that means has breast tissue formed?
A Yes.
Q And it's Very Likely, says the investigator,

correct?
A Yes, on this report, yes.
Q And sir, when you have a rate of 3.8 percent, it may not sound like very much, you know, three or four in a hundred. Why is three or four in a hundred a very significant finding?
A If I told you that the rate of getting hit by lightening, we all go, No chance, you know, less than a thousand, less than a hundred thousand, that's not me. But if I am a physician and I am going to treat, how many patients would I treat with this drug, could I treat a hundred patients? So if five of those patients, I mean it becomes very real for that doctor.
And most importantly, it's not about the doctor, it's about the child. And once you are five out of a hundred and there is that kind of, how many times the drug is used. So this drug is widely used, I forget the exact number of prescriptions but it's in the thousands and thousands, so those numbers translate into real patients.
Q And these here were real patients, correct, who were using the drug?
A Absolutely. This was, understand, this was a

trial and a trial is always, you know, certainly under ideal conditions. It was a trial of about 500 patients total. So you see these side effects occurring in that population.
Now, and this is what FDA always has to be thinking about, okay, if I am using a trial of 500. Now that the drug is used in thousands and thousands of patients, what's going to happen. That's why those numbers become -- when you are in FDA you are looking for red flags, you are looking for signals, because it's not just what's going to happen in these 500, it's what's going to happen once the drug is being used widely. That's what you have to think about.
Q Let's just look at a few more. We could go through them all but let's just go on the same page to a couple of girls with PRAE.
On the next-to-last slide, amenorrhea. We have a definition, and here it's Mild and Probably, correct?
A Yes.
Q Lack of period, correct?
A Yes.
Q A girl who had begun to menstruate and then

went on this drug and stopped, correct?
A I would have to look at the exact case report to know about this child. We would have to pull it up.
Q Okay. Now let's look at a nine-year old girl. It says here C F; female, correct?
A Yes.
Q Nine years old, correct?
A Yes.
Q Breast enlargement, correct?
A Yes, that's exactly what's been reported here.
Q And the investigators in this very study said that that was probably related to this drug Risperdal in this study, correct?
A Yes.
Q And this would be one of the youngsters that would be included among the 33 that were listed as having prolactin-related adverse events, correct?
A Exactly.
Q Their term, not your term?
A No.
Q No what?
A No, it's not my term. I understand what the term is.

Q That's what I wanted to know, you understand that?
A Yes.
Q And all of these patients were included on this table which we have already established bears the Johnson & Johnson/Janssen topic, correct?
A This was put together by the company and it looks consistent with the results, yes.
Q And I believe we established this study, until the end of the study, until the final study, went on about what period of time?
A Well, this study -- there were some extensions of this study, but I believe this was approximately a year. Maybe it was 48 weeks. I would have to look exactly.
Q The study report which we have marked as Exhibit 20 is a document which is, I just want you to confirm this for me, a hundred pages long, correct? Just this document alone, in terms of what you reviewed?
A And I am sure I have appendices and schedules but the body of the report, yes.
Q Just the body of the report, that would be just the writeup of the report, correct?

A Yes.
Q And the document which the jury has seen and which you have discussed with me is part of this report, correct?
A Yes, absolutely.
Q For the record, it's paginated as Numbers 81 and 82 of the report.
Now on page 79 of the report, briefly, the very last sentence, would you read that last sentence for me and for the jury?
A I am on Bates number ending 193?
Q That's correct, page 79 in the report, Bates number 193, within Exhibit 20?
A The last sentence --
Q No, I can display it since it's up, but I was just going to quickly go by it. But go ahead, it's up and it's fine.
A "In 15 patients gynecomastia was still present at the end of the trial."
Q And so the math on that would be 15 out of 419, which is something around --
A I get 3.6 percent.
Q 3.6 percent, okay. So 15 out of 419. Is that any significance to you as you review this?

A Sure. It goes to the question --
Q 3.4 you said?
A 3.6. Approximately.
Q Okay, go ahead.
A It goes to this question of whether this is transient or whether this persists, and that's why that issue is significant, because it's telling you that gynecomastia is not transient but continues to persist in these patients.
Q Okay, moving along, I will push this forward and go to the report of RIS 41.
MR. KLINE: I am marking as exhibit P-23 the article which is entitled, "Risperidone in Children with Disruptive Behavior Disorders and Subaverage Intelligence: A One-Year Open Label Study of 504 patients".
(P-23 is marked for identification.)
A Exactly, that's a study that was published in the *Journal of the American Academy of Child and Adolescent Psychiatry.*
Q And did it include authors from the Janssen company?
A Yes.

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Q If we can display just the first page -- I am sorry, Exhibit JJ RE 03849812.

MR. KLINE: For everyone's information, the Bates numbers is what we work with to pull up the document. So that's why we have this little bit of cumbersome system, because there were millions of documents.

Q Now on Exhibit 812, is this the format that one finds is a medical journal generally, that is to say, a title, authors, abstract, and then a discussion of the writeup of the study?

A Exactly.

Q And does that change from journal to journal, or is it pretty much the same?

A It's pretty much the same.

Q And eventually, this study was written up in January 2005, correct?

A That's when it was published, yes.

Q The final results were known when?

A We would have to go back, the final results, as to when they were known I would have to check that. I can tell you that the report date, to go back to the title page, I am reading that as October 25, 2001.

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Q If I can quickly side by side display 4114, that would be JJ RE 08344114.

And the study itself is now being published in the medical literature some three years and four months later or so, correct?

A Approximately, yes.

Q There were other studies that were done that we mentioned yesterday as part of the five behavioral disorder studies? RIS 93, 97 --

A 19, 20, and 41.

Q Did it take three years or three and quarter years for those studies to be written up?

A I would have to go through each one to be exact. So 93, if I am correct -- I would have to compare the dates to be exact how long it took.

Q Perhaps we will just pass that and I will work out the math on it and we will do it after our break and I will see if that's what it is.

Would it be fair to say that those studies were written up within a short period of time, not a three-year period of time?

MS. SULLIVAN: Objection, Your Honor, lacks foundation. The witness just testified he doesn't know.

(Kessler - Direct)

MR. KLINE: I will get that information in front of the jury.

Q This study, sir, the abstract, if I can now go to the first page of Exhibit No. 23, sir, in the abstract, does the abstract of that study have conclusions to it?

A Yes.

Q And do the conclusions even say anything about the fact that gynecomastia was a frequent occurrence?

A No, the conclusion is one sentence and it simply says it was well tolerated and effective.

Q And can we highlight that conclusion sentence.

Tell the members of the jury very briefly what an abstract is and what is its significance in the medical literature?

A If I am a physician, I can't read every journal article, I want to read the essential points, I am going to read the abstract, and within the abstract I am going to go to the conclusion for the key points, what I should know. The sum total.

Q If we can look at the bottom of the page, the italicized stuff, if you can pull that up, please. I am looking for the italicized portion which is the

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full, accepted July 28, 2004 --

MS. SULLIVAN: Your Honor, I am going to object -- I withdraw the objection.

Q I would like to call your eyes to the author, I think the second full paragraph?

A The second full paragraph of the footnote, sir?

Q Of the italicized portion that we have displayed.

I don't think we have to do anything more. "This research was supported by Johnson & Johnson Pharmaceutical Research and Development, Beerse, Belgium". Correct?

A Yes.

Q And notice it discusses the risperidone disruptive behavior study group that was working on this inside the company, correct?

A Yes.

Q And if I --

A And we can look at the exact definition how they defined that. There may be investigators in that, too. I just want to be careful.

Q Okay, and then if I can go to the first paragraph, we learn that Doctors De Smedt and

VanDongen are with Janssen Research and Development in Beerse, Belgium, correct?

A Yes, sir.

Q And this study, you need to go deep in the writeup of the study to find out the information that we put in my chart which is in front of the jury right now?

MS. SULLIVAN: Your Honor, I would object to lawyer argument, "you need to go deep" into the study. It's right in the study.

THE COURT: First of all, that's already marked and all you have to refer to it as P-22 or something.

MR. KLINE: The reason I got up is I didn't remember the number.

THE COURT: What is it, Marianne?

THE COURT CRIER: It's part of P-23.

THE COURT: What's your question?

MR. KLINE: I just didn't remember the number.

THE COURT: P-23.

BY MR. KLINE:

Q Sir, where do you get this information found

in this paper which has two Johnson & Johnson people who are the authors?

A So if you turn to five pages in, and you go to page 68 of the article, Bates number ending 816.

Q The article begins on page 64, and you go all the way to page?

A Go to page 68.

Q Go to page 68, four pages in, yes?

A And then you go to the paragraph that begins, "Increases in serum prolactin." It's the second paragraph on the left-hand column. And if you kindly go about halfway through, and in the middle of the sentence, if someone can he will help me highlight where it says "adverse events," if you look at that specifically if we are talking about prolactin elevation and gynecomastia, they are counting 22 boys and three girls.

Q We are going to learn later that there is a term that's invented called "symptoms hypothetically attributed to prolactin". Is that language used in this article?

A I don't see that term used here, no.

Q In fact, they are referred to as adverse events, correct?

A Adverse events, yes, that could be potentially attributed to prolactin, yes.

Q And it says here, were reported in 32 patients, correct?

A These are the prolactin, the PRAE of 32 events, yes.

Q Those are the boys with gynecomastia and added on the girls with amenorrhea and breast enlargement and lactation, all those together?

A Exactly.

Q And, sir, was this an important finding in this study?

A Sure.

Q Were some of the children who were -- and these were mentally retarded children, all of these children?

A I just want to be -- as a pediatrician I want to be very careful. Mild to moderate intellectual impairment. So again, I just want to be...

Q Precise?

A I want to be precise, yes.

Q And were children in this study, this study that paid special attention to prolactin-related adverse events, were some of them studied for an

extended period of time?

A Yes, so what that means is you do the clinical trial, you do the study of INT-41, that's a year, but certain of the children could continue the drug.

Q And like the previous study, did the extension study say that it was a study that was going to pay special attention to prolactin adverse events?

A I am not sure they used exactly that word, I would have to double check, we can find it but --

Q I will display a document.

A Thank you, sir.

Q If you go to the next sub -- tab, there is the topline reports of RIS-70. Do you have that in front of you?

A Yes, I have the topline results and the headline results for the extension.

Q I need to identify stuff.

MR. KLINE: I will mark P-24 is the next document that I am marking with a Plaintiff's number. It is the topline results for a study called RIS International 70.

I have a copy for Marianne and the Court.

(P-24 is marked for identification.)

Q I will be doing this every time, doctor, every time we discuss a study. We are going to be at a slower pace, a more mature pace.

The study itself, sir, RIS-41, let's look at it, if I can display it, assuming there is no objection, assuming the Court permits me to do so.

THE COURT: You may.

MS. SULLIVAN: I am just going to note, this isn't the complete document, but I don't have an objection.

THE COURT: P-24, the document may be displayed.

MR. KLINE: I presented this document exactly today to the Defendants, sir.

MS. SULLIVAN: It's still not complete.

MR. KLINE: To the extent it's not complete I will add anything that needs to be added. We are all familiar with the document having litigated this case now for years.

Q The topline results, is this the first page of the document, sir?

A Yes.

Q And if I can just show you the top box?

A I see it.

Q What is the title, sir?

A "The Long-Term Safety and Efficacy of Risperdal in Conduct Disorders in Children with Borderline, Mild or Moderate Mental Retardation, a Follow-Up Trial of RIS-INT-41."

Q When you say follow-up of RIS-41, have you read this document?

A Yes.

Q And do you believe you have read it in its entirety at some point, while the full thing may not be in your binder?

A I have the entire -- yes. I have gone through -- there are always schedules and appendices and these go on and on, but I have gone through this in detail.

Q When you look at the full document with all of its appendices, is it like this thick, sir?

A I only have it on the computer, I haven't seen how thick it is but it is very thick. These are very thick documents.

Q Now the extension study, I want to look down at the trial design.

A Yes.

Q And by the way, were other things being looked at as well in the study?

A Of course.

Q Of course, but does it say here on the third bullet point it's going to pay, again the same words, "special attention to serious adverse events and EPS prolactin." Do you see that?

A Yes, that's what it says.

Q And putting aside how anyone else might characterize it, what words does this Janssen document use? Serious adverse events?

A It says serious AEs, yes, it certainly discusses that, and it talks about -- an EPS is extrapyramidal symptoms, prolactin and glucose, glucose being sugar.

Q This study was completed; when were the results known?

A If you look, I am just looking for the -- the date of the study is September -- the date of this topline results is September 18, 2002.

Q Do you have, and I only put the topline in this presentation, do you by chance have in front of you or in your notes when the final results were known?

A Give me one second, sir. I may be able to get you that.

Q I would appreciate it if you have it.

A I have in my notes August 2002.

Q When the final was --

A Well, when the study was complete, is what I actually have in my notes. I would have to check my computer to look, but that's when the study was complete that I have.

Q Well, it appears the study was completed, if your notes are correct, and would you tell the members of the jury if you, when you were taking your notes you went through the documents and were taking notes contemporaneously with what you were observing?

A Sure. These are based off of documents, yes.

Q So it appears that the study was complete when the topline results were out; is that correct?

A That's what my notes indicate, yes, sir.

Q And do you have for the jury an explanation of what they found in the extension study -- before we get there, and I am sorry. In the extension study, it went a year, how many children did they study?

A In the extension study itself, in INT-70, I

have a total number of children of 48. And there are a number of different ways they are counting perfectly appropriate. This is sort of the second year study, as I am reading this.

Q Let me see if I can get an understanding with the quick math board here.

What you had in the RIS-41 study were 504 children; is that correct?

A Yes.

Q Okay, and in 504 children, being boys and girls, mostly boys, correct?

A Yes.

Q And then RIS-70 has how many patients, 48?

A Yes.

Q And please explain, are these 48 the same -- 48 of these same as the 504 kids?

A That's a subset of those, yes.

Q Just to be clear, when you say it's a subset --

A Sorry.

Q -- there are 504 and then they follow 48 of them for another year?

A Yes.

Q They don't follow 504 for another year, they

don't get 48 new kids, they follow 48 of the 504 for another year?

A Yes.

Q Got it.

A There is a footnote there, but it's probably -- their actual accounting here on INT-41 is 433, but the 48 is a continuation of that INT-41.

Q Okay. Now, tell the members of the jury, as to these 48 right here, what was found in the extension study?

A Can I point your attention to a table?

Q Sure.

A Because there are two tables and I just want to be, again, exact.

Q Which tables should we look at here?

A If you kindly look at Table 4, Bates number ending in 859. If you would kindly go to the last bolded heading on the page where it says Endocrine Disorders?

Q Yes.

A And then if you would highlight the line "gynecomastia".

And so you see, if you go over -- and I apologize, could you just go back and show the

headings to this table so we can see what those three columns are.

Right, so you have INT-41, and then you have another reporting, but the key column for INT-70 is the third column, where it says six. That's an absolute number of six gynecomastia, for 12.5 percent.

And just to add a footnote there, those are the new and ongoing cases of gynecomastia in INT-70, as I read this table.

Q So what we have here in INT-41 is displayed -- would you capture that as an exhibit, what we have displayed for the jury right now. Will you print it and I will give it a marked number. We will call it P-25, what is now being displayed?

THE COURT: You want this particular page of this particular --

MR. KLINE: This call-out is P-25. What the jury sees in front of them will be made into an exhibit that is printed, handed to Marianne and marked as P-25 at the next break.

(P-25 is marked for identification.)

Q Okay, so what we have here is, let me

understand this. When they followed kids for a year -- I am now going to add to my P-21, the Plus-70 study -- for gynecomastia, what we have is six patients had gynecomastia that happened either in the first year or the second year of the study; is that correct?

A Well, no. I mean I am reading -- correct me if I am wrong, the first year you have got 18 cases of gynecomastia in INT-41. This is confusing. Under INT-70 it says six cases. And in studying this report, those were defined as new and ongoing.

Q New and ongoing. So if you define new and ongoing cases of gynecomastia as they did, this is Janssen?

A Yes, exactly.

Q Janssen came up with, for gynecomastia in INT-70, a rate of six out of 48?

A Yes, for 12.5. Now I need to be exact. May I?

THE COURT: Mr. Kline, your witness is asking whether he needs to be exact. Obviously, my answer is be as exact as he can be. But I don't want to tread on the question.

MR. KLINE: I think he said I need to be exact. I don't think he said do I need to be exact.

A No, I need to be exact.

Q Go ahead, sir.

A Do me a favor, just kindly, if you can go ahead to two pages further and show Table 7.

THE COURT: One second. This is now for our purposes, Table 7 --

THE WITNESS: Bates number 861.

Q And in this study it is Table 3.2.2?

A Yes, sir. And if you kindly, if I may, just point you to where it says Endocrine Disorders, Gynecomastia, and then you have to have the heading, too, so you can see.

Q Yes, we will do the call-out for this.

A Where it just says Total, you see here in this table it's reporting for INT-70, those 48, three cases as opposed to six cases. This comes to 6.3 percent.

So again, it's a question of accounting, whether it's new cases or new and ongoing, and I just wanted to be complete here.

So you have a range. You can either

count three new cases or six new cases for a range of somewhere between 6.3 and 12.5 percent. Thank you for letting me get that exact.

Q Sir, do you interpret the three as being three that occurred in the second year?

A Yes.

Q So when they were studied the second year they picked up three more?

A Exactly, sir.

Q And they had six total in 48, studied two years, and three total in the extension year. Do I have it right, I hope?

A Not exactly. Because if you go back to Table 4, they are reporting 18 cases in 41. Do you see that?

Q Yes.

A So again, there are probably three cases that are overlapping with 41, they are reporting four. So again, you can basically say three new cases in this, six total in this period.

Q What is being displayed now, which is Table 4, incidence of All Adverse Events, is displayed as a call-out and I am going to mark it, print it, and hand it to the Court at the recess, it will be P-26.

The call-out.

THE COURT: That's Table 7, the call out.

MR. KLINE: Yes.

MS. SULLIVAN: Your Honor, are we going to be sub-marking all the call-outs now?

THE COURT: We are. Because anybody reading the transcript wouldn't know what the heck was going on unless they had the actual documents.

MR. KLINE: Yes, I wanted to be precise so we have a full record.

THE COURT: We are not taking photographs here, Ms. Sullivan.

MS. SULLIVAN: Okay.

(P-26 is marked for identification.)

BY MR. KLINE:

Q Now the RIS-41 study, sir, which was completed, as you told us, in August of 2002, was that published in the medical journals any time soon?

A We are talking about INT-70?

Q Yes.

A Yes. INT-70 was also published in the medical

literature.

Q And I am going to show you Exhibit No. 27, I am marking as Exhibit No. 27 --

THE COURT: Twenty-eight.

MR. KLINE: We are now at 27, I believe.

(P-27 is marked for identification.)

Q I am marking as P-27, and I have been advised it's in the Judge's hands, from Mr. Gomez to the Court Officer to the Judge, Exhibit 27, which is an article published in the *Journal of Child and Adolescent Psychopharmacology*, November 3, 2006, and it is entitled, "Long-Term Use of Risperidone in Children with Disruptive Behavior Disorders and Subaverage Intelligence: Efficacy, Safety, and Tolerability."

Sir, you alluded to this yesterday, but please tell us the medical definition of efficacy?

A Whether the drug works. Whether it's effective.

Q If we can display Exhibit 260 to the jury, assuming no objection, and the Court's permission.

MS. SULLIVAN: No objection.

THE COURT: All right.

Q The document has an abstract. We are now expert medical journal readers here, and we are going we know to look for the abstract. And when we look at the abstract do we find anything in it about the finding that there was up to 12 percent, 12.5 percent of the patients with gynecomastia -- I should say gynecomastia and other prolactin-related events?

A There is no reference here.

THE COURT: What was the answer?

THE WITNESS: There is no reference here, Your Honor.

Q If I can look at the very bottom of the page where it says page 260, the very bottom of the page -- actually, let's go to the top and the bottom and put it together, the authors and the footnotes.

As to the authors, the lead author of the study is someone whose name is Magali Reyes, R-E-Y-E-S?

A Yes.

Q And that person is from Johnson & Johnson Pharmaceutical Research and Development in Titusville, New Jersey, correct?

A Exactly.

Q And the third author, sir, is a person by the name of Marielle Eerdekens?

A Yes.

Q And that is a person from Janssen Research and Development, Beerse, Belgium?

A Yes.

Q And where in the article do I need to go to find, roughly four years later, this result?

A Approximately pages either six or seven. Actually, page seven. If you go to page 266 of the article, the article starts on page 260.

Q The article starts on page 260, and what page of the article is this finding that they have 12 percent of the kids with gynecomastia show up?

MS. SULLIVAN: Objection. That lacks foundation. Dr. Kessler made clear it's half that amount.

THE COURT: Overruled. Right now we are on page 266, the document is 1524575.

A If you go to 575, there is a discussion of gynecomastia on that page, and there is a table two pages further in on 268, Table 3, that also gives the numbers.

Q And if you go into the numbers, with the

article starting on page 260, so eight pages in, in Table 3, twelve lines down, you get a report to the medical literature which the doctors could read that says these rates of gynecomastia you and I are talking about?

A Exactly.

Q But I don't see the 12.2 percent -- 12.4 percent that they had in their study?

A As I said yesterday, the data, it says what it says. It says that --

THE COURT: Well, hold it, doctor. Again, you are now reading something. Please tell us what you are reading.

THE WITNESS: I apologize, Your Honor.

MR. KLINE: Yes, we are in the article which was marked as P-27, the article begins on page 260 with its abstract. The article is published in 2006. In fact, I failed to mention it was published November 3, 2006. That would be four years after the final results are known of this study, and we are now, on page 268 of the article, Your Honor, that's eight pages into the article, in a table.

THE COURT: All right, Dr. Kessler is going to read us something. Is that where you are going to be reading from?

THE WITNESS: Yes.

MR. KLINE: And he is showing us the line which the technician Mr. Smith is highlighting in front of the jury, which is the table with the results of gynecomastia in this four-year-later published study.

Q Correct, sir?

A Yes.

Q And I just need to know what it says so that we can then hopefully move forward?

A So, in the column talking about -- the first two columns talk about the original Year One study, that's INT-41. And the first column says, "Patients Continuing into the Year Two study, and you see there were four cases of gynecomastia that continued into the Year Two study. You see them reporting 18 cases not continuing into the Year Two study.

And then you see where it says Year Three Extension, that third columns of numbers, where it says three children, all patients, 6.3 percent.

Q Every piece of information that you have discussed here, sir, that's now published in a medical journal in November of 2006, was it known to Janssen four years earlier?
A It was known at the time of those studies, yes, or at the time of those study reports, absolutely.
Q And so in terms of how it's reported here, with two J&J, Janssen authors on it, is to say what, in terms of the percent of patients with gynecomastia?
A So you have approximately, let's call it 6 percent.
Q So in P-70, the published article, the 2006 published article of P-70, it has approximately -- do you have the numerator or the denominator to give me?
A Yes, I have 3 over 48. These are the new patients in the second year. 3 over 48 or 6.3 percent.
THE COURT: Counsel, we are going to take a break. Jury, we will take a recess and we will continue. Please don't discuss the matter with each other and we will be back in

about ten minutes.
(A brief recess is taken.)
- - -
(The jury enters the courtroom at 11:17 a.m.)
THE COURT: All right, be seated, everybody.
BY MR. KLINE:
Q Dr. Kessler, continuing with the 2006 published article, if I could call your attention to, and we will not actually be displaying this, I call your attention to page 266 of that study. There is a sentences that begins, "Two cases of gynecomastia," I want to look at the next sentence that says "Importantly"? Do you see that word "Importantly"?
A Yes.
Q It says, "Importantly, as has been previously observed, Findling, et al, 2003, occurrence of gynecomastia was not related to increases in serum prolactin levels."
Do you see that?
A I do.
Q And, sir, we are going to be discussing the

study which has the lead author Findling down the road today, but as to that statement, sir, I just wanted to point out that it's in this article for right now.
Also, I would like to turn our attention to -- I would like to move forward from this study. There was a discussion, you and I discussed the fact that the Janssen company people did 18 children and adolescent studies. Do you recall our discussion?
A Yes.
Q Now at the end of our line here, at least for our -- what I am presenting, in 2006, October of 2006, in the label there is a discussion of the percent of incident rate of gynecomastia, and I would like to display that as a reference point for discussion. The jury has previously seen it as P-9.
And there is a section of that label which says -- this is the 2006 label -- which says 2.3 percent, and I am going to display it right now, as part of P-9. It is Bates number 00838260. The jury is familiar with that.
"Gynecomastia was reported in 2.3 percent."

Now, you have reviewed all 18 of the studies at some time, in some way, as part of your engagement in this project at my and the other lawyers' request?
A Yes.
Q And, sir, is this 2.3 figure the figure of when you combine all of the children that were in all 18 of the studies?
A Exactly. So as of 2006, what this 1885 children and adolescents, these are the studies in autism or other psychiatric disorders treated with risperidone. So there were a total of 18, we talked about a number of them, but if you add up all 18, and you do the math, you find that 2.3 percent of all of those children that were enrolled ended up with gynecomastia.
Q And I think it says there are 1865 of those children, correct?
A 1885. But I don't need to quibble.
Q Please do. You won't be the first.
And in 1885 patients, I have yet to mark this -- for all studies there are 1885 is the denominator, and I know it's 2.3 percent, so do you know what the numerator is?

A Not off the top of my head.
Q We will fill that math in, but it includes all the studies. Now of all of those studies, sir, of those 18 studies, how many of them were even long-term studies?
A I don't have the exact number, but I think there are some eight studies that were long-term. I would have to count them.
Q So --
A The important point is there were short-term studies, there were long-term studies, some looked, as we talked about, looked specifically for gynecomastia. So this was the totality of all those studies.
Q At the next break or over the lunch period, and then I will go back to it, and you are under examination so I am not going to be talking to you but I want to save time. At the next break will you look at the total number of long-term, total number of short-term, and I want to ask you that question?
A I would be happy to. I have it in my notes.
Q Here is what I would like to discuss with you briefly. There are, of the 18 studies, I want you to assume that ten are short-term, and you can

confirm it for me when you get here later, okay?
A Of course.
Q So that would be, if you take the short-term studies, and how many of the other studies were paying special attention to gynecomastia and prolactin-related side effects?
A That term were in the two studies that we talked about.
Q So when you use the denominator of 1885, does that dilute, if you will, the percentage? Does it make it appear to be a smaller percentage than actually is found in RIS-41 and RIS-70?
A I think I understand your question. The answer would be yes, as I understand the question.
Q And in fact, sir, most of the patients that are found in the 1885 are found in the two special attention studies, correct?
A Yes.
Q Where they were looking for it, correct?
A Yes.
Q And then when you add up all of the studies, which is what the drug company and the FDA eventually agreed upon in 2006, correct?
A Exactly.

Q They end up dividing by a bigger number and have a smaller percentage?
A Yes. That again, as I said earlier, the data is the data. When you take all those studies, some had zero, some had in short-term studies were not looking for, others had other numbers. Bottom line is all those studies come to 2.3 percent.
Q But I was asking a different question. Does adding up all of the studies dilute what the real percentage is in RIS-41 and RIS-70?
A It certainly dilutes that number because it includes other studies that are short-term.
Q Of some of the studies you have seen, sir, how long were some of them? Do you have those studies to get out in front of you?
A Sure. I have, for example, NED-9 was six weeks.
Q Six weeks?
A That's what I have.
Q Would you expect to see gynecomastia in six weeks?
A I don't think so, but you could. But I would not expect. You want to look over, you know, a year or so in order to assess.

Q How many of the studies, since maybe it is a good time to do it, do you have in front of you that are weeks in duration, not six months or a year in duration?
A So NED-9 was six weeks. Belgium-22 was four weeks. Belgium-24 was four weeks. USA-93 was six weeks. CAN-19 was six weeks.
THE COURT: What was that, sir?
MR. KLINE: Can, meaning Canada.
A My apologies, they abbreviated, C-A-N.
So CAN-19 was six weeks, USA-150 was eight weeks. CAN-23 was eight weeks. USA-231 was eight weeks. BIM-301 was nine weeks. SCIL-302 was six weeks.
Those were the short-term studies that I saw.
Q Okay, now I won't have to come back to you on that. Ten of the 18 studies -- and do you know the number of subjects that were in those studies?
A I can read them off to you. I don't know the total. I would be happy to -- we can do that. I have the number of children for each one here. Do you want me to read it off?
Q We can do it efficiently and rather quickly.

A I am giving you the total number of children. NED-9 was 38. BEL-22 was seven. BEL-24 was 13. USA-93 was 118. CAN-19 was 110. CAN-150 was 101. CAN-23 was 80. USA-231 was 279. BIM-301 was 169. SCIL-302 was 160. That's what I have in my notes.

Q All of these studies, of the 18 studies that they did on the drug for children and adolescents, which is what we are concerned about, were done in six weeks or less, correct?

A In weeks. I don't know if there is any eight-week studies. I gave you the exact numbers. Yes, they were all short term.

Q Short term being less than eight weeks?

A Yes.

Q We will add those up while I continue to question you.

So when the jury sees that eventually, when they did warn they were Warning about 2.3 incidence, which was something that included all of these ten of 18 short-term studies, correct?

A Yes.

THE COURT: Let's get this marked here.

MR. KLINE: Oh, this, I have done an 18-studies document, which is P-28. Thank

you, Your Honor.

(P-28 is marked for identification.)

MR. KLINE: And while we are marking that, I am going to mark the -- can somebody do the reverse math on this for me, 2.3 percent of 1885? And I will mark this as well.

(P-29 is marked for identification.)

MR. KLINE: For identification purposes, P-28 is the exhibit whic is entitled 18 studies, and then the ten short-term studies, demonstrating the math -- I have two different post-its handed to me -- of 1075.

THE COURT: 1075 is the total number of patients in the short-term studies?

MR. KLINE: In the short-term studies.

THE COURT: All right.

MR. KLINE: And out of the total of the 1885, out of 1885, which is the total number that's shown up here as the number of children in the clinical trials.

BY MR. KLINE:

Q So on P-28, sir, and I will get to marking P-27, of 1885, which is the label number, and the

total in all studies?

A The 2006 label, right?

Q Yes, the 2006 label. 1075, by the math you just read, are from the short-term studies that are eight weeks or less?

A Yes.

Q And yet they are included in getting to the 2.3 percent that's actually in that label?

A That's the way that math was done, yes.

Q And even though the special attention studies showed these much higher rates, correct?

A They do.

Q I have marked as Exhibit 29 the page that's developing, which is Special Attention Studies, RIS-41 having 504 patients and RIS-70 having 48 of those patients included.

And if I might do the math, sir, of the 1885 patients, if you take out 1075 short-term studies, that leaves you 810 for the long-term studies, correct?

A That's what I see, yes.

Q Of which, of which 504 are in RIS-41. Correct?

A Yes.

Q 504 of 810, 504 is from RIS-41, 62 percent?

A Yes.

Q 62 percent of the patients who were studied here in long-term studies are right here in front of our eyes in Exhibit P-21. Correct?

A Yes.

Q Showing the incident percent that's on here, correct?

A Yes.

Q Shows these incidence percents ranging from 3.75 up to 12.5, correct?

A That's what that sheet shows, yes.

Q Yes, "that sheet" referring to P-21.

And our reverse math is something like -- we will get to that, I don't need that exact number.

Okay, back to my desk and back to work on some other stuff.

So, sir, as to whether there was a high incidence rate of gynecomastia in this drug, a frequent rate, was a good answer provided in RIS-41 and RIS-70?

A It certainly gives you important data, there is no question in my mind.

Q Is it more important data than adding in all the other ten short-term studies and the other studies that weren't special attention studies?

MS. SULLIVAN: Objection. Your Honor, I haven't been objecting but there has been a lot of leading and lawyer argument.

THE COURT: That's sustained. Get it another way now.

BY MR. KLINE:

Q All right, now, we will move on. The Janssen folks, after they have this information, do they -- I want to step back. I have to do one more thing as a predicate, and that is, we had mentioned, and I want to put on the sheet of paper, five of the 18 studies on the drug -- and again, I may not have been very precise. The studies we are talking about, the 18, these exclude any studies on adults, correct?

A Yes.

Q We are only talking about the studies that were done by these companies as it pertained to children and adolescents, correct?

A Yes. Those 18 were part of what the company gave to FDA as part of the autism application.

Q And the autism application had to do with an indication for children, correct?

A Yes.

Q And the indication for children required studies on children and adults which had never been done before, correct?

A I am sorry, just say that question again.

Q I am just trying to get through this part in a hurry, I believe it's not objectionable.

The children in autism studies had not been done before because it was an adult drug before?

A Yes.

Q And so the studies that we are talking about, that's the only point that I was making.

Now, of the 18 studies there were five that you called, I think, or you didn't call them, the company called them something like, but you can give me the precise term, conduct disorder studies? There were five?

A Disruptive behavior studies or conduct disorder.

Q Okay, and just bear with me. And they called them the DBD studies, correct?

A Disruptive behavior, yes.

Q And there was a series of them, five you mentioned. I want to get them out on a sheet of paper, mark them as an exhibit and talk about them. They are RIS?

A They are CAN-19, CAN-20, USA-93, USA-97, INT-41.

Q Okay. Does the Janssen company, after they have the results or at or around the time they have the results -- I am going to mark this as P-30. I am marking DBD, studies showing DBD as P-30 in my handwriting on the chart.

(P-30 is marked for identification.)

Q Does Janssen decide to do, to use their words, "reanalysis"?

A Yes.

Q And is the reanalysis designed to combine all the information in the five studies, sir?

A Yes. All information may be too broad a term, but certainly, it's looking at a very specific set of questions about the association of prolactin and side effects.

So again, I don't need to quibble, sir.

Q Yes. Now in the -- let me follow-up on what

you just corrected me on.

Was the purpose of the reanalysis to look further at this prolactin question?

A Exactly. The purpose of the reanalysis was to explore any relationship.

Q From what you have seen so far, and now what this jury has seen so far, and from documents you have seen so far, was there in the company something perceived as a "prolactin problem" with this drug as it related to children and adolescents?

MS. SULLIVAN: Objection to the leading.

THE COURT: Sustained.

Q Did they have an issue with the drug and how did they define it, sir?

A Yes, there was an issue. And the issue was this second generation antipsychotic Risperdal, as I believe we talked yesterday and as we showed in the 2006 label, they knew that Risperdal increased prolactin levels, a hormone, higher than other second generation antipsychotics.

Q And what did they know now about this drug as it related to those? I thought we saw an E-mail earlier about what they knew?

(Kessler - Direct)

A That's exactly what I said. I am sorry, did I miss --

Q I thought you said they knew that all these drugs caused --

A No, that's not what I meant. I apologize if that's what I said. What they knew was that their drug Risperdal increased prolactin levels higher. There was an increased elevation. Those are the E-mails that we saw yesterday.

Q And did they also know from RIS-41 that they had a high incident rate of the gynecomastia appearing?

MS. SULLIVAN: Objection, Your Honor. This runs afoul of the Court's ruling. He can read the E-mails but he can't say this is what they meant when they said it. The real witnesses should be asked.

THE COURT: Why don't you rephrase it within the lines of what this said.

MR. KLINE: I didn't even know it had anything to do with an E-mail. I didn't have an E-mail in mind.

THE COURT: Whatever the data is, ask him strictly from the data.

(Kessler - Direct)

MR. KLINE: I will just move to the documents, Your Honor.

BY MR. KLINE:

Q Did you review an E-mail which described what the company was doing when they had a meeting in Toronto, Canada in January 2002?

A Yes.

Q And I would like to discuss it with you. It's in the next tab of our book, and are you on the same page with me, sir?

A I am at a Bates number ending in 121.

MR. KLINE: Yes, I have stopped using these tab numbers because it gets overly confusing.

THE COURT: Are you using a Plaintiff's exhibit number for this document?

MR. KLINE: Yes, I am.

THE COURT: What is it?

MR. KLINE: It's the next plaintiff's Exhibit. It's Exhibit 31.

(P-31 is marked for identification.)

Q I would like to review 31 with you and have you tell me a few things.

MR. KLINE: MR. KLINE: So with the

(Kessler - Direct)

Court's permission I will ask this to be displayed. It was the subject of some pretrial discussion. It's Bates number 02250121, and with the Court's permission I will display it.

THE COURT: Go ahead.

MR. KLINE: Subject to the prior objection.

MS. SULLIVAN: Your Honor, that's not proper. He has objected to a whole bunch of things and I don't refer to all of his objections.

MR. KLINE: Here we go.

THE COURT: Is this the first E-mail or the second one in this case?

MR. KLINE: This is the bottom E-mail, Your Honor, which we discussed.

THE COURT: All right, thank you. If you could publish here just the bottom document, that's all.

MR. KLINE: The whole bottom, if you would.

THE COURT: Yes, that's it.

MR. KLINE: We are calling no one's

(Kessler - Direct)

attention to the top.

THE COURT: All right, here we go.

MS. SULLIVAN: I don't mind the whole thing published, Your Honor.

THE COURT: Now you don't mind, all right, then we will have the whole thing published. Right now, though, counsel, you want to focus on the bottom line, correct?

Now that we have the whole document in front of us, right now we are just focusing on the second part.

MR. KLINE: Now that we have the whole thing up, Your Honor, it does help context.

THE COURT: All right.

BY MR. KLINE:

Q At the very top, and there isn't a person in the room that doesn't know that these things are generated with a later E-mail coming on top, but to put it in context, there is an E-mail from Dr. Pandina, we are going to hear a portion of his deposition, I am sure, or see him live in the courtroom. He is the psychologist that's involved, and he says, "Team, it appears that the child prolactin advisory board held this week in Toronto

went quite well. Below is a high level" -- high level -- "summary passed on by Caren Binder. We can discuss but overall it looks very optimistic. I will keep you posted."

Sir, do you have that in front of you?

A I do.

Q The jury has it in front of them as well. Did you see documents, including this E-mail relating to that meeting that Janssen and outsiders that they hired had in Toronto?

A Yes.

Q And in that E-mail, sir, it was entitled -- if we could highlight those words -- "the child prolactin advisory board". Do you see that?

A Yes.

Q Is there anything uncommon or unusual that a company like Janssen would hire or would have an outside group of advisers brought in to discuss the development of a drug?

A Perfectly appropriate.

Q And was it in fact something encouraged by the FDA and as well as by good pharmaceutical practice?

A Of course. Get the best minds you can get. Get the best scientists you can get, always.

Q When it mentions Caren Binder, I know it was a day later, Ms. Binder to your understanding, while she was an MBA by training, was she the Director of Medical Affairs?

A I believe that was her title at one point in time, yes.

Q And what is a MBA, sir?

A Masters in business administration.

Q I want to focus now on the second half on the bottom, and look at her E-mail to a group of Janssen individuals. Do you see that?

A I do.

Q One of the individuals -- well, I will just identify by name but not title without discussing it with the Judge, is Carmen DeLoria. Do you see that?

A Yes.

Q And --

A Let me just see where exactly -- yes.

Q And you will see, and I know you have reviewed thousands of these documents, J-A-N-U-S, would that be Janssen USA?

A Yes.

Q And JANBE, would be Janssen in Belgium?

A I believe that's correct, yes.

Q And do you understand in reviewing these documents was part of the development of this drug being done in Belgium?

A Yes, you saw the international aspect of it in the trial.

Q Part of it being done in Canada?

A Yes.

Q Part of it being done in the U.S.?

A Yes.

Q And I'd like to look at the "Dear All." Let's look at the first paragraph. It says, "A quick update on the prolactin expert meeting held in Toronto January 22, 2002."

So we now know the date when they had the meeting, correct?

A Yes.

Q And to put it in perspective, January 22nd, 2002 is roughly three months after the final INT-41 study was known, correct?

A I take your word on that, yes.

Q All right, now, it says here, "Attendees including two P Endos." You will have to help us with that. What are two P Endos?

A Pediatric endocrinologists.

Q And they are listed as T. Moshang and D. Daneman. Do you see that?

A Yes.

Q And do they figure in what we are about to learn later on?

A Yes. They are authors on a paper that I reviewed.

Q To fast forward ahead, Janssen does a, what's called a pooled analysis, correct? To give everybody a fast forward, they pool these five studies together, right?

A Exactly.

Q And then what they do is eventually it gets written up in a medical journal, correct?

A Yes.

Q And the authors include Janssen individuals, correct?

A Yes.

Q And they also include some of these outside individuals, correct?

A Yes, exactly.

Q And it has "and two psyches". That would be two psychiatrists?

A Exactly.

Q Again a little clarification, is a psychiatrist different than a psychologist?
A Yes.
Q Briefly?
A One is an MD, one is not an MD. One does drugs, the other does more popular --
Q One does drugs?
A Sorry, I apologize.
Q We are talking about --
A I am sorry. The MDs prescribe drugs. I apologize to my colleagues.
Q Anybody who was raised in the 60s, sir.
A No, no, I am not going there, sir.
Q Let's go back to the second sentence: "The group discussed that there are several factors which affect prolactin levels."
This is a report of a discussion, correct?
A Yes.
Q And it says, "For example" -- can we take down the Dear All part and work on what we have in front of us. That's it.
"The group discussed that there are several factors which affect prolactin levels. For

example, estrogen during adolescence increases prolactin in the natural population, 25 percent of boys over eight years of age will develop gynecomastia which disappears.
Do you see that?
A I see that. You didn't read it exactly?
Q Please let me not do the reading. What does it say?
A Is said, Estrogen during adolescence increases prolactin in the natural population, 25 to 40 percent of boys greater than eight years of age will develop gynecomastia which disappears.
Q By the way, sir, as a pediatrician, is that a phenomena of which you are aware?
A There are certain increased transient, as it says here, breast development in boys that as you go through puberty, yes, that's been well recognized.
Q And they say it disappears, correct?
A That's what Janssen says, yes.
Q A whole group of them agreed according to these notes, correct?
A Yes.
Q Now, next, the next sentence, please.
A "The expert endocrinologists agreed that the

pediatric trial data shows no relationship to prolactin elevation and prolactin levels decreased to within normal ranges by Week 48 to 54."
Q Now, the other thing is I would like to go to the next page ending in 122 which is part of this exhibit which is now marked as P-31.
And they have a plan, correct?
A Yes.
Q All right, now they had an analysis plan written up, correct?
A That's what it says, exactly.
Q Circulated, correct?
A Yes.
Q And they were -- they hired a company called BrainWorks -- BrainWorks -- and BrainWorks was hired to write the manuscript on the results. Correct?
A I see that, yes.
Q So the document, the writeup of the study was going to be done by somebody outside called BrainWorks, correct?
A Yes, that's -- I learned that from here and from deposition testimony.
Q And they identified who their authors were going to be, correct? "Authors will be Moshang,

Daneman, Findling, Kusumakar." Correct?
A The docs that were talked about earlier in the E-mail.
Q So when these articles end up in the literature, sir, according to the E-mails that you have seen, who is selecting the authors of these studies?
MS. SULLIVAN: Objection, Your Honor, this relates to one study, this E-mail, and I would request we just limit it to that.
THE COURT: This study.
MR. KLINE: I thought we already showed it in the others because it said so, okay.
Q Who in this study, who was picking the authors?
A Janssen.
Q Are there sometimes studies -- Oh, and it says in the last sentence, "To discuss inclusion of Janssen people as authors." Correct?
A Yes.
Q Now, they have five studies, 19, 20, 93, 97, 41, they are going to pool them together, they are going to look at prolactin, correct?
A Yes.

Q They can going to look and see how it affects these boys and girls, correct?
A Can we be precise?
Q Yes.
A So again, they are going to look at prolactin in the pooled data, prolactin levels. They want to see whether those prolactin levels were associated with side effects. So it was that relationship between prolactin and prolactin-related side effects that they were looking for.
Q Was that something important and in fact commendable to look for?
A Sure. It was especially important because, as we talked earlier, we know that Risperdal increases prolactin, especially. It's a higher elevation of prolactin with Risperdal, compared to other antipsychotics.
Q And did they also have the results of 41 in front of them?
A Yes.
Q And --
A 41 was done because they are now going to pool those results. If you look at the E-mail you just showed me.

Q Yes?
A It says that, if you look at those studies, the endocrinologists are saying, in January 2002, this data they don't think shows any relationship to prolactin elevation. Right?
So that's why the question is so important.
Q Is this -- again, certainly, we have qualified you -- is this something which is, in terms of issues, is this a safety issue?
A Of course. We are talking about, one, hyper-prolactin levels, which are an issue of themselves, that's the hormone. But what we are also talking about is the adverse events: Gynecomastia, the lactation, the amenorrhea. And the issue is, is there an association between prolactin and those adverse events. Very much a safety issue.
Q And in order to do a study do you need to have a plan?
A Sure. You should have a plan, yes.
Q And while it is rudimentary, did they have a plan?
A Yes.

MS. SULLIVAN: Objection, Your Honor, to the testifying by Mr. Kline.
THE COURT: Overruled.
Q You are correct, was the plan that they had, which we are going to mark as the next exhibit, Exhibit No. 32.
(P-32 is marked for identification.)
MR. KLINE: Marking P-32, we have a document, I believe it's only two pages, it's marked P-32. It is Bates, for my technician, Corey Smith, as JJ RE 14119170 and 171. And I believe there is no objection?
MS. SULLIVAN: No objection.
MR. KLINE: So I will ask the court to display it, in time.
MS. SULLIVAN: No objection.
THE COURT: All right, you can play it.
BY MR. KLINE:
Q Sir, when you have a plan, are those the rules of the road?
A Yes.
Q And the plan here, is it set out in Prolactin-Revised Analysis?
A Yes.

Q And does the plan make certain statements as to what is going to be done?
A Yes.
Q As far as reanalyzing the data?
A It's a little rudimentary. I just want to be careful.
MS. SULLIVAN: It's a draft.
Q Ms. Sullivan wants me to ask you is it a draft? Whatever she would like to ask right now is okay with me.
THE COURT: Why don't you ask the question, Mr. Kline, for her.
Q Okay. Sir, they sat around a room in Toronto, and it says right here that it's a revised analysis, outcome of the January 22nd, 2002 meeting, correct?
A Yes. And if you go back to the earlier E-mail you showed me, it says, "The revisional analysis plan has been written up." So I read it in that context.
Q Yes, it says the analysis plan has been written up, and then the analysis plan, if we can focus in on the very top words, please, everyone, it says here: "Outcome of the January 22nd, 2002 meeting." Correct?

A Yes.
Q That's the meeting that we learned they had all of their outside advisers at -- yes, sir?
A They had the authors of this paper.
Q They had two pediatric endocrinologists, correct?
A Yes.
Q And they had two psychiatrists there, correct?
A Yes.
Q They had the four people there whose names ended up when this was written up as an article for the doctors in the medical literature?
A Along with some Janssen folks.
Q Along with some Janssen folks, yes. My point is that it says here "outcome" of the meeting?
A Yes.
Q So I want to focus in on what they said they are going to analyze. Now, by the way, let's step back. I would put this down so we can focus on some questions and then we will put it back up.
Sir, Study 19, 20, 93, 97 and 41 were already done, correct?
A Exactly.
Q So we are not now going to do some new

studies, correct?
A Not for this, no.
Q That's my point. What they are going to do is take the data they have and they are going to ask some new questions?
A Exactly.
Q That surprises me that I got that right.
And what they are going to do is they are going to --
MS. SULLIVAN: Objection to the leading, Your Honor.
THE COURT: There is some leading, but I am going to give some leeway. It's getting close to the lunch hour so let's get to the point.
Q I am going to get to the point. So what they do is they decide what the rules of road are, as you said -- let's put it back up -- and they say they are going to use the "full dataset." Correct?
A Yes.
Q I am going to use a word that's been heard in the courtroom already. Do they say they are going to cherrypick out the kids under ten?
MS. SULLIVAN: Object to the --

Q I am sorry, cherrypick out the kids over ten and eliminate them from the study.
MS. SULLIVAN: Objection, Your Honor, it's not opening or closing argument, it's witness examination.
MR. KLINE: May I ask --
THE COURT: Sustained, unless "cherrypick" appears in this document.
MR. KLINE: It does not, it appears in my head.
THE COURT: Let's stick with the document.
BY MR. KLINE:
Q Does it say anything in this document -- I can rephrase the question -- does it say anything in this document about only studying the children who are under ten years old?
A It says, in fact, the opposite. It says let's look at the full dataset.
Q The full dataset, how about that. Okay. What they are going to do is pool all the five studies together and they are going to have to run now some analysis of it, correct?
A Yes, because they are asking a new question

here.
Q And, since they are asking a new question, which you described as -- as you described it, they are going to need some help. Do they have to hire some statisticians, for example, to look at the data?
A Yes, they do that.
Q And who did that, Janssen or someone else?
A No, Janssen did that. Perfectly appropriate.
Q They could have gone and got any statisticians in the world. Did they pick who they wanted?
A Yes.
Q And they ended up coming up with some answers to the question, correct?
A Yes. They asked certain questions, they asked the data to be run; and the "statistician," the data company runs the data and does the statistics.
Q Okay, now before we get to that question -- looking at my time.
THE COURT: I guess we are looking at 12:30 as the maximum.
MR. KLINE: As the break point?
THE COURT: Any time you want.
MR. KLINE: No one will complain?

Q What I want to do before we get to the question is, these five studies, sir, included how many kids total? This 19, 20, 93, 97, 41.
A There's two numbers. Approximately -- the ITT analysis, which is a very technical term, was 700. The primary analysis was 592.
Q And if you could briefly, without bogging us down, tell us the primary analysis number and why that's the analysis number you look at?
A The primary analysis number was 592. Those are kids who were actually enrolled and took one dose.
Q And do we have among those, because I want to put it on my chart, if we add up 19, 20, 93, 41, if I could just go back to this developing chart, if we pool 19, 20 -- what are the five of them?
A I am sorry, I didn't hear your question.
Q What are the number of five studies?
A They are CAN-19, CAN-20, USA-93, USA-97 --
Q 19, 20, 93, 97, 41?
A Yes, sir.
Q And we have been keeping a scorecard here. When you added those together, sir, all five studies, putting aside the question that we are

going to discuss with the jury after lunch about the relationship between prolactin and adverse events, when you pool the studies together, just what are the incident numbers? First of all, for PRAE?
A So, for PRAE I have, of the 592, I have 30 out of 592, for an incidence of 5.1 percent.
Q 30 of 592 is what percentage?
A 5.1.
Q How about for gynecomastia?
A So gynecomastia in boys, I calculate that as 4.4, which I have 22 into 489 for an incidence of 4.4 percent. That's the overall bottom line for all five studies.
Q Recognizing that most of it showed up in the 41 study?
A Exactly. There was one case of gynecomastia in 97, but the vast majority -- and there was zero in three studies, and then there was, depending on whether you just count boys, there were 22 in the INT-41.
Q And for the record, I have put on the bottom of my chart, Pooled Analysis 19, 20, 41, 93, 97, and I have now updated the chart P-21 which is being displayed to the jury at this very moment.

The Janssen statisticians ran things according to this plan, correct? They followed the plan?
A They ran it per the instructions that Janssen gave them.
Q Right, under that analysis document that we looked at?
A I have seen that analysis plan and I have seen that data. I have not seen any other plan in that time period.
Q Did they come up with a result that was very important and significant?
A Yes.
Q Was there a table that was in the studies run by the statisticians which told them information which was a red flag?
A In my view, yes.
Q And did that have to do with the relationship of increased prolactin and the side effects which we have been discussing now in this courtroom for days?
A Exactly.
Q And is there a table number for that study, for that information?
A Yes.

Q Now I need a little bit of background before I display it. I think I can do this and break before 12:30, for those that are thinking along those lines.
When studies like this are done, and statisticians are hired, do they set a rule, do they set certain rules as to what is going to be considered in their technical terms, which I need you to explain. You are a professor of biostatistics?
A I am.
Q Which is -- statistically significant, something which reaches the level that whoever is doing the study says this finding shows an association and I can't dispute it anymore. Can you explain?
A What statistical significance means is it's mathematical and scientific calculations, but when we say something is statistically significant, it's unlikely to happen by chance.
So that association is very likely to be real. If you redid this, general statistically significant says if I redid this and redid the analysis a hundred times, I would get the same

result 95 of those times.

So it's a reliable result. It's not a quirk, to use a scientific term.

Q So, sir, if we see on a study -- and by the way, do the investigators of a study decided in their own criteria what is statistically significant? Do they assign what's called a P value?

A Exactly. So you can set it at 95, you can set it at 98, you can set it at 90. Generally, 95 significance level, for those of you who are mathematicians or scientifically inclined, it's a P less than .05.

Q As a general rule?

A Yes.

Q So if I see a number that is .0158, next to a dataset, that would mean that it occurs by chance less than two in 100. Correct?

A Yes, that's what the P value is saying.

Q And in fact, if I saw, regardless of this statistically significant stuff, if I saw something that said .0958, that would mean that it would be less than 10 percent likely that it happened by chance, correct?

A Yes.

Q Here, it's less than 2 percent chance, correct?

A That it's happening by chance, yes.

Q .05 means it's 95 percent likely that it did not happen by chance, correct?

A Yes.

Q And it's less than 5 percent likely, I will state it the other way, that it happened by chance?

A Right.

Q So you look to these numbers when we are looking at the table to see what we are looking at, correct?

A To see whether it's a reliable result.

Q Now we had information in the Table 21 when they ran the data on the five studies together, they looked at the particular thing -- let's display it -- now or later?

THE COURT: I think we have a good education here, I think we need to kind of nurture it along and save it for later.

MR. KLINE: We will save it for after lunch, stay tuned.

THE COURT: All right, everybody, I

think we have done pretty well. Let's take our luncheon recess here until about 1:30 and we will get started as soon as we are all together.

Same rules, yellow badges, please do not discuss the matter with each other or anyone else. Have a good lunch and we will see you back here at 1:30.

We are in recess until about 1:30.

- - -

(A luncheon recess is taken.)

- - -

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

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I N D E X (Continued)

COURT CRIER: Come to order, please. This court is reconvened.

Good afternoon, Your Honor.

THE COURT: Good afternoon.

You can be seated. Okay.

(Pause.)

COURT CRIER: All rise as the jury enters.

- - -

(The following transpired in open court in the presence of the jury:)

- - -

(Whereupon the jury entered the courtroom at 1:46 p.m.)

- - -

THE COURT: All right. Good afternoon. Please be seated.

All right. We are now going to continue the direct examination of Dr. Kessler.

Okay.

MR. KLINE: Your Honor, good afternoon.

Good afternoon, all.

(Dr. Kessler previously sworn.)

- - -

DIRECT EXAMINATION (Continued)

- - -

BY MR. KLINE:

Q. And good afternoon, Dr. Kessler.

A. Good afternoon.

Q. We were in Statistics 201 or so and -- we were beyond 101 -- and I just want to go back and understand stuff before we talk about it.

I've marked as Exhibit P-33, just a working blackboard that I have here.

And I want to focus kind of on what I'm writing on the bottom, one more time.

If someone -- if something has a p-value of less than .02, the converse of it is that your 98 -- .98, that would be 98 percent certain that the result is not by chance?

A. Yes. That's a fair way of saying it.

Q. And if you have a p-value of .10, that means the converse of it is 90 percent, or 90 percent that it's not by chance, correct?

A. Yes.

Q. Okay. And to stick with the conventional term that you told us about in science, when they go .05, the converse of it is .95 percent, and so you have

95 percent that it's not by chance, correct?

A. Fairly said, yes.

Q. That course would be taught -- that basic course would be taught somewhere in college, correct?

A. Sure.

Q. Okay. And the last thing I'd like to ask about -- sorry to keep going back and forth -- is so if the jury saw a .0158, that's of course less than .02, which means that it is 90 -- almost 99 percent not by chance.

A. Yes. It's statistically significant, as I would call it.

Q. Okay. Just one more.

Do you have Table 20 handy?

And if the jury saw .0992, that would mean it's roughly 90 percent not by chance because this is almost .10, and therefore, it would be the converse which is 90 percent not by chance; do I have it right?

A. Yes.

Q. Okay. Because we're going to see numbers like that and --

A. Again, it's a little more complicated, but generally you're -- that's a fair statement.

Q. Okay. We -- meaning we laypeople who are in this room -- would be on the same page as -- right now in terms of what we're looking at -- a physician who's looking at these numbers basically. Can we agree?
A. Sure.
Q. Okay. Now --
A. You'd have to ask everyone else. I can't talk for everyone.
Q. I understand. I just want to make sure we had the basic understanding.
So where we were when we broke for lunch is that Janssen pooled the studies together and asked the question, and again, put the question in my mind that we're going to see in Table 21 and then we'll push forward.
A. Okay. The question we're looking at -- that Janssen is looking at now is whether prolactin, that hormone, whether elevations in that hormone are associated with side effects.
Is prolactin elevation associated with gynecomastia, lactation? And they're doing the analysis to answer that question.
Q. Okay. So the data is run, and there is a table in the pooled analysis, which is Table 21,

correct?
A. Yes. And can I just point out the date of it?
Q. Yes.
A. Because it -- it's May 15, 2002. That's the data set that I'm referring to.
Q. Yes. And we're going to display it.
I'm going to mark what is a table from "Long-term Risperidone Treatment versus Prolactin Statistical Documentation for Manuscript Support, May 15, 2002."
I'm marking this one page out of a long -- much longer document as P-34.
THE COURT: Okay.
MR. KLINE: I have marked a copy. I'm handing it to the court officer and to counsel and requesting, so long as there's no objection --
MS. SULLIVAN: Your Honor, I don't have a problem with Mr. Kline using this document, but it's part of a whole data analysis; and I just prefer, because we're going to be referring to it, that he show the witness and the jury the entire set. It's --
MR. KLINE: Huge.
THE COURT: Well, we can introduce

the entire set as P-34 and make this page a subset.
MS. SULLIVAN: But he's just going to pick out one and ignore the rest. That's the problem.
MR. KLINE: That's their theory, Your Honor.
But I will promise, by asking some questions, that we can get there.
THE COURT: Okay. P-34 is going to be the entire document and then this page is P-34A.
MR. KLINE: Yes. And we'll furnish it so that now the Court has about this much paper to add to the case (indicating).
THE COURT: Well, no. I think Ms. Sullivan will have that.
BY MR. KLINE:
Q. The question that I have, sir, is did you review the entire document?
A. So I asked for the entire document.
Q. Okay.
A. And I asked to search the database for the entire document. If my memory is correct, I saw the tables. That was what was in the database, okay.

Q. Okay. To give the jury an explanation as to what we have here, when we consulted with you, did we as lawyers -- I wasn't the lawyer at the time involved in all this legwork. I don't take credit for it either. But did the lawyers provide you certain documents? Yes or no?
A. Yes; this at my request.
Q. And then did you along the way say, based on my knowledge, education, experience, I'd like to see other information?
A. Yes.
Q. Okay. And is there a enormous databank, a database, like millions of documents?
A. Yes.
Q. And were they produced with Bates stamped numbers on them? The plaintiffs' lawyers representing these children and the Janssen people are exchanging documents. And did you see -- or did you ask people for the documents when you thought you wanted to see something else?
A. Yes, exactly. I asked for this entire plan, yes.
Q. Okay.
A. This entire data set and saw certain tables, was given certain tables because that was what was

in the database.
Q. Okay. And just by way of an example, when you had asked for something, for example, Ms. Brandon here, is she someone -- who you came to know -- to know this database of millions of documents and you would say to her, Ms. Brandon, get me this or get me that?
A. Exactly, because she would key in -- I would give her key words, for example, or I say I'm looking for the statistical documentation, can you tell me what's in the database.
Q. Okay. And while we may not be at Janssen, did you make an effort to find what you thought was the important information?
A. I was searching for this information, yes.
Q. Did we -- when I say the "we," collectively -- ever find anything about the statistical tables in these 3 million documents?
A. Let me go back at a break and just check my binders so I'm absolutely certain. I remember a collection of tables sitting here right now, but I can double-check.
Q. Okay. I'm sure if there's a write-up to it, then you'll be able to see that, too, if it becomes germane. And you'll be prepared to answer, you'd be

willing to answer any questions about it, correct?
A. Absolutely.
Q. Okay. Was there -- I'm going to ask you it again since it came up and you said only one table. Did you look at a stack of data on a computer screen and print it out that contained what you believed to be the tables, many tables from this study?
A. Yes. I looked at many tables from this study.
Q. And when you look at many tables from a study, sir, is the point to look for that which is important at the end of the day?
A. I certainly looked at the -- yes.
Q. In your experience at the FDA -- I'm going to ask you a general question back to the FDA, sir. Your experience with the FDA, have you had the subject of what you could call data dumps, people throw you millions of documents and then they say, oh, we gave it to you?
MS. SULLIVAN: Objection.
BY MR. KLINE:
Q. We gave it to you.
MS. SULLIVAN: Objection, Your Honor. That's lawyer argument.
THE COURT: Overruled.
MR. KLINE: It's not lawyer argument

at all.
THE COURT: Overruled.
BY MR. KLINE:
Q. Have you had that experience?
A. I'd get -- when I was at FDA, I got millions and millions of pages. I mean --
Q. Is it important -- I didn't want to cut you off, but I wanted to get to the next thing. Is it important -- is it important to get to the key data and for a pharmaceutical company to flag the key data?
A. Sure. Can I -- can I explain?
Q. Yes.
A. So if you look at the data on Risperdal at FDA, I mean, it's vast, right. I mean, it is -- I don't have an exact number, but it's hundreds of thousands of pages, okay.
I would venture to say that no one individual, right -- never say never -- but no one individual looks at every single page that's in that application.
In fact, I mean, when I would go testify in front of Congress, if they wanted to make fun of the FDA, what they do is they bring in what's the application and the application would fill up

the -- all -- you know, a big part of the room. There would be boxes and boxes, right.
So, yes, it's very important for the manufacturer to share everything. But it's also important for the manufacturer, I mean, to be able to summarize and tell the FDA what's important.
Q. Does the FDA actually rely upon -- and when the FDA relies upon, that means do the American people rely upon the drug companies to flag safety problems?
A. The -- certainly in the 30 years that I've studied this and have been involved in this, the important point from my perspective is it's the manufacturer's responsibility to assure the safety of their drug. FDA tries very hard, right, to review the data. I mean, FDA works with the manufacturer. But at the end of the day, it's the company that sells the product that is responsible, I mean, to the patient ultimately, to assure the safety. FDA plays a very big role, but the company, certainly in my view, in my opinion, has primary responsibility.
Q. Okay. So when we have a key safety problem that's found in a particular document, is it the responsibility of the company to say here's what it

is to the FDA?
A. Yes, absolutely. You will see not only tables, you'll see summaries that are submitted of the data, and it's very important for the company to be up-front with the agency so that you -- you can't go look, I mean, through millions and millions and millions of pages. You have to rely on the manufacturer to make sure that they're helping the FDA and ultimately the physician and patient.
Q. Okay. Now, I would like to have a discussion with you about information that's in Table 21 and then what ended up happening to that information. Are you prepared to discuss it with me?
A. I'd be happy to.
Q. And Table 21, which we will display.
Before I leave, I marked as P-33 my blackboard, which is now complete, on statistics and what they mean.
Now, in Table -- I'm going to display -- I'm going to display a document. It's one page of a document. And it's a larger document which we will furnish as the larger part of P-34, and this will be 34A, this one page.
And in this P-34, I'd like to look at what it says on the top. I'd like to get some

information about it before we go into what you found on it. So let's display it, so long as there's no objection, so long as the Court allows me to do so.
THE COURT: Yes. Please, go ahead.
BY MR. KLINE:
Q. And let's look at the very top of the document.
The document says, "Long-Term Risperidone Treatment versus Prolactin, Statistical Documentation for Manuscript Support, May 15, 2002." And it says, "Protocols, RIS-CAN-19, RIS-CAN-20, RIS-USA-93, RIS-USA-97, RIS-International-41, and it contains Janssen-Ortho, Inc." And it says "Confidential," correct?
A. Yes.
Q. And looking to the title of this table, the words that are used by the company at the time are: "Prolactin-related side effects by prolactin levels, at or above upper limit of normal, paren ULN, paren PAP dash as observed, end of paren: Frequency tables."
Did I read it correctly?
A. Yes.
Q. Thanks for being my checker.

And does the paper -- does the table indeed relate to prolactin-related side effects by prolactin levels?
A. Yes. It gives numbers of prolactin-related side effects down below.
Q. Okay. Now, we have to look at something different here because this now just isn't the incidence of gynecomastia which we've been discussing before, correct?
A. It's a different question.
Q. Yes. Different question. Important question?
A. Of course.
Q. Now, let's look on the bottom because I don't -- let's look at the bottom. I won't tell you why, but just look.
And it says SciAn Services, Inc. Who do you understand that to be?
A. That was the statisticians that Janssen had contracted with.
Q. And we know the date of this document is May 15, 2002, correct?
A. Yes, both from the top and the bottom.
Q. So we know that this data was available to and known to Janssen by that date, correct?
A. Yes, sir.

MS. SULLIVAN: Again, Your Honor, this is not cross-examination. I object to the constant leading. If he could just ask a question and let the doctor -- Dr. Kessler answer.
THE COURT: Well, again, I would allow some leeway since the answer really is self-evident. But for these self-evident answers, I'll permit it.
Go ahead.
BY MR. KLINE:
Q. Now, is there anything more about the table or explanatory which you believe is needed before we delve into the finding that's here?
A. So I think we should probably define -- there's -- if you look in the middle, it says "prolactin" in that heading. And I think we should define above the upper limit of normal and normal.
Q. Okay. Let's take down everything that we have on the screen. So the record is clear, while this testimony is going on, we're displaying this exhibit, which is now 34A, in front of the jury.
And if you can focus in, sir, on this section here, "prolactin," so the jury can see.
(Technician complies with request.)

There you go, "prolactin." And if you would explain and then we'll get back to the full chart.
A. So where it says above the upper limit of normal, there's a footnote that's also related. Janssen selected a laboratory value of prolactin, right, and it did it, 18 for males and 30 for females. Those were the laboratory numbers for prolactin. And Janssen said above those numbers, we're going to consider that above the upper limit of normal, and then below those numbers we'll consider within normal limits. So there's a cutoff here.
Q. Is this, sir, like when we may -- not many of us may have had prolactin levels done or that we know about, but is this like when you have your sugar level and you get the lab result back and it has ULN and then it's boldfaced and you say, Oops, I got to -- I got to eat less Necco wafers?
A. Or your cholesterol level.
Q. Or your cholesterol.
A. There's a cutoff.
And those who are elevated and you're comparing those who have normal. So you have two groups here, in essence.

Q. Okay. Now, when we look at this chart, and let's see the best way to do it and it can also be enlarged to see. What I'd like to do is display it.
Take that down.
And there's no enlarging towards this, right?
But get rid of everything on the top and the bottom and give us kind of the middle, the core of it as big as you can.
(Technician complies with request.)
MR. KLINE: Yes.
BY MR. KLINE:
Q. That's what we need to see, correct, sir?
A. Yes. I'm happy to explain what that is.
Q. Okay. Now, let me ask some questions and then I'm going to ask you generally to explain.
First of all, is this looking at -- we learned -- we learned that they're pooling five studies together; correct so far?
A. Right. So all the children that are in those five studies.
Q. And we know that all of those studies, every child was on Risperdal. They were looking at all kids that were on Risperdal, correct?
A. Exactly.

Q. Okay. Step back to footnote. Some of these studies -- sometimes there's a study where they study people on a drug and people on a sugar pill. They're called a placebo and you're comparing the ones on the drug to the ones on the sugar pill. This is not that kind of study?
A. It can -- it's a comparison, the way they did it. But it's comparing a different aspect. It's not comparing to a placebo because everyone's on the drug. It's comparing those who are within the normal limits of prolactin versus those who are elevated.
Q. And a couple of more predicate questions.
Every -- okay. I saw a look or two, so I just want to -- I want to go back.
Every child in this study, every number in this study relates to a child who was actually on the drug, correct?
A. Yes.
Q. And some of them had prolactin levels which were above normal, and some had prolactin levels which were within normal.
A. Exactly.
Q. Okay. And --
(Microphone feedback.)

- - -
(Whereupon an off-the-record discussion was held.)
- - -
BY MR. KLINE:
Q. Okay. Trying again. Now, let's tackle it, if I may.
So we have the time periods set up on the left side, correct?
A. Yes.
Q. And we have predose -- I'll tell you what to mark -- predose.
A. Before the drug even starts.
Q. Weeks four to seven?
A. After four to seven weeks.
Q. What do you mean after four to seven weeks?
A. Well, it's -- predose is before, at sort of time zero. These children have not received any drug. Weeks four to seven means that we're doing the measurements after four to -- at between four to seven weeks on the drug.
Q. Weeks 8 to 12.
A. Exact same thing. Children have now been on the drug for 8 to 12 weeks.
Q. And the same thing would be true weeks 16 to

24; weeks 28 to 36; and weeks 40 to 48?
A. Exactly.
Q. Now, we have numbers that are there, and we see actually the numbers are higher and continue to get lower as the weeks go on.
A. Children drop out of the study, I assume.
Q. Every number that's in this -- on this page, when we get to weeks 8 to 12, do you see weeks 8 to 12, there are 499 children?
A. Yes.
Q. Every one of those is a child with a disability, correct?
A. Those are all children that are enrolled in that trial. They have conduct -- I mean, they've met the eligibility for disruptive behavior conduct disorder with intelligence limitations.
Q. Now, let's go to the analysis.
If I can go all the way to the right side first, the chi-square test?
A. That's a test for statistical significance for an association.
Q. For an association.
And tell us, I don't think we've that -- we heard the word; but tell us, sir, what is an association?

A. Is this related to that (indicating).
So I want to know whether this, in this case, is elevated prolactin levels related to, associated with, gynecomastia, lactation, with side effects. Is that abnormal? Is that increased laboratory value?
Q. And here did they set the test for what they would say was the association?
A. Yes. They're doing the chi-square test. And they're setting all -- they're setting the parameters. They set the upper limit of normal. They set the statistical analysis, yes.
Q. When you teach biostatistics, sir, how many days or weeks would we spend on the chi-square, if I said to you what's the chi-square?
A. I think in a college course, you would spend a number of days on it.
Q. Okay. Well, I don't think that I'm going to be giving it.
And I just saw His Honor shake his head.
So what I'd like to know, in three sentences or less, what's the chi-square?
A. Chi-square test is a statistical test to determine whether there is an association between

two variables.
Q. Okay. By the way, who picked it? Who picked this test with these -- with this parameter?
A. It was Janssen.
Q. And I want to put the statistic chi-square. It says .3 down at weeks -- of all of these, three, six, does one of them stick out as being less than .2 -- .02, which is statistically significant?
A. I look -- when I look at these numbers, I actually look for .05, at 95 percent. But you're correct that it's less than .02. But generally when I look at a chi-square test, I'm looking to see whether there's statistical significance at the 95th percentile.
Q. By the way, how do we know that they were looking at .98? How do we know that they were looking at .02?
A. I think we can -- you'll see -- in certain manuscripts I see it written down in that way.
Q. Okay. But in any event, this number is less than .95, correct?
A. Yes.
Just if we can highlight it so everyone knows the number we're talking about.
Q. By the way, the one above it, if you could

highlight .0158.
A. Right.
Q. Does that mean that this finding, which we're going to discuss with the jury in a moment, is approximately 98 percent certain that it's not -- that it didn't happen by chance?
A. Yeah. The best way to say it is it's statistically significant. And that, I mean, certainly you're right. You're adding that 98 percent. Again, I tend to look at these things at the 95th percentile. That's why that sticks out. That's the way I'm trained.
Q. Okay. And look at the one above it. Is the one above it within the 95th percentile, too?
A. No, it's not.
Q. The one weeks four to eight.
A. Four to seven, no. That is not within the 95th percentile.
Q. Okay. I'll come back and talk about that later maybe.
Now, let's look at weeks 8 to 12. Was there a statistically significant finding at weeks 8 to 12?
A. Absolutely, no question about it.
Q. And, by the way, from the documents you've

reviewed and what we're about to go through in this with the jury this afternoon, was Janssen well aware that they had this statistically significant finding?
A. Yeah. This is not controversial, I don't think. Yes, Janssen referred to this finding as statistically significant, I believe.
Q. Now, let's look at what they found. Let's go in weeks 8 to 12. And if we can circle -- if we can get in our yellow that little square there, 2237, 257, 7.8, 92.2. Do you see it, sir?
A. Yes, I do.
Q. Okay. No, no, the next one. That's it, Cory, the whole thing.
(Highlighted the screen.)
MR. KLINE: Excellent.
BY MR. KLINE:
Q. Now, let's highlight the other -- if you have another color, that would be good; if not, use the yellow. That's fine. But let's look at this as well.
(Technician complied with request.)
Okay. Now, explain to the members of the jury what we have up there in front of us.
A. So --

Q. Can everyone see that far? Are we too far away?
Too far away.
THE COURT: Well, can that be expanded or zoomed?
There you go.
MR. KLINE: How about that?
(Jurors responded in the affirmative.)
How about one more up?
BY MR. KLINE:
Q. Okay.
A. So this study, remember, is looking for the -- I mean, the end point of this study is a prolactin-related side effect. So that's either gynecomastia or lactation or amenorrhea. That's what you're counting. And they have two groups. First group are -- I mean of the kids who are on this study and on this drug, the kids who have the upper limit of normal who have an abnormal level, they find 20 of the children with the upper -- who have the abnormal level of prolactin, 20 prolactin-related side effects. And they calculate a percentage here of 7.8.
Now, 237 do not. That's 92.2. But

the way you need to look at this is you look across. So they're comparing the number --
Q. Look across you said.
A. So if you can highlight some or put a box around the 20 and the 7.8 and the 7 and the 2.9, I'll explain, because that's the statistical significance.
Q. Okay. Let's do this. Let's take all the yellow off of it. Give us a moment. If everyone will indulge us.
Great. And you're suggesting --
A. And if you can just do me a favor and just add the heading so everyone sees that the 20 is related to the above the upper limit of normal and the 7 is a limited -- it relates to the normal.
(Technician complies with request.)
Q. Excellent.
Do we now have the data that's needed in front of us to understand this?
A. Yes.
Q. Okay. I'm going to --
A. At the 8- to 12-week interval, which is an important interval.
MR. KLINE: Okay. And I am going to snapshot that and mark it as P-35. And we

will copy it, give it to defense counsel, give it to the Court at the most opportune moment.
BY MR. KLINE:
Q. Okay. Now, you were saying, sir.
A. So you see a total of -- remember we were dealing, I believe, at that 8- to 12-week period. Let me just tell you, there were 499 children who had measurements in that 8- to 12-week period. And 257, if you can highlight it, were in this upper limit of normal. So they were above the upper limit of normal, excuse me. So they had abnormal levels of prolactin, we'll call it.
So there were 257 in that group and 242 who had normal levels of prolactin.
Q. Okay.
A. But the analysis, what stands out, is that 20 of the kids who had abnormal levels of prolactin had prolactin-related side effects.
Q. Gynecomastia being the main one?
A. Yes.
And of the normal, kids who did not have -- had normal levels of prolactin, there were seven.
Q. Three times as many if they had -- if they

were -- they're all on the drug, correct?
A. Yes.
Q. Ones who are on the drug get a raised prolactin level. And we know the drug raises prolactin level, correct?
A. Yes.
Q. And --
A. And the question -- the question is whether that prolactin level is associated. We know the drug is related to the gynecomastia, right.
Q. Yes.
A. And the question here is whether the prolactin is related to the gynecomastia. That's the question that's being asked.
Q. And the answer was?
A. In the weeks 8 to 12, this is statistically significant and there's an association.
Q. And, by the way, did they learn in their studies -- you reviewed all these studies -- did they learn that prolactin levels in the patients who took the drug went up and then went down?
A. Yes. So that's -- that's a very important point, because you see a number of -- if you can go back to, kindly, the underlined chart.
Q. Snapshot it. We're going back to the full

chart.
A. And you see that there's a number of different -- these are measured in a number of different week intervals, right. So there's a predose before the drug and then this analysis is done at weeks 4 to 7, 8 to 12, 16 to 24, 28 to 36, and 40 to 48.
So the one statistical finding that jumps out is the 8 to 12 weeks. The others are not statistically significant.
Q. But do you see, sir, if we can focus in on the portion of it that says "prolactin" -- if we can just grab that piece of it right here (indicating).
A. Can I just finish my answer?
Q. Yes, please.
A. So, again, what's very important when you look at an association, to see whether there's an association, and you're doing that and you're looking, this isn't just about statistics, because statistics alone are not going to tell me necessarily the whole story. So what I'm very interested in and what I am trained in, because you also have to look at the biology, and what Janssen knew was that there was the rise in prolactin early on and then it came down. And you can see graphs of

when it came up, right. But it peaks early on. It peaks in that 4- to 7-, 8- to 12-week period, those periods. So I know the biology. I know prolactin levels are increasing in that period. And it's in that period also, this 8- to 12-week, that I see a statistically significant finding.
So I have to put the biology, does it make sense in terms of the biology with the statistics? And that's what -- when I looked at that and put that together, that's why, when I saw that, I said that was an important finding.
Q. And, by the way, when Janssen saw it -- we're now going to look at their drafts of their manuscript, of their write-up of this.
When Janssen saw it, did they think exactly what you're telling this jury today, that this was a significant finding?
A. You don't have to take my word for it. I mean, that's Janssen's --
MS. SULLIVAN: I'm just going to object again, Judge. He's not a mind reader. Let the Janssen people talk about this.
THE COURT: Wait a minute. Is there an objection?
MS. SULLIVAN: Yes. Objection, Your

Honor. No foundation. He doesn't know what the Janssen --
THE COURT: Well, again, why don't you leave us not in suspense. Let's see the document.
MR. KLINE: Sure. I'm about three questions from getting to the draft, but I will --
THE COURT: Skip the three questions and get to the draft.
MR. KLINE: Well, I want to do one thing, which was the trend.
THE COURT: All right. Go ahead.
MR. KLINE: But -- and then I think I could put this document down.
I know it's dense, but stick with me, please.
BY MR. KLINE:
Q. Sir, in weeks four to seven, do you see week four to seven?
If we can pull that out.
A. Yes.
MR. KLINE: Do it all the way across, Cory, and do it with the titles, if you would, please, as efficiently as we can.

THE WITNESS: Yes. I see it.
BY MR. KLINE:
Q. Was there a trend leading up to the 8- to 12-week, as you saw it?
A. Yes. Yes. Let me explain, if I may.
And you may want to also just highlight the weeks 8 to 12 underneath that so I can explain.
So what's important to compare, in weeks 8 to 12, which we just talked about, there were 20 cases with abnormal levels that had adverse events. And within that normal levels, there were seven, not -- almost three times, not quite. There was 20 versus seven. And that was statistically significant, right. And it makes sense. I mean, you see you have 20 in one group, seven in the other group, and it turns out to be statistically significant.
Q. And same question in weeks 4 to 7, sir.
A. I was just going to talk about those.
Q. Go ahead.
A. So if you look -- let's look at the data in weeks 4 to 7. In the kids who had the abnormal level of prolactin, above the upper limit of normal, you see 21. If you can highlight that.

(Technician complies with request.)
And you see in the normal group you have six. So in fact you have more than three times, but that result is not statistically significant.
Q. So if it says -- if the p-value is .3979, that to me is less than point -- is less than .5. Why isn't it statistically significant?
A. No. .05, okay. So that is -- that is not statistically significant. But let me just make my point.
Q. Oh, I see. It's .39.
A. Yeah.
Q. I understand.
A. But if I can make my point.
You see in the weeks 8 to 12, you have 20 and 7, and you compare that, and that's statistically significant and it's not even three times. Weeks 4 to 7, you have 21 versus 6, right. So you really have three times more kids in this upper limit of normal, right. And you say, well, that's three times more. But when you do the math, it's not statistically significant.
Now, I can explain that because, I mean, it has to do with the -- the denominator and

whatever. But when you see three times more, and again, I really think we should focus on the statistically significant data, but it is important to point out that there is three times more, but it's not statistically significant. That's generally, statisticians will tell you that's a trend, because you're building up. Because these are not -- this is not just --
Q. That's what I wanted to ask you.
A. This is not numbers on a page.
Q. Yes.
A. These are patients, right. And you see this 4- to 7-week period early on and then these kids continue.
Q. Yes.
A. So what you see is the numbers are rising here, in this early period.
Q. Okay. I don't know if we got too much or too little, but I am going to move on.
We now are -- we now know that there's that statistically significant result. Did Janssen go about the writing up of this -- of these statistical data into a paper?
A. Yes.
Q. All right. And I'm going to mark as Exhibit

36 an e-mail which is from Carin Binder to Gahan Pandina, dated July 16, 2002. It's now P-36. And attached to it is a draft document which is entitled, "Prolactin levels in children and adolescents with long-term risperidone use."
MS. SULLIVAN: And, Your Honor, I'm just going to object to these manuscripts because the prescribing doctor never saw this study, so it has nothing to do with this case. So I'll object on relevance and 403 grounds.
THE COURT: No; it's overruled.
MR. KLINE: Same things that were ruled upon...
THE COURT: Let me see it. All right. This is overruled.
Objection overruled.
BY MR. KLINE:
Q. Okay. Now, sir --
A. May I just ask so I know we're exactly referring to the same thing.
Q. I'm on your Tab 15, if that helps you. I'm at draft one of the paper.
A. And the e-mail is from whom to whom?
Q. It's from -- the draft one contains an e-mail

on the front of it from Binder to Pandina.
A. And the Bates number is 718?
Q. And the Bates number is 718, yes.
A. Thank you for that.
Q. Okay. Thank you.
I want to try to kind of get to the end of the road, which has been a long road. And I appreciate everybody's patience.
Now, here we go. I need to get to see whether they put this in the study. I want to go through the study, some highlights of it.
Do you have the e-mail in front of you, sir?
A. Yes, I do.
Q. Okay. And do you see the subject on Page 14079718?
Cory, if you would be prepared to display it -- or don't display it.
It's listed as "Subject: Draft Prolactin Manuscript," okay.
Do you have it there, sir?
A. I see it, yes.
Q. Is that what it says?
A. Yes.
Q. Did you review this document?

A. Yes.
Q. Is this document as well as all these other documents, the ones that I have asked you about, as to whether you have an opinion as to whether Janssen's warning to physicians was inadequate?
A. Exactly.
Q. And, by the way, when we're talking about whether on that question, before we get to this document, on whether the warning was adequate, are there various ways that a drug company, especially with an off-label drug like this being used in children, can warn?
MS. SULLIVAN: Objection, Your Honor. Well beyond this expert's report. He's testified it should be in the WARNINGS section. His report said it should be in the WARNINGS section of the label, so I'll object. It's not in his report. Everything beyond that --
MR. KLINE: Your Honor --
THE COURT: This document --
MR. KLINE: Let's straighten it out at a break, Your Honor, otherwise we'll end up at a sidebar.
THE COURT: Well, the objection at the moment is sustained and we'll look at it.

MS. SULLIVAN: Thank you, Your Honor.
MR. KLINE: I can assure the Court that it's in his report. Dear Doctor Letters and all the rest.
THE COURT: I'm sure you'll be able to show me something.
All right. So let me see.
MR. KLINE: Okay. But let's -- I'll move so we can do it at a break rather than a sidebar.
THE COURT: Go ahead.
BY MR. KLINE:
Q. Now, sir, I'd like you to look at the abstract which is two pages in.
I'm going to try to avoid rushing, which was my problem yesterday, even though I have a tendency to want to do it.
I would like you to look at Bates No. 721 -- Cory, are you with me as well, sir?
VIDEO TECHNICIAN: Yes.
BY MR. KLINE:
Q. And it's the abstract of the paper. So long as there's no objection, other than the ones that have been raised, and the Court allows me, I will

display it, if the Court --
THE COURT: All right. You may go ahead.
MR. KLINE: -- permits it.
THE COURT: This is at 9721.
MR. KLINE: Yes.
THE COURT: And for all of us, this was an attachment to an e-mail, is that correct, or part -- this is a page of an attachment to an e-mail.
MR. KLINE: It's really -- I would not identify it that way, sir. The e-mail simply -- I would say that the e-mail happens to be the transmittal to a draft document. What I'm displaying is a draft -- draft number one of a paper that is entitled, "Prolactin levels in children and adolescents with long-term risperidone use."
THE COURT: All right. And this is -- and this goes back to July of 2002.
MR. KLINE: That is correct.
THE COURT: Okay.
MR. KLINE: It is dated July 16, 2002.
THE COURT: All right. Very well.

Thank you.
MR. KLINE: The very bottom of the page, it says "Revised July 16, 2002."
I'm sure that Mr. Smith will highlight that briefly.
And as long as we're on that first page, would you please step back a minute and not jump ahead of me.
Thank you.
If we can go back to 4719 which we were on.
(Technician complies with request.)
MR. KLINE: Thank you.
BY MR. KLINE:
Q. On the bottom of the page it says "Acknowledgments supported by Janssen-Ortho, Inc." Do you see that, sir?
A. Yes.
Q. And the information I now want to go to is contained on Page 721. The document itself is not paginated internally, so I can't refer to their pages.
And under abstract and background, I'd like to look at the first paragraph, sir.
A. Yes.

Q. And I'd like to not highlight the whole thing, Cory, I'd like to just focus on the word "any relationship with side effects."
No. No. I'd like you to pull up the whole paragraph and simply highlight "any relationship." That was my intention. I gave a -- I didn't give a full enough request.
Yes.
Was the purpose to explore any relationship?
A. Yes. That's exactly what it says.
Q. And is there any indication yet that they were going to take out kids over 10?
A. Not at all.
Q. And in fact under Method, in the -- before we get here. If you can put that back up, Cory.
They now are using a different terminology. For the first time we see the words used --
MS. SULLIVAN: Objection, Your Honor, to the lawyer testifying.
MR. KLINE: I think that it would be stipulated to, but maybe I'll have to prove it.
THE COURT: You're going to have to

prove it. If you want to, you can compare them to another document that has some other statistic --
MR. KLINE: I'll ask a different question which I don't think will be objectionable.
Would you take the highlighting off, please?
(Technician complies with request.)
MR. KLINE: Again, I apologize. I have a lot I want to cover and I want to rush, but I don't want to rush. So I'm going to slow myself down.
BY MR. KLINE:
Q. Do you see the words -- do you see that sentence, sir? Would you read it to the jury?
A. [Reading]: "This analysis was designed to investigate prolactin levels in children with long-term risperidone treatment and explore any relationship with side effects hypothetically attributable to prolactin open parentheses S-H-A-P close parentheses, SHAP."
Q. Okay. Now, way back when I started, all the documents you saw prior to this point, did they talk about PRAE, prolactin-related adverse events?

A. Or prolactin-related side effects, yes.
Q. Did the main documents with those tables we were looking at, did they say prolactin-related adverse events?
A. Yes.
Q. Now, this document is talking about something called "SHAP," symptoms --
A. Side effects.
Q. I think it's "symptoms," sir.
A. If you look at the -- just look at the background.
Q. Okay. Side effects.
A. "Side effects hypothetically attributable to prolactin." Sorry. I didn't mean to -- there's a small difference, symptoms, side effects.
Q. Hypothetically.
A. "Attributable to prolactin, SHAP."
Q. Attributed [sic] to prolactin.
And my first question, sir, is -- I'll have to write this out better later.
Symptoms hypothetically related.
Well, was there anything hypothetically related, going back in the other studies that you saw?
A. They didn't use that term, no.

Q. And when they started to use in this draft the term "SHAP," is SHAP a word that -- in any document you had seen prior to this write-up, had you seen the word in the Janssen documents relating to the prolactin-related adverse events?
A. So there is an e-mail that I saw.
Q. Yes. Other than that e-mail which I don't want to discuss with you right now.
A. I don't recall seeing it.
Q. Okay. Just bear with me one second.
Now, let's look under Method.
Here we are under Method.
And just very briefly. Children -- all the kids were age 5 to 15 in the study, correct?
A. Yes.
Q. And did they change that at this point?
A. No.
Q. And I'd like to look at page Bates stamp number ending in 740 and 741.
And I'd like to display that.
- - -
(Technician complies with request.)
- - -
MR. KLINE: With all that fancy footwork by Mr. Smith, can everyone see it?

(Jurors responded in the affirmative.)
MR. KLINE: We okay?
BY MR. KLINE:
Q. Now, sir, I'd like you to -- what we have displayed are two pages from the write-up. Do these two pages -- is what's before the jury right now the write-up as it relates to Table 20 -- the key finding that you flagged for us in Table 21?
A. That's discussed in these -- what's on the screen, yes.
Q. And I'd like to, first of all, snapshot it, if I may, and give it a number, and print it for the Court. It would be P-37.
We will have that done for the court officer momentarily.
(Whereupon Exhibit P-37 marked for identification.)
MR. KLINE: We're now printing them right out of the printer here.
BY MR. KLINE:
Q. And, sir, would you tell the members of the jury, would you, if I first can point this out, the manuscript goes to -- down to where the bold print is, and then somebody interjects a question, which we'll talk about.
So first would you tell us what it states here in the -- first what we're going to learn is the first of a number of drafts of this paper.
THE COURT: Well, we're only going to do this draft before we take a break, correct?
MR. KLINE: Okay.
THE WITNESS: So this -- these paragraphs describe what we talked about on Table 21. Would you like me to read it?
BY MR. KLINE:
Q. Yes.
A. It says [reading]: "The percentage of children with SHAP was assessed for patients with prolactin levels above the upper limit of normal versus patients with prolactin levels within the normal range at the various analysis time periods.
"The proportions were all comparable except for the weeks 8 to 12 time period, in which 7.8 percent of the patients who had prolactin above the upper limit of normal had SHAP at some point during the trial, while 2.9 percent of patients with prolactin levels within the normal range at weeks 8 to 12 experienced SHAP at some time during the study."
And then it gives the statistically significant result -- remember you asked me about a p-value -- less than .02.
Q. Yes.
A. And that's where that -- that's that symbol. And then it goes on to say [reading]: "There were no statistically significant differences in the percentage of patients who reported SHAP for any other analysis time period [sic], whether or not prolactin levels were normal or above the upper limit of normal." And they gave the range of 3.7 to 6.9.
Q. Okay. A couple of questions, a few questions before we take the break.
First of all, sir, you see this thing that has P equals less than 02?
A. Yes, sir.
Q. And if you can highlight that, Cory. Do you see it?
In science jargon, now that we're all clued into it, is that saying we have a statistically significant finding by our standard that we picked?

A. Exactly.
MS. SULLIVAN: Objection, Your Honor. This is again mind reading. They could ask -- they did ask the witnesses. They can play their actual testimony.
BY MR. KLINE:
Q. Sir, I have a different question.
THE COURT: All right.
BY MR. KLINE:
Q. I have a question, sir. Is this mind reading? Is this mind reading?
A. That's statistical significance. Every scientist will tell you that's what that means.
MS. SULLIVAN: I don't object to the statistical significance.
THE COURT: I'm not --
MS. SULLIVAN: I object to him just talking about what's meant by the words.
THE COURT: Counsel, you'll have your opportunity to ask Dr. Kessler what that means and what it's not, but right now we are pressing on.
MS. SULLIVAN: Thank you, Your Honor.
BY MR. KLINE:
Q. Next, is what's flagged here, sir, in this

write-up exactly what you flagged for the jury today?
A. If you -- even if you pull up that highlight, that 7.8, and that 2.9 percent for that weeks 8 to 12 where you highlighted it and had it pulled out last time, that was exactly what they're talking about, that time period.
Q. And every time they're now saying "SHAP," is that referring to what they were always calling before a prolactin-related adverse event?
A. Yes. They're calling it by this other term.
Q. And, sir, when it says -- someone interlineated on the bottom, someone who was in the group said how do you want to handle -- how do you want to handle the one significant value? It goes on to say, "The poster."
Briefly, what is a poster?
A. Poster is a presentation of data at a meeting, for example.
Q. The poster says, "There was no direct correlation with prolactin elevation and SHAP. What analysis was used for this? Can we get correlation coefficients for prolactin levels versus SHAP as was done for prolactin levels versus age, and if no correlation, just stick with that."

Is that what it says there?
A. That's exactly what it says.
Q. Is this science, sir, what you're looking at right now?
MS. SULLIVAN: Objection, Your Honor. It's argument.
THE COURT: That's sustained as to whether it's science. You can ask him what it means to him, though.
BY MR. KLINE:
Q. What does it mean to you, sir?
MS. SULLIVAN: Objection.
THE WITNESS: Somebody realizes who's read the paper that there is a significant value here. They also state that they have -- there's a poster that they put out that says there's no direct correlation, and, in essence, this is saying we have a problem.
THE COURT: Anything else?
MR. KLINE: Not right now.
THE COURT: All right. We're going to take a break here. It is ten of 3:00. Let's come back at 3 o'clock. Please do not discuss this matter with each other or any other source, okay?

COURT CRIER: All rise as the jury exits.
- - -
(Whereupon the jury exited the courtroom at 2:48 p.m.)
- - -
THE COURT: All right. We're in recess for ten minutes.
- - -
(Whereupon a recess was taken.)
- - -
(Whereupon an off-the-record discussion was held.)
- - -
THE COURT: You're on notice that I am in no way going to limit the time of cross-examination. If this witness needs to come back on Monday, then certainly he will be able to come back.
THE WITNESS: Whatever Your Honor wants.
THE COURT: He needs to be somewhere this weekend, but he's coming back on Monday.
MS. SULLIVAN: Well, the only thing we would object to is another witness going

on before we get to finish the cross-examination.

THE COURT: Well, again, that's not my practice. I wouldn't mind taking a morning off and catching up on all these other activities that I'm involved with.

MS. SULLIVAN: Understood, Your Honor.

THE COURT: So we'll look at it, what the situation is, after today's testimony.

MS. SULLIVAN: Okay. Thank you very much, Your Honor.

MR. KLINE: I just know I got aways to go.

THE COURT: Okay.

COURT CRIER: Jurors are now entering. Please stand.

- - -

(Whereupon the jury entered the courtroom at 3:05 p.m.)

- - -

THE COURT: All right.

COURT CRIER: Please be seated. Court is now back in session.

THE COURT: Be seated everybody.

All right. Just -- and have you all met Ms. Zeller? Kathy Zeller is our court crier for the afternoon. Marianne had an appointment she needed to make. So I also wanted the lawyers to know that Ms. Kathy Zeller is going to be helping us out.

All right. Mr. Kline, when you are ready, you may proceed with Dr. Kessler.

MR. KLINE: Okay. I am ready.

I'd like to return to where we were at the break, which was that call-out of the -- yes.

BY MR. KLINE:

Q. Dr. Kessler, the statement that we have there relating to the poster, if we can go down to the poster, the question that was asked about the poster. It was interlineated, "the poster states that there was no direct correlation..."

Do you see it, Cory? If you would highlight that. "The poster states there was no direct correlation with elevation between SHAP."

Now, you told us what a poster was, which is a presentation that apparently had been made on the -- about this, correct?

A. It says -- I don't know if it had been made or

was going to be made, but clearly there was another presentation of data.

Q. Okay. And in fact if there was a poster that said that, then that would be incorrect?

A. Yes, for a number of reasons.

Q. And what are those number of reasons?

A. Well, there is an association. There is a relationship, okay, at 8 to 12 weeks. There are other periods where there's not a relationship but there is that statistically significant finding.

Q. Does this --

A. Can I just finish?

Q. Yes. You were going to say something else.

A. I apologize. And I don't want to take -- I could spend the next hour --

Q. Please don't.

(Laughter.)

A. But I promise, but this is -- I could spend the next hour discussing the difference between correlation and association, okay.

Suffice it to say, if you look at the purpose of this study -- and it's right up there in the write-up -- is to see whether there's any relationship. And you can't do a correlation unless there's continuous variables.

So Janssen was correct to do the chi-square, which is a test of an association. So there is not going to be a direct -- the correlations -- the right way to measure the relationship is with chi-square, and they see a relationship.

So anything that says there's not an association or not a relationship or leave that impression would be incorrect.

Q. And the other 58 minutes?

A. If you want I'd be happy to.

THE COURT: No. Doctor, not 58 minutes.

MR. KLINE: No. I said the other 58 minutes, the remaining.

Okay.

BY MR. KLINE:

Q. So we have in -- at this time, sir, the -- when this -- when this draft is being written, which is July of 2002, to go back to a benchmark earlier, was the drug, from the documents that you've seen, this prescription medication, continuing to be prescribed to children around the world?

A. Oh, yes.

Q. Okay. Now, that would take us, or at least

me, to asking the question with this in mind and those questions being -- this question being asked, is there anything else in this document that needs to be reviewed in support of your opinion or can I go on to the second draft?

A. You could certainly go on to the second draft. I just want to, if I may, just point out that the language here gets it right. I mean, this language adequately, in my view, explains the data in Table 21. This is a fair representation in this draft.

Q. And insofar as picking out a data point, was that data point actually zoomed in on, picked out, and focused on by Janssen?

A. Yes. They -- they did that and they did that appropriately. That's the statistically significant finding.

Let me just -- that "data point," right, I mean, underlying that data point are hundreds of data points that go into that statistically significant finding. You saw those denominators, the number of children. So, I mean, that is, I mean, just -- when you say a data point --

Q. Yes.

A. -- I just want you to understand that there's

a lot of data that gets rolled up into that analysis and into that finding.

Q. Okay. That takes us to draft two. Was there a second draft which you became aware of relating to this pooled analysis?

A. Yes.

Q. Okay. And just to focus, I know there's a lot in a short time in this trial, the pooled analysis involves putting the data of these five studies together, correct?

A. Exactly.

Q. All right. And there is -- there is an e-mail which transmits a second draft. And I would like to -- and have you reviewed that e-mail, internal e-mail between people on the Janssen team, attempting to develop the drug for use in children and adolescents on label; is there an e-mail?

A. There are actually three e-mails on one page that I have reviewed.

Q. And I'm going to mark -- I'm going to carefully go slow on this. I'm going to mark an exhibit which is 168 -- Bates No. 168. I'm going to mark the e-mail that we have -- the e-mail chain we have in front of us as Plaintiff's Exhibit 38. It's a two-page document. I'm going to hand it to the

court officer to hand to the Court.

And just assure myself that in our discussions, that this e-mail I believe to be usable, top and bottom. That's my understanding.

I plan to --

THE COURT: All right. Any objection, Counsel, P-38?

MS. SULLIVAN: Your Honor, I think you've already ruled on this one.

THE COURT: Yeah.

MR. KLINE: Okay.

Then I intend to go to the entire chain of the e-mail, top and bottom e-mail.

BY MR. KLINE:

Q. And let me just make sure on one point, if I may.

(Pause.)

MR. KLINE: Okay. I wanted to make sure, Your Honor, that we have the requisite testimony --

THE COURT: Okay.

MR. KLINE: -- that we've discussed.

BY MR. KLINE:

Q. And let's look at the e-mail that is on the bottom of the page from Binder to a number of people

on the team.

A. I see it.

Q. And it includes Pandina as well, correct?

A. (No response.)

Q. You see his name there?

A. Yes, I do, on the second line of the two.

Q. And, by the way, because I may be able to tie this in later, you see Carmen DeLoria as well, correct?

A. Yes.

Q. And Ms. -- or Ms. Binder says -- addresses the e-mail: Dear Pediatric Publication Team.

I'd like to display the document, so long as there's Court approval, for me to display the bottom e-mail.

THE COURT: Right. P-38, the bottom.

MR. KLINE: Yes. And this would be the first page which ends in 168. 00115168.

Your Honor, in gauging, are we on a hard stop at 4:30 like yesterday?

THE COURT: No.

MR. KLINE: Was that the issue?

THE COURT: No. But before 5:00 we're going to be out of here; or not.

MR. KLINE: Okay.

THE COURT: I mean, we can go a little bit past 4:30 today.
MR. KLINE: Okay.
THE COURT: I doubt it.
MR. KLINE: I'll be at a point probably when I want to break, but I'll discuss with the Court.
BY MR. KLINE:
Q. And it says, Dear Pediatric Publication Team, correct?
A. Yes.
Q. And Ms. Binder says, "May I ask you to please review the attached draft manuscript within the next two weeks, if possible. Since this is a holiday time, leeway will be extended to early September." The date here being August 15 of 2002.
"I have inserted some comments in yellow for our authors to clarify. Please ignore these."
And then she says here -- and I'd like to call it out, if I can, so that you can enlarge it -- "Key message."
"Key message." If you can get that enlarged, please, so that we can actually see it from the jury box.

(Technician complies with request.)
MR. KLINE: That's the best you can do, Cory?
Can you see?
BY MR. KLINE:
Q. Okay. It says there's a Key message: "Prolactin rise is transient and not related to side effects hypothetically attributed to prolactin, EPS, or efficacy response."
Do you see that, sir?
A. Yes.
Q. And based on what you've reviewed, is that consistent with what they found in Table 21?
A. No.
Q. How can you -- how can a pharmaceutical company have a key message --
MS. SULLIVAN: Objection, Your Honor. It's going to be argument.
THE COURT: That's sustained.
MR. KLINE: I'll ask it instead of the "how."
BY MR. KLINE:
Q. Is it acceptable, sir, for a prudent pharmaceutical company to have a key message inconsistent with the data in its very files?

MS. SULLIVAN: Objection on foundation. And it's argument. And it's beyond the scope of the --
MR. KLINE: It's a general question.
THE COURT: Well, I'm going to sustain it.
Why don't you relate it, Counsel, to the actual opinion being offered to the jury.
BY MR. KLINE:
Q. Sir, does this -- when you said that the Janssen Pharmaceutical Company provided an inadequate warning in the period 2002 to 2006, does this document relate to the opinions which you've formulated?
A. Yes.
Q. Tell us how.
A. The most important thing for me, I mean, both at the FDA and as a doc, a physician, is, and as someone who sits on the boards of the pharmaceutical companies, is -- the one thing that you have to do when you're dealing with all medicines, including very powerful medicines, is to tell the truth, and you tell the whole truth and you tell the whole story and you make sure that the data support that -- support what you're saying.

A key message -- and pharmaceutical companies have key messages, they have -- what that means is what they want to convey. And what they want to convey here -- and as you'll see in their own words -- don't match what the data show. And to me, that's not telling the whole story, especially when you're talking about adverse events that are significant and there's a relationship.
So you just make sure that FDA knows that, make sure doctors know that. Tell them the whole story, the good and the bad. It's not statistically significant at every time point, but it is statistically significant at one important time point. Tell them that, the good and the bad. And that's what I care about. That's what went into my opinion.
Q. And, sir, what flows from that opinion, I have a question.
Did Janssen, knowing that this was being used off-label in thousands of children, did they have an obligation to get the word out as to this finding?
A. Absolutely.
MS. SULLIVAN: Objection, Your Honor, in terms of foundation. An obligation based

on what regulation?
THE COURT: Well --
MR. KLINE: Based on this information that's here.
THE COURT: Well, if you're opening the door to it, we could ask the witness all about what goes into that opinion.
MS. SULLIVAN: Well, Your Honor --
MR. KLINE: Of course.
MS. SULLIVAN: I would -- Your Honor, it's our position there's been no violation of any regulation. And this witness can't tie anything to his expertise which is a regulatory expert.
MR. KLINE: That's also not true.
THE COURT: No. You're --
MS. SULLIVAN: He's basically saying I think --
THE COURT: You're making a speech, Counsel. You may rephrase the question. But if there is some explanation to be made about the last statement or last opinion, then have him do it.
MR. KLINE: I will ask -- I will clear it up.

I believe I have that question and answer.
BY MR. KLINE:
Q. My next question is, sir, is a general one.
Is there any -- was there any regulation in effect between 2002 and 2006 that said that a pharmaceutical company could not warn of a key safety finding? Yes or no.
MS. SULLIVAN: And I'm going to object, Your Honor, on preemption grounds. And the issue is did we violate any. And Dr. Kessler can't point to any --
THE COURT: Again, are you making a speech?
MS. SULLIVAN: Well, Your Honor, it should --
THE COURT: Objection overruled.
MS. SULLIVAN: All right.
THE WITNESS: May I respond?
BY MR. KLINE:
Q. Yes.
A. There have been a number of points that have been raised and let me address them, okay.
Most important, okay, and I'll do this from memory, but I'll give you the citation,

Your Honor. The FDA has been very clear, and that goes back to 1979. It's in the Federal Register. There is -- a manufacturer can always warn about safety and should warn doctors about safety. There is nothing in the labeling regulations -- this is almost a quote from the Federal Register -- there's nothing in the regulations that prevent a manufacturer from warning. A manufacturer can warn in many different ways. Manufacturer can warn in a Dear Doctor Letter. A manufacturer can have their detail people warn. A manufacturer can warn in the label. They can warn in many different places of the label. There's something called the WARNINGS, with a capital W. That's not the only place for a manufacturer to warn.
On the duty, I'm going to be very specific, there are two duties, I mean, as I see them, okay. If you're going -- put very simply: If you're sending a sales representative in to a doctor's office multiple times --
MS. SULLIVAN: Objection. Again, Your Honor, can I have a sidebar? This is not in his expert report at all. They're just coming in and making up a new series of --

MR. KLINE: I'm not making anything up.
THE COURT: This is in response to your objection. Overruled.
THE WITNESS: If you send a sales representative in to a pediatric neurologist and you do that multiple times, right, you have an obligation under the regulations to provide adequate directions for use. That's required under the law.
I can explain that. I've written about that. But the important point is leave aside the regulations from an FDA point of view. Just look -- I can just tell you from sitting on the boards of pharmaceutical companies and I could tell you as a doc, if you have information that relates to the safety of a drug, you have to communicate it. It would not be reasonable, it would not be prudent not to do that. Tell the good. Tell the bad. Make sure that doc is informed. That's what FDA cares about when it comes to safety.
BY MR. KLINE:
Q. Now, sir, I'd like to look at draft two.

We had covered the e-mail leading up to that, and I'd like to go to the one above it. Carin Binder wrote that e-mail on Thursday, August 15th, at 11:06 a.m., saying what the key message should be.

By the way, she's writing that, as we know, as the medical -- strike that. I don't need to tell you again.

We have Dear Team, an e-mail above it from -- from the --

A. The August 21, 2002.

Q. Yes.

And if I can focus, this is from Pandina back to Binder and the group. He's one who responds, correct?

A. Yes.

Q. And if I can go three sentences down, beginning with the words "If, if we can demonstrate." It's that sentence which will be my call-out, Cory.

"If we can demonstrate" -- yes. He'll get it in a minute. Okay.

That's the extent it will rise.

"If we can demonstrate that the transient rise in prolactin does not result in

abnormal maturation, or SHAP, this would be most reassuring to clinicians."

Do you see that?

A. Yes.

Q. And did you include that -- did you review that as well in forming your opinion as to what was said there by Dr. -- or by the psychologist, Pandina?

A. Yes.

Q. Now, the very top document of the e-mail attaches a document, and I'd like to look at it.

Draft number two. I'm marking draft number two --

A. Yes.

Q. -- as P-39. I'm handing it -- Mr. Gomez is handing it to our court officer.

THE COURT: Okay.

(Whereupon Exhibit P-39 marked for identification.)

THE COURT: All right. This was the -- you don't call it an attachment. But this was referred to in the e-mails.

MR. KLINE: Yes, exactly.

THE COURT: P-39.

MR. KLINE: And it's P-39. It's

actually what we would describe as draft two of the study.

THE COURT: All right. This says 00115170.

MR. KLINE: Correct.

THE COURT: All right.

MR. KLINE: Thank you, Your Honor.

And I'm going to display some portions of it. I don't believe there's an objection, and so I believe it's fair game to display.

MS. SULLIVAN: I believe the Judge has already ruled on this, subject to our objections.

THE COURT: Yes. The objection's been preserved.

MR. KLINE: All right.

BY MR. KLINE:

Q. Let's look at the draft very quickly, the draft. The title doesn't change. As of now, it says, "Prolactin Levels in Children and Adolescents with Long-Term Risperidone Use," correct?

A. Yes.

Q. And if we go to, again, the -- it's not paginated as an original document, but -- yes. I

need the revision date of the draft -- my colleague reminds me -- which is on the bottom. It's now revised July 30, 2002. July 30, 2002 draft.

And I'd like to call your attention to page, the Bates number ending in 192; 00115192.

A. I see it, sir.

Q. And I want to call it out, that paragraph, the whole paragraph, if you will, Cory.

THE COURT: All right. For the record, this particular page is going to be marked eventually as P-39A.

MR. KLINE: Yes.

THE COURT: All right. So now we're looking at the second -- a certain paragraph of 39A.

MR. KLINE: Yes. I'm going to snapshot this call-out as the next P number, P-40.

We will print it. We will hand it to the court officer momentarily.

BY MR. KLINE:

Q. And this document, sir, as to the write-up of what we've been discussing, it says, "The percentage of children with SHAP was assessed for patients with prolactin levels above normal versus patients with

prolactin levels within the normal range at the various analysis time periods. The proportions were all comparable except for weeks 8 to 12 time period in which 7.4 percent of the patients who had prolactin above the upper limits of normal had SHAP at some period during the trial, while 2.9 percent of patients with prolactin levels within the normal range at weeks 8 to 12 experienced SHAP at some time during the study, paren, P equals .02."

A. I see that.

Q. And, sir, is the language essentially the same?

A. As the prior draft.

Q. And, by the way, did you see e-mails where they were essentially sending these drafts back to brainworks to be redrafted, or don't you have that recollection?

A. I don't have that recollection.

Q. Okay. And there's a note --

A. Should I read the note?

Q. Oh, no. Before we read the note, let me finish the paragraph.

There's a note in there underlined in bold that has Gahan there. Do you see that?

A. Yes.

Q. And I don't believe it will be controversial to say that that was added by Gahan Pandina, and we'll produce the deposition testimony of him.

But the last paragraph -- the last sentence says, "There was no statistical significant -- there was no statistical difference in the percentage of patients who reported SHAP for any other analysis time period, whether or not prolactin levels were normal or above the upper limits of normal, paren range 3.4 to 6.5 with SHAP, end of paren."

Putting aside that comment, which we're going to discuss in a minute, did draft two contain the write-up which was in number one and which you also pointed out to the jury before we started to look at these drafts?

A. This is a -- yes. This is a write-up. It includes the important information.

Q. Now, Pandina, who we know is on the team, he adds something. And he says what, sir?

A. He -- the parenthetical says "this" -- and he's talking about the finding that I talked about, that week 8 to 12 increase, that statistically significant finding. He says, "This may be notable, as this could be seen to suggest that patients who

show an initial rise during the peak period above the upper limit of normal do have a higher propensity for SHAP."

And then he goes on --

Q. Well, before you go on. Is that a correct statement, as you understand it, based on the data?

A. Yes. That's exactly what I was saying, yes.

Q. And he says -- go ahead to finish it.

A. He says, "I think we need to discuss this somewhere in the manuscript."

May I comment?

Q. Yes.

A. Perfectly appropriate, and I applaud him for writing that. He points out the significance of the finding as well as I could, and he says "I think we need to discuss this somewhere in the manuscript."

Q. Okay. Now, let's continue and go to something that happened from there. That last draft was September -- or was July 30th of 2002.

A. Yes, sir.

Q. In September of 2002, did Janssen decide to write a new data analysis plan?

A. Yes.

Q. Well, I have a question, sir. I thought they -- if they have a data analysis plan already,

why would they have a new data analysis plan? Do you know?

A. I don't know. You can certainly amend data analysis plans. But you certainly don't want to change your statistical plan after you know your results, after you get your data. That's what you -- I mean, unless there's very, very, very specific circumstances. But you don't want to get the results and then have a statistical finding.

Q. Okay. Now, there is a document which I'm going to mark as Plaintiff's Exhibit 41. I will -- it is a multiple page document entitled, "Statistical Documentation, Long-Term Risperidone Treatment versus Prolactin Pooled Analysis." It begins with Bates Nos. 03888723 and ends with 03888729. Yes, they are JJRE documents.

So I will hand it up to the court officer.

This, plan, sir, if we can display it. I believe there's no objection. And I would ask to display it at this time.

MS. SULLIVAN: No objection.

THE COURT: All right.

MR. KLINE: I'm displaying Bates No. 723 first.

THE WITNESS: Yes.
BY MR. KLINE:
Q. Okay. Note the date, September 27, '02. We now have a new plan as to how to analyze the data, correct?
A. Yes.
Q. And is there a significant change, sir?
A. Yes.
Q. I'd like you to look at Page Bates number ending in 725.
A. Yes.
Q. And look at the very top which says Key Variables.
A. Key Variables Analyzed, yes.
Q. And tell us what are the -- what is the terminology, Key Variables?
A. It's what you're going to include -- what you're -- what the instructions, in essence, you're telling the statisticians to run the data using.
Q. Uh-huh.
And previously, have they included all data sets?
A. Yes.
Q. And have they run data on all the boys?
A. Yes.

Q. And now, sir, if you look under Key Variables, on the second bullet point.
A. Yes.
Q. Now, we know that the studies included boys from 5 to 14, correct?
A. Yes.
Q. Now, they're including all of the boys under 10 years old, correct?
A. They are including only the boys less than 10.
Q. Only the boys less than 10.
That means it now eliminates all the boys who are 11, correct?
A. Yes.
Q. All the boys who are 12, correct?
A. Yes.
Q. All the boys who are 13, correct?
A. Yes.
Q. And all the boys who are 14, correct?
A. Yes.
Q. And most of the boys that are in puberty, correct?
A. Yes.
Q. Was that the plan to begin with?
A. That's not the way the data was run to begin with.

Q. And was this -- this new statistical plan, sir, if I can go back to Page 723.
A. Yes.
Q. If we can look at the sponsor of the plan, the sponsor was Janssen-Ortho, Inc., correct?
A. Yes.
Q. And it was prepared by the statisticians, correct?
A. Who ran that initial set of data back in May.
Q. But I thought you told me that SciAn had already run data for them.
A. Well, you saw on those -- yes. I showed you on those tables back on May 15, I showed you that they were prepared by this company, the May 15th data were prepared.
Q. Okay. Well, I guess it would -- the fall then brought a different plan.
They had a -- the other plan was dated when?
A. The original --
Q. May 15.
A. -- the original meeting was back in January 2002.
Q. If I can just step back for one second. When was the original plan?

January 2002, okay.
So of the two plans for 2002, there's a winter plan and now we have a fall plan, correct?
A. You have -- yes. You have data run based on one set of instructions in the early part of 2002 and you get that data and you get a statistically significant finding, and then there is this document that's sort of after -- after that data has been run. It's after that data.
Q. Okay. Now, did they run the very same table that we saw as Table 21?
A. Yes. They ran something almost identical.
Q. And in this paper it became -- it had a different number. It had Table 20; would that be correct?
A. Yes.
Q. And only this time it's done without the boys over 10, right?
A. Yes.
Q. And let's see what we got.
I'm going to mark as the next exhibit number, P-42. It's part of a larger packet. And I will put the larger packet together and make it as part of the exhibit. But this will be 42A. And we'll bring in the full document.

(Exhibits P-42 and P-42A marked for identification.)

THE WITNESS: Can you tell me what tab?

BY MR. KLINE:

Q. Yes.

A. I'm sorry.

Q. That's okay. There's a lot here. I have it under tab -- I have it in my book right in Tab 17 behind the statistical plan.

A. Thank you, sir, very much.

Q. Do you have it that way in your book?

A. I can find it now. Yes.

MR. KLINE: Okay. 42 is going to be the bigger document.

THE COURT: 42 is also September 27, 2002, right?

MR. KLINE: Yeah.

THE COURT: All right. So now we're looking at 42A, which is Table 20 of the entire document, and it's a one-page document, and it's Table 20.

MR. KLINE: Yes.

THE COURT: All right.

MR. KLINE: I'm just waiting for

Mr. Smith to put something up together so we can see it.

(Pause.)

And I know they're small, but on the left side we have Table 20 from the January run, and now we have Table -- I'm sorry -- 21. And then we have Table 20 from this run. But they're too small to see. I'll zero in, promise.

BY MR. KLINE:

Q. Now, let's look at this Table 20.

Table 20, let's look at the very top and see what it says.

It says, "Long-Term Risperidone Treatment versus Prolactin Levels -- Statistical Documentation for Manuscript Support, September 27, 2002."

Did I read it correctly, sir?

A. Yes.

Q. Now, is there anything different that's said there in that table versus Table 21 that we've already seen other than it has a new date on it?

A. Just the date.

Q. And we know they're using protocols for CAN-19, 20, 93, 97, and 41, correct?

A. Yes. Correct.

Q. And we now look at the table itself. You can take the Table 21 down, and let's just work off Table 20, which is Exhibit 42A.

(Document displayed.)

And let's go to weeks 8 to 12.

Are you able to do better?

How did we get it bigger before?

We singled out this.

Okay. Let's single out this and then put the title on the top, just like we did before so that we can actually see weeks 8 to 12.

(Technician complies with request.)

BY MR. KLINE:

Q. Okay. Well, there are far fewer boys with gynecomastia now, correct?

A. Yes. There's -- there was 20. Now there's nine. Well, in the upper limit of normal there was 20 and now there's nine.

Q. And there's far fewer in the ones that weren't above the normal limit on their prolactins, correct?

A. There's only three here.

Q. Yes.

And the ratio appears to be about the same, sir. It's still three to one.

A. Yes. But the statistical significance disappears.

Q. Oh, disappears.

A. Yes. At the -- at the .05 level.

Q. Hmm.

So now when a pharmaceutical company -- now when Janssen is going to report this data and information, at least as to the boys who are -- when you eliminate all the boys over 10, can you say that it's not a statistically significant finding?

A. That's what this would -- yes. The data are the data if you do it that way.

Q. Would that be the full story?

A. No.

Q. And if you look under Footnote 3 way down there in the footnotes. Wait. Before we do it. Can we take the -- can we get the full page back up again?

If you were to look for what you are looking at here, on this page what's in front of the jury is Exhibit 42A which is a full page, only we've enlarged it on the screen. And if you wanted to know that it was only the boys included up to 10 years old, you would have to go down to Footnote 3,

correct?
A. It's there, yes.
Q. And it says in Footnote 3 at the very end right here and "males."
Males under 10 are included?
A. Yes.
Q. By the way, they excluded also I think a very narrow band of females, correct?
A. They didn't have the age restriction on the females, if my recollection is right.
Q. They had to have -- for a girl to be included, they had to have at least one week of amenorrhea for it to be a prolactin-related side effect, correct?
A. That's how they define it, yes. They don't apply the same age restriction.
Q. Okay. So now we have Table A and Table B in terms of May 15, 2002 and September 27, 2002, correct?
A. Yes.
Q. And, by the way, does running the new statistical analysis make this key finding now insignificant?
A. The statistical significance goes away. You still have that nine versus three. But, in essence, if you're looking at statistical significance, it

would get rid of the problem.
Q. Okay. Now, let's go to the next place, next spot.
Now, with the new data in hand, did the manuscript get drafted a third time?
A. Yes.
Q. And if I can go back to draft two very quickly and look at the cover of it. That would be, Cory, call out one -- that would be call-out JJRE -- if you'd write this down, Cory -- JJRE00115170, previously marked as Exhibit -- we'll have to check. It was the second draft.
COURT CRIER: It's 39.
MR. GOMEZ: 39.
MR. KLINE: 39. Thank you. Much appreciated.
BY MR. KLINE:
Q. And do you see the title that they had on draft two, just to focus on it, that we've been looking at. "Prolactin Levels in Children and Adolescents with Long-Term Risperidone Use."
A. Yes.
Q. Now, and if you can do this, Cory, I would like to see how draft three gets a new title.
First I'll mark the exhibit,

"Normalization of Prolactin Levels in Children and Adolescents with Long-Term Risperidone Use." "Normalization of prolactin levels."
That would be Bates Nos. JJRE04405229 through 256.
And this is going to be marked as 43. Draft three of the article is going to be marked as Exhibit 43.
(Exhibit P-43 marked for identification.)
I believe there's no objection so we will display the titles of both.
THE COURT: All right. Before --
MS. SULLIVAN: The Court has ruled.
THE COURT: We have ruled. That's right.
MR. KLINE: I'm sorry.
THE COURT: All previous objections are preserved.
MS. SULLIVAN: There was an objection to the manuscript because the prescriber never saw it, so...
MR. KLINE: Right.
THE COURT: All previous objections are preserved, but you may proceed.

MR. KLINE: Right.
BY MR. KLINE:
Q. I'd like to look at the new title that we have here for the document.
"Normalization of Prolactin Levels in Children and Adolescents with Long-Term Risperidone Use." That's now the new title in draft three, correct?
A. It is.
Q. Well, does that title, sir, match the statistically significant finding that was in Table 21?
A. No.
What I -- I think that if you just turn the page, I think this -- if I can answer it this way. If you can just turn the page to Bates No. 230.
Q. Yes.
A. And just look at under the abstract, the first sentence. The key scientific question that's being asked does not change.
Q. Okay.
A. It's to explore any relationship, right, with side effects. But it's looking for any -- any relationship between prolactin and these side

effects, and so that title doesn't match the -- I mean, it's dealing with whether prolactin levels normalize. But the key question is, is there any relationship? That's what the paper is saying it's looking at.

Q. Okay. And if I may, the -- the -- I'm okay. If I can look at Page 230, Bates No. Bates stamp 230, the first sentence you've already shown us, which is it was to explore any relationship. And there's a sentence here in the Results, under Results. Can we pull up Results? And there's only one sentence I'd like to ask you about, and then I'd like to see if you can enlarge it, Cory, so we can actually see it, which is, "There was no direct correlation between prolactin elevation and SHAP." Was that a true statement as it pertained to all of the information they had?

A. No. And let me just explain.

Q. Yes.

A. Again, subject to my 58 minutes still on correlation and association, they are using this -- and I've read the depositions -- they're using correlation and association interchangeably. And they're using the chi-square. There are footnotes

that they should be using chi-square.

There is a relationship, okay, at that 8 to 12 weeks for when you count all the kids. That would be a misleading statement, in my view.

Q. Now, sir, in the prior drafts, the prior drafts, we saw those long -- that paragraph, that paragraph that talked about the 7.8 versus the 2.9.

A. This is a statistically significant finding.

Q. The statistically significant finding.

A. Yes.

Q. We're now in draft three of October -- this is revised, and I did not do this. If I can step back to the front page, Page 229, and show to the jury the very bottom. It's October 4, 2002, correct?

A. Yes.

Q. In this draft of October 4, 2002, is the statistically significant finding mentioned at all?

A. No, it's not. It's gone from this draft.

Q. And, sir, on Page JJRE04405248, Bates No. ending in 248, in the paragraph at the bottom of the page going over to the top of the page, Mr. Smith, I'll come back and show you. You got it. Yes. And up to the top. (Document displayed.) I'm now looking at the last four

lines. And can you highlight there was -- it says, "The percentage of children with SHAP was assessed for patients with prolactin levels above the upper limits of normal versus children with prolactin levels within the normal range at various analyses time periods." Now, I don't need that highlighted.

THE COURT: All right. Counsel, before we take a break, can you just tell me where that's coming from here.

MR. KLINE: Yes. It's coming from Bates No. 248, Your Honor.

THE COURT: 04405248.

MR. KLINE: Yes. 5248 and 5249 is exactly where we are.

THE COURT: All right. We will mark these as P-43A.

MR. KLINE: Terrific.

THE COURT: All right.

MR. KLINE: Yes.

THE COURT: All right. We're going to take a recess right here for ten minutes so that we can do our homestretch, all right?

MR. KLINE: Okay. Yes.

COURT CRIER: All rise, please, as

the jury exits the courtroom.

- - -

(Whereupon the jury exited the courtroom at 4:00 p.m.)

- - -

(The following transpired in open court outside the presence of the jury:)

- - -

THE COURT: All right. We're going to take a recess for about ten minutes.

MS. SULLIVAN: Your Honor, I have a motion -- we can do it when you come back -- on a motion to strike and then a request for an instruction on the Dear Doctor Letters and the sales reps. Nowhere in his report, Your Honor. A big surprise at trial because they don't have us on the regulations that required a new warning label, so now they're going to say we should have sent a Dear Doctor Letter. It's not in his report. He wasn't deposed at length. We don't have an expert prepared to deal with it. I request that the jury be instructed to disregard that and that's not in this case.

THE COURT: I'll address jury -- I

don't see anything to caution anybody about. There's no surprise that Dr. Kessler was admitted as an expert in pharmaceutical regulations. There was no objection to that, in fact.

MS. SULLIVAN: But, Your Honor, they've changed their whole case.

MR. KLINE: We did not.

MS. SULLIVAN: It used to be that it had to be in the warning label. That's --

(Counsel speaking over the Court.)

COURT REPORTER: One at a time.

THE COURT: The record will speak for itself. There was an objection and there was a response permitted.

All right. We'll take a ten-minute recess.

- - -

(Whereupon a recess was taken.)

- - -

COURT CRIER: Are you ready for the jury, Your Honor?

THE COURT: Yes.

COURT CRIER: Okay. Jurors are now entering.

- - -

(Whereupon the jury entered the courtroom at 4:13 p.m.)

- - -

(The following transpired in open court in the presence of the jury:)

- - -

THE COURT: All right. Please be seated everybody.

COURT CRIER: Court is now back in session.

THE COURT: All right. We're going to go till about ten of 5:00, okay? Maybe a little bit earlier.

MR. KLINE: I can't finish like anywhere near --

THE COURT: Well, we're not going to be finished with this witness no matter what we do, so it's okay.

MR. KLINE: I'll try to say I'm done a little bit earlier.

THE COURT: All right.

MR. KLINE: And I'll try to see what Your Honor says.

I'll tell you a convenient break

point anyway.

BY MR. KLINE:

Q. Well, here we are in October -- October 4, 2002. And we're on the third draft. And I believe I had asked you -- can we have up where we were?

Can we highlight, "There was no statistical difference in the percentage of patients who reported SHAP for any analysis time period."

Would that be true if you took out 10-year-olds -- or the above the 10-year-olds?

A. Yes.

Q. And would it be true if you reported all the data?

A. No.

Q. The full sentence would read: "There was no statistical difference in the percentage of patients who reported SHAP for any analysis time period, whether or not prolactin levels were normal or above the upper limits of normal, paren range 1.8 to 3.5 with SHAP." And if we could highlight the rest of it.

And does that, that end language, sir, that range 1.8, does the sentence kind of look the same?

A. (No response.)

Q. I'll withdraw the question. I don't know that it's a good one.

But in any event, that's what it says, correct?

A. Yes.

Q. Now, is there a table in this -- Table 2 on the same page, Page 248?

A. Yes.

Q. One second.

And by the way, as of this draft, had they -- had anyone used the word SHAP A versus SHAP B or not yet?

A. Not yet.

Q. Well, there's a table, and let's look at it. Table 2.

Side effects hypothetically attributable to prolactin, PA and non-PA populations. That's the primary analysis and non-primary analysis populations, correct?

A. Yes.

Q. Under the primary analysis here -- I think you've explained that earlier -- there were 592 patients, correct?

A. Yes.

Q. Thirteen had at least one prolactin-related

adverse event that they're now calling SHAP, correct?
A. Yes.
Q. And by either later today or very early tomorrow morning, we'll talk about what these numbers -- what your analysis of the numbers are. And is there any reproduction in this draft three of Table 21?
A. No.
Q. From January, how about Table 20?
A. I don't see -- there's some numbers from 20, I believe. The 1.8 and 3.5. I'd have to go check. Certainly not from Table 21. The statistical significant finding is not in here.
Q. And if I may push you to page 5251.
At the very bottom of the page there's a sentence that begins "no correlation." That's my only call-out here, just that sentence.
"No correlation" -- this was the discussion section. And what is a discussion section of a paper like this?
A. It's sort of where you're discussing the results.
Q. And it says here, "No correlation was found between SHAP and prolactin levels." Is that true if

you take out all the boys over 10?
A. Yes.
Q. Is it untrue if you leave all the boys from under 10 in?
A. It would be misleading.
Q. Now, that takes us to November. This is October of 2002. We get to October 4, 2002. We get to November of 2002. The leaves have fallen, I guess.
It's a long day.
And there's a meeting November 15, 2002, in New York City, correct?
A. Yes.
Q. At the Palace Hotel, correct?
A. I got to check the hotel.
Q. I see it right on the page. It's page -- I'm going to mark as exhibit number --
A. It is on the title page. I missed it. Sorry.
Q. No; that's okay.
I'm marking Exhibit No. 44, which is a Meeting Report. The Risperdal Child and Adolescent Psychiatry National Advisory Board Meeting.
A. I see it.
Q. A Meeting Report, and I'm going to, as I mark

it, as Exhibit Number -- tell me again -- 44. I've handed it to the Court.
I believe there's no objection to this document, so with the Court's permission, I'll display it.
MS. SULLIVAN: Well, Your Honor --
THE COURT: Well, for your understanding, all objections relating to these documents are preserved.
MS. SULLIVAN: Thank you, Your Honor.
THE COURT: Welcome.
So 44, yes.
MR. KLINE: Okay. So 44 may be displayed. Thank you.
(Document displayed.)
BY MR. KLINE:
Q. Let's look at the front page which we have in front of us.
A. Yes.
Q. We're now November 15, 2002. And we are three drafts into the pooled analysis writing, correct?
A. Yes.
Q. And the Meeting Report is on the top. On the bottom it says meeting date, which is incumbent on me to establish is November 15, 2002. The location

is the Palace Hotel, New York City. And the document contains on Page 2 -- oh, by the way, for identification purposes, the document goes from JJRE03900098 through 0113.
A. Exactly.
Q. Yes. And on the front, it is -- this document -- this Meeting Report was prepared for Janssen Pharmaceutica Products, L.P., correct?
A. Yes.
Q. So this is a Janssen document as you would understand it, correct?
A. It certainly --
MS. SULLIVAN: And, Your Honor, just for the record, it's clear it's prepared by an outside company called Helix. This is not prepared by Janssen. It's not a Janssen -- it's in the Janssen files because they received it, but they didn't create it.
THE COURT: All right. I guess why don't we --
MR. KLINE: So stipulated. And in fact -- thank you, Ms. Sullivan.
And in fact it was prepared for Janssen.
MS. SULLIVAN: And, Your Honor --

MR. KLINE: Which I pointed out, correct?

MS. SULLIVAN: And, Your Honor --

THE COURT: I think that's a rhetorical question because that's what it says on the title of the page which is up on the screen.

MR. KLINE: Yes.

THE COURT: All right. So we can move on. Prepared for Janssen Pharmaceutica Products, L.P.

MR. KLINE: Yes.

BY MR. KLINE:

Q. Pharmaceutical companies like Janssen hire outside vendors, correct?

A. Of course.

Q. To run their statistics and to prepare documents, prepare reports and the like, correct?

A. Sure.

Q. Now, the next thing that I would like to know is in the back of the document are the participants, correct?

A. Yes.

Q. And we're already familiar with many of the people, but is Ms. Binder, the Medical Affairs

Director, MBA, there?

A. Yes.

Q. And is Mr. DeLoria there?

A. Yes.

Q. And also is Mr. -- or is Psychologist Pandina there?

A. Yes.

Q. And is there a list of advisors who are listed there?

A. Yes.

Q. If you can look -- I think we can see it even with the full document. There's a list of advisors. I know everyone can't read all the names from this distance, but there's a list of advisors and a list of Janssen attendees, correct?

A. Yes.

Q. There were, my count is, 14 Janssen attendees at this meeting, correct?

A. I take your -- no reason to dispute that. I assume that's right.

Q. And there were 14 advisors there, correct?

A. It looks exactly that way, yes.

Q. And the advisors came from -- from Boston to Los Angeles?

A. Yes; academic institutions.

Q. From Yale to Columbia?

A. Yes.

Q. And what is --

A. This is a different group of advisors, the outside, than in the Toronto meeting. The Toronto meeting were the authors. These were not the authors.

Q. Okay. And, for example, it included -- and it included -- it included, if I may, showing this thing, we may want a couple of call-outs on the top. It included Judith Rapoport from the National Institutes of Mental Health.

A. Yes. I know her.

Q. And it included Larry Scahill from the Yale School of Medicine?

A. Yes.

Q. And others?

A. Yes.

Q. And among the Janssen people who were there who I did not mention was a name we're already familiar with, Olga Mitelman, correct?

A. Yes. We've seen an e-mail earlier in the day, I believe.

Q. Now, knowing who was there, let's talk about the report on page ending in 99, 099.

Is there on Page 099 a table of contents?

A. Yes.

Q. Does it include an executive summary?

A. Yes.

Q. And does it include -- if we can go all the way down and highlight -- a subgroup analysis on prolactin?

A. It says a subanalysis of prolactin, yes.

Q. No. Actually, the words there --

A. I'm sorry.

Q. This is my only time to correct you rather than you correcting me.

A. You're right. I'm on the next page. I'm sorry.

Q. It says, "Subgroup Analysis: Prolactin," correct?

A. Yes, exactly.

Q. And I'd like to -- when there -- in this study -- or in this meeting, I'd like you to turn to the Subgroup Analysis: Prolactin on Page 8. And in the middle of the page you'll see it was being -- you'll see two names that are identified with it, and they are Binder and Pandina, correct?

A. Yes.

Q. And if I can just give some context, in the first paragraph there it says, "The next two presentations focused mainly on the prolactin data. Carin Binder's presentation focused on data addressing the change in prolactin levels over time. The relationship between prolactin and risperidone dose, age, gender and comparisons between children with prolactin levels below versus above 50 ng/mL."

I don't want to get bogged down in this, but I also don't want to have things in front of us that we don't know. What is ng and mL? Just the definitions.

A. This is nanograms per mL. This is not what we're talking -- what we've been talking about.

Q. Thank you, sir.

And I'd like you to go over to Page 9 -- and I know we're very late in the day -- but on Page 9, first of all, does this document indicate that there was a discussion and interchange between the Janssen Pharmaceutical people and the outside advisors?

A. There was.

Q. And did part of that discussion involve prolactin levels and issues as they relate to prolactin levels and side effects such as

gynecomastia?

A. Yes.

Q. And according to this, did Dr. Pandina present data there?

A. Yes.

Q. And I'd like to focus on this. And I'd like to focus on what it says the discussions were.

By the way, is this the kind of document that is customarily produced after a lengthy meeting like this in a pharmaceutical company with detailed notes written up as to what was done and what was said?

A. Very much so.

Q. And are these the kind of notations that are customarily relied upon in the industry as records of these type meetings?

A. Sure.

Q. Now, we're on the top paragraph of some things that I'd like to address with you.

It says Dr. Pandina in the -- let's take it kind of a few sentence at a time, the best way for you to put it up as large as you can.

- - -

(Conferring with technician.)

- - -

BY MR. KLINE:

Q. "Dr. Pandina then presented data on the relationship between prolactin and side effects hypothetically attributable to prolactin, parentheses SHAP." Do you see that?

A. Yes.

Q. Down below it says there was some discussion. Do you see that?

A. Yes.

Q. There was some discussion focused on -- or there was some discussion about the definition of SHAP. Do you see that?

A. Yeah. In fact, it says there was -- earlier on it says there's substantial amount of discussion and then --

Q. Okay.

A. -- and then further there was some discussion. I see both, yes.

Q. You know what, let me go back and we'll do some highlighting. I'm inclined to rush and I shouldn't. The top, "Dr. Pandina then presented data on the relationship between prolactin and side effects hypothetically related to prolactin" -- stop there -- at SHAP." We're not interested in the other stuff, if you would, Cory, at the word "SHAP."

Yes.

And then if you would highlight "most of the discussion focused on SHAP," and let's leave there.

And then the next part is, "There was some discussion about the definition of SHAP."

A. Yes.

Q. Now do you have it in context, Dr. Kessler?

A. Exactly.

Q. And it says here, "The advisors thought that the most inclusive definition should be used for transparency." Do you see that?

A. Yes.

Q. Okay. Would you strike everything off of there that you've highlighted, sir.

(Technician complies with request.)

MR. KLINE: And would you highlight there? (Indicating.)

BY MR. KLINE:

Q. Sir, what would be the most inclusive definition of what they're now calling SHAP?

A. You'd want to include all the children -- those under 10 as well as those over 10.

Q. And were the advisors -- and the advisors were telling them that they would want to do it -- and

there's a word up there -- for transparency, correct?
A. Yes.
Q. Meaning?
A. Whole story. Tell the whole story.
Q. It goes on to say -- bear with me one second.
It appears -- it goes on to discuss Dr. Pandina's presentation, and look at the first bullet point.
The presentation, it says, can be summarized as follows: "There appears to be no relationship between prolactin level and SHAP."
Do you see that?
A. I see that.
Q. That would be -- what's being reported here is that's what -- that's what Psychologist Pandina told them, correct?
MS. SULLIVAN: Objection, Your Honor, to speculation.
THE COURT: That's sustained.
BY MR. KLINE:
Q. Do the words here say, sir, "The presentation and ensuing discussion can be summarized as follows"?
A. Yes.

Q. Does it say: "There appears to be no relationship between prolactin level and SHAP"?
A. That's exactly what it says.
Q. Based on the data that was in Table 21, is this a correct statement?
A. No.
Q. And, sir, on Page 14, coming out of this meeting, there were action items, action items.
And the action items that came out of the meeting -- this would be on Page 03900111, ending in 111, Your Honor.
Going over to Page 112, they have the action items.
Now, the action items, I would like to go to just Number 112, and I would like to go to just the top lines 1 through 6 as to their action items on prolactin levels --
A. Yes.
Q. -- coming out of this meeting with their advisors.
A. Yes.
Q. Would you, sir, read to the jury the number one action item coming out of this meeting about -- coming out of this meeting as to prolactin.
A. You want me to read number one or you want me to tell you the --
Q. One, yes, just read it.
A. "Reanalyze the data on SHAP to include all boys with gynecomastia, not just those under the age of 10."
Q. And, sir, read number three to the jury.
A. "The definition of SHAP should be as inclusive" --
Q. A little slower, sir.
A. I'm sorry. "The definition of SHAP should be as inclusive as possible; then compared with the incidence of SHAP with the more inclusive definition to that with the more narrow definition."
Q. Does that mean include the boys under 10 there, too?
A. It means tell the whole story, show all the data.
Q. And number four came out of this meeting with the advisors. Could you read number four, what's now displayed to the jury and right in front of them, number four.
A. "When publishing the prolactin results, data on all children with gynecomastia should be included."
Q. Now, moving forward, the Janssen people had some discussion internally in e-mails following this meeting, correct?
A. Yes.
Q. And I'm marking as the next document, 45, P-45, so long as Your Honor allows, these will be the last two I would do for today.
THE COURT: All right.
MR. KLINE: I think I would be right about at near time.
P-45 is a document, an e-mail from Binder to Pandina. I'm sorry. The Judge doesn't have a copy yet. I'll wait.
THE COURT: Okay. Thank you.
This is at 0389270, being marked as Exhibit 45.
MR. KLINE: Yes.
THE COURT: All right. You may proceed. This is on the second e-mail here?
MR. KLINE: It is. It's on the bottom half of the page.
THE COURT: All right. You may proceed, on the second e-mail.
MR. KLINE: Yes, sir.
BY MR. KLINE:
Q. On the bottom half of the page coming out of

this meeting there's an e-mail dated -- and keep in mind that that meeting was November 15th, November 15th, this is an e-mail dated November 18th, the following Monday, the meeting was on Friday. This is the following Monday. There's an e-mail from Binder to Pandina, et al.

And that e-mail, sir, we're going to display as Exhibit P-45, Bates number ending in 170, to be precise, JJRE03892170.

Bottom paragraph under number 2, "Secondly."

Sir, does it say here, "Secondly, the US group recommended that the manuscript list all cases of gynecomastia in males and state whether prolactin levels were normal or elevated as well as state all the new rates of gynecomastia as identified by the endos. They felt that applying the endo's position of gynecomastia in boys with puberty not being SHAP without listing all gynecomastia was" -- and do you have a yellow marker for me there -- "hiding data."

(Highlighted.)

Is that what they were told by their advisors?

A. Yes.

Q. Is that what this e-mail says from Binder to Pandina?

A. And et al, yes.

THE COURT: Can this be a good place to stop?

MR. KLINE: One more, sir. It's literally one more. It's kind of the module I have here.

THE COURT: All right.

BY MR. KLINE:

Q. And, sir, there was an e-mail -- there was an e-mail that was dated -- that was November 18.

There was an e-mail dated three days later that was the lead-in to the draft four. And it says -- and I'm displaying it. I have to mark it as an exhibit. Exhibit 46. Handing it to the Court.

It is Bates No. JJRE14088063.

(Exhibit P-46 marked for identification.)

MR. KLINE: This will be the manuscript we'll review tomorrow morning, the fourth draft.

BY MR. KLINE:

Q. And it says JJRE ending in 063, from Binder to Pandina and others. "Attached please find the revised November 19 prolactin manuscript."

I'll represent to the Court that will be our starting point tomorrow.

"The revisions now include a nauseating amount of info on SHAP, specifically gynecomastia throughout [sic] the ages and RIS total dose versus prolactin analysis."

"There's nothing to find, people!"

Was that considered by you when you rendered your opinion when we started your testimony? Was this a document considered by you in formulating your opinion?

A. Yes.

MR. KLINE: Okay. We will pick up tomorrow, Your Honor, with the e-mail that's attached to this -- the report that's attached to this document that describes a nauseating amount of gynecomastia.

MS. SULLIVAN: Objection, Your Honor.

THE COURT: All right. Well --

MS. SULLIVAN: It says a nauseating amount of information, Mr. Kline. You should read it correctly.

MR. KLINE: Yes; "a nauseating amount of information on SHAP." That is correct.

THE COURT: All right.

Well, we did it, okay. We're done for the day. We're done for the day.

Let me just say a couple of things. We will return tomorrow. I'm going to ask that you try to come in about 9:15, 9:15, okay. Try to make it 9:15.

Second, there is a birthday in the house, Juror No. 13 has a birthday.

- - -

(Applause in the courtroom.)

- - -

THE COURT: And I specifically want to acknowledge this birthday because I want you to know that in order to serve on this jury, she has given up a special trip to the Carolinas in order to be here. So I mean this is -- you know, she chose to spend her birthday with us here.

(Laughter.)

THE COURT: Okay. Thank you very much. Unbelievable.

All right. Then a couple other things, just to remind you. I am asking that

you come back tomorrow with your yellow badges; that you keep an open mind about this case. You've got still some ways to go; that you not talk about this case with anyone within -- anyone, yourselves, family, neighbors, kids, anybody; that you please, very importantly, refrain from reading or listening or anything about this case from any media whatsoever. And that's radio, TV, newspaper, websites, anywhere, anywhere, all right?

And I said this also that the evidence that you're getting has been filtered by this Court through the rules of evidence, all right? And it's our case, all right? It's our case. That's why we're putting all this time and we're relying on you to make it our -- to keep it our case. To keep it our case, okay?

So just please do, please follow that rule, please, okay? It's our case, nobody else's. That's what makes it very interesting for all of us here. You can see we have attendants in this courtroom because they want to know what you think about this

case, not what somebody else might have said or written or reported or anything else, all right? We're clear about that everybody?

(Jurors nodding.)

THE COURT: All right. Then we will see you tomorrow at 9:15.

- - -

(Whereupon the jury exited the courtroom at 4:47 p.m.)

- - -

(The following transpired in open court outside the presence of the jury:)

- - -

THE COURT: All right. Let's close the door.

All right. We will try to -- I'm hoping that by setting an earlier time, we might get people in here by 9:30, so.

MR. KLINE: Right. We figured that one out.

THE COURT: So we'll see you tomorrow everybody.

MR. KLINE: See you tomorrow. Good night.

(Court adjourned at 4:46 p.m.)

C E R T I F I C A T I O N

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.

I further certify that I am not a relative or employee of any attorney or counsel employed in this case.

_____

John J. Kurz, RMR, CRR
Registered Merit Reporter
Certified Realtime Reporter
Official Court Reporter

(The foregoing Certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or supervision of the certifying reporter.)

(Hearing is reconvened at 9:54 a.m. with all parties present.)

THE COURT: Good morning, everybody. Please be seated. We do have the jury now, and they sort have been reprimanded. Let me tell you a couple of things on the jury front.

One is that we have gotten an agreement from the president of a charter school to pay our juror at least until their board makes a decision on her payment. So right now that particular juror should not be worried about being paid while she is here.

Another juror had a situation involving community college, and I received an informal understanding that her tuition will be refunded, and that will require a letter from me and we will take care of that.

I also want to caution all witnesses, all counsel and parties, that because of the situation here that we have in City Hall where there is a very narrow hallway dividing the courtroom from the jury room, that all actions of the parties, witnesses, lawyers can be observed by our jury.

So I am just putting it out there that it would probably be best, given the fact that we have taken a lot of precautions with the yellow badges and everything else, for all parties, witnesses and lawyers to be mindful of that and to stay away from jurors, unless they wish to have jurors judging lawyers, parties and witnesses, based on their conduct outside of the courtroom.

All right, so we can have our jury now come in.

MS. SULLIVAN: Your Honor, would the Court at some point during the trial give the jurors or tell the jurors that lawyers and jurors are not permitted to talk to each other, so don't think any of us are rude by not --

THE COURT: I have said that.

MS. SULLIVAN: I am sorry if I missed it, Your Honor.

THE COURT: I know that both counsel don't seem to really be listening when I am making my remarks to the jury, because I was asked whether I have told them about the radio

and TV and all of that. If you look at record, I do warn them about these kind of issues.

But this matter of the contact, the actual physical contact between lawyers, parties and witnesses is a serious matter.

MS. SULLIVAN: Your Honor, was there an issue with that, in terms of contact between jurors and --

THE COURT: No, I just think that, you know, it's one of these things where we are in an old building, an old setup, and I think people need to be mindful that we are all walking around together in the hallway, going to the men's room and ladies room, and I think that all of us should be aware that we are constantly being observed by this jury. Okay?

MS. SULLIVAN: Thank you, Your Honor.

(The jury enters the courtroom at 10 o'clock a.m.)

THE COURT: Good morning, please be seated. All right, when everyone is ready, we are ready to resume now the direct examination of Dr. Kessler by Mr. Kline. You may proceed.

MR. KLINE: Your Honor, official good morning. Dr. Kessler, good morning. Good morning, all.

(DAVID A. KESSLER, MD, having been previously sworn, resumes the witness stand.)

\- - -

DIRECT EXAMINATION

\- - -

BY MR. KLINE:

Q Dr. Kessler, I would like to complete your examination, and here we go.

Right when we left I was displaying an Exhibit marked 46, and that was an E-mail from Caren Binder to Gahan Pandina, et al, dated November 21, 2002, and I'd like to re-display it to the jury. It is JJRE 14088063. It's in front of the jury. And if I can just have the "From:/To:" Portion displayed.

That E-mail was an E-mail, it appears to have been from Binder to Pandina 10:01 p.m., correct?

A Yes.

Q And the E-mail attaches a draft which we have described as the fourth draft of the pooled analysis

paper. And this is the draft which, right where we left off yesterday says, "Attached please find the revised November 19 prolactin manuscript. The revisions now include a nauseating amount of information on SHAP, specifically gynecomastia, throughout all ages and a RIS total dose versus prolactin analysis. There is nothing to find, people! I have highlighted the conservative approach to measuring the prolactin in the discussion and would like your view as to whether we should delete prolactin monitoring."

Do you see that, sir?

A I do.

Q Now I would like to ask you a number of things. First of all, at the meeting, and you saw the report of the meeting, was there a discussion in that meeting as to whether there should be a recommendation to do prolactin blood testing on children and adolescents who are getting the drug?

A I have to review the executive summary. I have the meeting minutes. I don't know that off the top of my head. I have to review that report.

Q We will pick that up in the next E-mail. Let's continue on this document first, however.

The manuscript which was attached, sir, we're going to mark as the next exhibit number, which is P-47. P-47 that is Bates number JJRE 14088064 through 093.

So it's 064 through 093. And we will display the first page. I believe there is no objection and the Court will permit it.

(P-47 is marked for identification.)

THE COURT: All right, you may.

MS. SULLIVAN: Your Honor, again, subject to the Court's rulings.

THE COURT: We understand that. All of these matters are of record and so any objections that have been made are preserved. Go ahead.

MR. KLINE: Thank you.

Q The title of the paper -- this is now draft four -- the title of the paper remains the same, which is, Normalization of Prolactin Levels in Children and Adolescents with Long-Term Risperdal Use." Correct?

A Yes.

Q When I say "remains the same," remains the same from the changed version in the prior draft,

correct?

A Exactly.

Q And under the Acknowledgments, of course, it still says it's sponsored by Janssen-Ortho, and now we know this revised date of November 19, 2002. Correct?

A Yes.

Q To put this in perspective on our timeline, the meeting at the Palace Hotel in New York with the Janssen outside advisors that we discussed at length yesterday was November 15, 2004. So they have put a new draft together within four days?

A Yes.

Q And this draft that we are going to be looking at is attached to the E-mail which had said it now includes a "nauseating amount of information on SHAP, specifically gynecomastia, throughout all ages and a RIS total dose versus prolactin analysis." Correct?

A Yes.

Q And if we can look at see, are we able to tell what analysis is now in draft four, having seen draft three where they had eliminated Table 21?

A Yes. Would you like me to explain?

Q Yes.

A If you could kindly go to Bates number ending in 8084, please.

Q Okay, I have it in front of me, 084. We will display it, it will become -- this we will make 47(A).

(P-47(A) is marked for identification.)

A Again, and I apologize, go back to 8065.

Q Okay, 8065.

A And again, I just want to point out, the background and what the purpose was remains the same, it's to explore any relationship between prolactin with the side effects hypothetically attributable to prolactin.

Q I see. The words "any relationship" still appear?

A Yes. I just want to point that out. And if you go to 8084, you see two things, there is two important things on this page. Let me just point you to something called Table 4. And here, if my memory serves me right, this is the time when you asked me about SHAP(A) and SHAP(B).

Q First of all, if I can step back and then I will let you answer my question, but just a few

things. Prior to the drafting of this paper, SHAP was known as prolactin-related adverse events?
A Yeah.
Q And then when the word SHAP appeared, was there any such thing as SHAP(A) and SHAP(B)?
A I don't believe so, no.
Q Please explain?
A You see in Table 4 -- let me explain. Under where it says SHAP(A), if you could kindly highlight. N is the number of children and adolescents that are in that group. So SHAP(A) includes, in fact, all children above ten and below ten. So it includes 30 children.

What you see now, if you can highlight SHAP(B), and this is explained elsewhere in the paper, that now SHAP(B) only includes 13 children. So all children above ten -- I apologize, I have that wrong. All boys above ten are no longer in SHAP(B).

The key thing, if you go to the next paragraph in the page, because you can't tell this from the table, and if you highlight the sentence beginning with, "The proportions were all comparable". And then please continue that down

through that p equals .02, which is a sign of statistical difference.

So you see in draft form, and again it's important, this is not from the table but from these words, you see that notable finding that Janssen had referred to earlier in the documents we saw, the finding that I pointed out at week 8 to 12, it was statistically significant, you see that's now back into manuscript draft four.
Q Sir, now that it's back in, is that the correct thing to do?
A Absolutely.
Q And telling the story about the statistically significant finding, would that be exactly what would be required from a reasonably prudent pharmaceutical company?
A Of course.
Q And by the way, the breaking down of SHAP(A) and SHAP(B), would that be reporting the numbers, at least as the numbers are reported, reporting a table with their breakout of kids, excluding the ones over ten in SHAP(B), and then reporting all of them in SHAP(A)?
A I am sorry, your question?

Q They reported all of them in SHAP(A), and they reported breakout ones when they excluded the ones over ten in SHAP(B)?
A They are showing all the data.
Q All the data; is that correct?
A Yes.
Q Broken down two different ways?
A Yes.
Q But as far as the writeup is concerned, does the writeup point out to someone who is looking at it this statistically significant finding?
A Yes. You can't tell that from the table, you can only tell that from these sentences that I have read.
Q And, sir, would that in your opinion, would you share the opinion that that's a nauseating amount of information on gynecomastia?

MS. SULLIVAN: Objection, argumentative.

THE COURT: Sustained.

Q Okay, so moving on, what we have is this draft four. And that's November 19?
A Yes.
Q And, by the way, if I can go back while we

still have this up, in this particular writeup, is it important, is there any significance or importance, sir, to the written analysis in papers like this? That is to say, you present tables and you write up what are the findings. Is it important to write up the full, complete, and important findings?
A That's a very important point, Mr. Kline. You can't tell the statistically significant finding. That's only mentioned in that sentence. It's not mentioned -- you don't see any p-value of .02 in the table.

So that sentence is not a redundant sentence, that adds important information.
Q Moving on, I am marking the next exhibit as Exhibit 48, an E-mail. The E-mail is from Caren Binder once again to Gahan Pandina and others. And the subject is, "Re: Latest prolactin manuscript."

(P-48 is marked for identification.)?

MR. KLINE: So we now have it marked and I will hand it to the Court. And it is my understanding that when I request it I will be able to display it.

Q Now, sir, we are looking at the second E-mail

from the top, the one that says December 3, 2002 at 2:13 p.m., and I apologize, I was looking at the top E-mail. This is not Binder to Pandina, this is Pandina to Binder, et al. And it says:

"Dear Carin and Team:" Do you see it, sir?

A I do.

Q And to put it in perspective in terms of our timeline, the last draft was November the 21st, the one that attached draft four, and this E-mail is December 3rd. So we are a couple of weeks later, correct?

A Yes.

Q And the year 2002 is now in December, correct?

A Yeah.

Q And the E-mail by Pandina to Binder starts out, Dear Carin and Team, and it says, "I think the results of these analyses are striking and made stronger by the inclusion of the additional SHAP, as well as the dose information."

Do you see that sentence?

A I do.

Q The "additional SHAP," was it actually more people, or was the additional SHAP analysis less

children studied?

A I read this as including SHAP(A), which is all children. That's just my read, Your Honor.

Q The next word, and I would like to highlight the first part of the sentence, if I may, "The issue of prolactin and SHAP is obviously a charged one, and one that has hurt every segment of individual treated by risperidone based upon criticism from our competitors, with the potential for continuing to negatively impact CONSTA."

Do you see that?

A Yes.

Q Do you know what CONSTA was?

A A different formulation, I believe.

Q It was Risperdal in a different formulation, correct?

A Yes.

Q "The manuscript may need some reworking as the additional information does as some bulk. With respect to normal development and SHAP, does the Rogel, et al. reference cover the estimates of normal developmentally appropriate rates for gynecomastia? I know that there were recent references that might be relevant."

That's the first paragraph, correct?

A Yes.

Q The second paragraph which I would like to call your attention to discusses the question of whether to do blood testing, monitoring that is, of prolactin levels in children who are taking this drug. Correct?

A Yes.

Q And were blood levels ever either recommended or required for this drug?

A If you kindly go back to manuscript four, you have some context. And if you kindly turn to the Bates number 089.

Q 089?

A And if you could zoom in, please, under the gray area. This is, I believe, this is the last page of the draft.

So here in the draft there was this sentence -- again, I don't know the history of the highlighting here -- but the sentence as I read it was in this draft. It says, "Based on these results" -- we can discuss those if you would like -- "obtaining prolactin levels at baseline" -- baseline means before you go on the drug -- "and at

six months after the most recent increase in dose of Risperdal would appear to be sufficient monitoring."

And then there is a phrase: "Do we need to give any clinical guidance here?"

Again, I don't know the history of these two sentences.

Q But as you read the draft, this consideration was clearly in this draft. Is that what you are telling us?

A Yes.

Q Based on what you have seen?

A This issue is clearly in this draft, yes.

Q And when you were reading the words you said based on these results, you said to me in our discussion and therefore to the jury, we can discuss this if you would like, what discussion do you have?

A Well, there is an earlier paragraph that talks about the considerations. If you go to the prior paragraph, or I can just summarize it. It says --

Q Well, let's look at it.

THE COURT: Again, just for my own benefit, what document is this now?

MR. KLINE: The document is P-47. The Bates number, Your Honor, is the page before,

088, on the bottom of the page.

THE COURT: P-47, all right, go ahead.

MR. KLINE: Yes, as part of P-47, this fourth draft.

BY MR. KLINE:

Q You are looking at the words "the clinical implications"?

A Yes. So this is all referring to this issue of increased prolactin due to Risperdal, and there is a certain discussion about whether that's in fact -- Janssen is discussing whether that's active and what the role is. And this is just putting this in context and saying the fact is that a small percentage of children will ever develop SHAP and that require intervention, and then the question becomes what do you do.

All right. I mean if you know that you are going to put a child on a drug, and you know that drug increases prolactin more than other second generation antipsychotic, and you know that you have an increase in gynecomastia with these drugs, do you want to follow, or can you do something to prevent or minimize the risk. Because that's really what, when it comes down at the end of the day, what you

are concerned about if you are FDA or a doctor or a pharmaceutical company is you are going to give a powerful medicine that does have side effects, and we recognize that drugs have side effects, it's what are the steps you take to minimize the risks.

So the issue of prolactin monitoring, the question is, can I do a blood test, and if I see an elevation or a super elevation, will that give me information that I can do something about.

So that's what's being discussed here. And if you go to your E-mail --

Q Yes?

A -- you see the advisors at that New York meeting, in that second paragraph on the December 3rd E-mail, the second E-mail.

Q And so we have it, this is Exhibit 48. A call-out with the paragraph beginning "Finally" is being displayed. We are going to mark that call-out on that E-mail as 48(A), and we will snap a picture of it.

(P-48(A) is marked for identification.)

Q Tell us about it, sir?

A So you have in the manuscript a discussion of prolactin monitoring at two points, at baseline and

six months, and here, Gahan Pandina from Janssen is saying, "Finally, I would advise against any recommendation regarding monitoring of prolactin.

"The advisory panel" -- that is the group that met in New York -- "that we had clearly stated that this wasn't warranted, even conservatively, as this would not be reflective of the data. As one advisor aptly said, if we were an HMO" -- that's a health insurance plan, as we all know -- "if he were an HMO he would not agree to pay for any monitoring based upon this information, as there is not a higher incidence nor a correlation that would lead one to expect aberrant, abnormal or increased symptoms above and beyond the general population.

So he is saying here, he is advising taking out any monitoring, because the advisory committee looked at the data and they didn't see any increase of risk between prolactin and side effect.

Q But what data was shown to them, based on what we know?

A Clearly, if there is no increase, that would be the "SHAP(B)" data, right, which took out the boys above ten. I do that by some logical

inference.

MS. SULLIVAN: I am going to object, Your Honor, this is speculation. He wasn't there, he doesn't know. We have got witness testimony that they can play to show what was actually happening. He is speculating about what was shared and what was not shared.

THE COURT: Overruled. Go ahead.

Q Sir, you read all those depositions, didn't you?

A Yes.

Q And there were a number of these witnesses, including Binder and Pandina who have been deposed, correct?

A Yes.

Q And you have taken into consideration what they have said, correct?

A Yes, and I have the minutes of the meeting. We saw the minutes of the meeting.

Q Were the minutes of the meeting prepared during litigation or were they prepared sometime before?

A No, the minutes were prepared by the contractor for Janssen, who again, I mean, is taking

the minutes at the meeting and then writing them up. It has nothing to do with Janssen.

Q Let me try to target some questions. The prolactin analysis group, because I want to move on -- the prolactin analysis group when they were presented information, did they eventually have a recommendation as to whether all kids had to be included in the study; that is to say, the under-tens and the over-tens?

A That advisory board of child psychiatrists clearly recommended it was important to include everybody.

Q And all of this time, sir, while there is this discussion about this, whatever in this courtroom the Plaintiffs have to say about it, whatever in the courtroom the Defendants have to say about it, all of this time, is this drug known by Janssen Pharmaceuticals to be used off-label throughout the country in -- we are going to show you at some point, I hope, jurors the large number of prescriptions? Was it being used by large, large numbers of children?

A There was very significant use off-label, yes.

Q Now that takes us to the writeup of this paper

that ended up published as part of the medical literature. Are you familiar with the paper?

A Yes, very familiar.

Q Okay, and to put it in context, it was written up; about a year later it got published, November of 2003, correct?

A Yes.

Q And it had a lead author; we know that he was chosen by Janssen, correct, sir?

A Yes.

Q This is not a paper that Dr. Findling decided as a researcher at Case Western Reserve to write himself --

MS. SULLIVAN: Objection, Your Honor. Again, Dr. Findling has been deposed, they can play it, instead of saying having Dr. Kessler say this is why Dr. Findling did X and Y. It's speculation.

THE COURT: I haven't heard anything about speculation yet. Overruled. You may want to introduce the author through this witness in some way if this is a document relied upon by this witness.

MR. KLINE: Yes. Well, what I would

like to do is I will go to the document itself. Let's first of all mark it, as we are now accustomed to do, P-49.

(P-49 is marked for identification.)

Q P-49 is an article that's entitled, "Prolactin Levels During Long-Term Risperidone Treatment in Children and Adolescents."

A Yes.

Q And it has a number of authors to it, correct?

A Yes.

Q Is it a writeup of the Janssen study?

A Yes. The Janssen pooled analysis, exactly.

Q And is it fair to describe it as the Janssen study, the Janssen pooled analysis study?

A Sure.

MR. KLINE: I think we can display it now. I think we now have permission to display it?

MS. SULLIVAN: No objection.

Q I would like you to look at the top of the article, first of all.

First of all, Caren Binder, her name appears on the article, correct?

A Yes.

Q She is the Director of Medical Affairs at Janssen, correct?

A Yes.

Q So while she is listed last, she is the one who we have seen all the E-mails about throughout the entire drafting of the article, correct?

A Yes, you have seen her E-mails, yes.

Q And there is another person who happens to appear next to last who is De Smedt. Goedel De Smedt, I am told her name is pronounced. She is from Belgium. Is she a Janssen person, too?

A Yes.

Q And in all of those E-mails going back and forth, did you see her name over and over again about her involved in the study?

A We have certainly seen her name before.

Q And if we now take that down and look at the right side italicized portion and the last two lines here relating to Pharmaceutical Research and Development Johnson & Johnson, Belgium. Can you start from Pharmaceutical Research and Development and highlight the rest of that paragraph.

De Smedt was from Johnson & Johnson Belgium, and Binder was from Janssen-Ortho in

Toronto, Ontario, both part of the Janssen/Johnson & Johnson group of companies, correct?
A Yes.
Q And let's look at who supported the paper. The paper was supported by Janssen-Ortho, correct?
A Yes.
Q Now I would like to go back, if I can take this down, the background of the article. The background of the article, does it stay in line with what Janssen was saying in the internal documents as to what it was going to try to study?
A Yes, that has not changed. If you can highlight, "explore any relationship." That's been -- that was the reason for the study from the beginning.
Q Okay, now, let me ask you in advance of going through some questioning, is going through this article something which is detailed and complex but understandable?
A Detailed and complex?
Q But understandable?
A I think this article is -- from my perspective sitting here, yes. This is detailed and complex. I mean, I can understand this, I think.

Q Can you also explain it?
A I will try.
Q Now we are going to work through this article and what was said and what wasn't said. First of all, what wasn't said. What wasn't said.
Does this article contain the description that we saw in draft four, highlighting in the text that there was a statistically significant finding of the children who are on the drug in weeks eight to 12?
A No. Not only doesn't it highlight it, I don't see it there.
Q In fact, at one point in the article does it say the exact opposite?
A It says there is -- go to the last sentence of the abstract. It says there was no direct correlation between prolactin elevation and SHAP. My footnote on correlation and association: That's misleading, in my view.
Q To say there was no direct correlation between prolactin and SHAP, did they have in their files a known association when they round the data based on the original study design?
A At weeks eight to 12, it was statistically

significant when you looked at all the children, and that should have been in here.
Q And should it have been in the abstract?
A Sure.
Q And should it have been reported in the article itself?
A Sure.
Q Now, I want to go to a statement which is made in the article. The article is now marked as 49, and I want to go to a statement that's made in the article, on page 1368 of the article. The article begins in the journal on page 1362 and runs through 1369.
THE COURT: What journal is this in?
MR. KLINE: Thank you, Your Honor, I neglected to say, that it is published in the *Journal of Clinical Psychiatry.*
THE COURT: And again for the record, and for the information, what volume -- do we have a volume on this?
MR. KLINE: I do, yes, and thank you for the an assistance in the question. It's Volume 64:11, November 2003.
THE COURT: Thank you.

MR. KLINE: Sure. And it also says on it received January 23, 2003, accepted July 23, 2003, and the publication is November of 2003. So all of this was happening during the year of 2003 leading to a publication in 2003 in the *Journal of Clinical Psychiatry.*
BY MR. KLINE:
Q And the *Journal of Clinical Psychiatry* would be a journal -- would that be a journal that would be received and read by physicians practicing in that specialty, generally speaking?
A Yes.
Q Would that be read, for example, generally -- generally, in the medical literature -- an item we haven't covered -- are there specialty journals and even subspeciality journals?
A Yes. You tend to read the journals in your specialty. There are a few journals, like the *New England Journal*, the *Journal of the American Medical Association* that are general journals, but these are specific fields.
Psychiatrists read psychiatry journals.
Q Neurologists read neurology journals?
A Yes.

Q And when we sometimes hear on the news there was a study in the *New England Journal of Medicine*, that would be something that would have a much wider circulation?

A Exactly. The New England Journal is one of the most famous journals maybe in this country or in the world, they publish articles that are of interest to all of us.

Q Now in this article in the *Journal of Clinical Psychiatry,* I was about to focus on one statement that was made, and the statement is on page 1368.

MR. KLINE: Are you okay with that for this document? It's Bates 230.

Q And in the "Discussion" section, I want to pull out something that's stated there:

"No correlation was found between SHAP" -- that's their word for the adverse events with prolactin -- "and prolactin levels even when male gynecomastia during puberty was included."

That would be the SHAP(A) analysis including all children, correct?

A Yes.

Q Is that a true statement, sir?

A I have problems with that statement.

Q When you say you have problems with the statement, does the statement reflect the data that they had in their files?

A That's my problem. The data that are in their files, that statistically significant finding in eight to 12 weeks, is not in that article. And that sentence, in my view, obscures that fact.

Q It says pointblank that there is no correlation. How about an association, sir, was there a definite association?

A There is certainly an association that's statistically significant. And I have read the depositions of some of the authors, and they use correlation and association interchangeably. I am trying to be very careful.

Q Okay. Now let's look at what was reported, and to do so let's first of all look at what they said that they did.

First of all, does this article reflect what was written up in draft four which had the SHAP(A) reported in the body in the text?

A No.

Q And let's look at what they said they did --

A Excuse me. No to that statistically

significant finding.

Q Yes.

A Yes.

Q And let's go to page 1364, and the bottom of the page, with their description.

Beginning on the very last paragraph on the right side, the paragraph beginning "Adverse events" at the bottom: "We have patients with SHAP who were classified according to two sets of criteria." Do you see that? SHAP(A) and SHAP(B)?

A Yes.

Q Predicate question before we get here: When they started this whole study with the studies, was there any SHAP(A) and SHAP(B)?

A No.

Q And it says here, "The criteria used to define SHAP(A) were breast enlargement, amenorrhea, menorrhagia?

A Menorrhagia, excessive bleeding.

Q Lactation, nonpuerperal, menstral disorder and vaginal hemorrhage. And then it says here, "An alternate definition of SHAP." Do you see here "an alternate definition of SHAP"?

A Yes.

Q Was there any alternate definition of SHAP when this whole thing got started, when they did their pooled analysis and got their statisticians together and began writing this paper?

A No.

Q "An alternate definition of SHAP was used for the SHAP(B) population," and do you see it says right there, and we will highlight: "SHAP(B) excluded males ten years or older with gynecomastia."

And then you don't need to highlight the rest right now -- "females with less than 31 days of breast enlargement, and females with amenorrhea less than a week."

And it goes on to say, "It is considered normal for males to have gynecomastia at some point in the evolution of puberty, with the frequency estimated as high as 50 percent." Do you see that?

A I do.

Q Is that something that they put in the original study design, that they have a puerperal gynecomastia and therefore they are going to exclude all the boys over ten?

A No, that was not part of the original design. And most importantly, it wasn't part of the initial statistical run that gave results.

Q And also, sir, you have seen this, I know -- I hope we don't have to go back to other documents -- prior to the original study design, did they have endocrinologists involved in the study design?

A They had the authors. They had the two endocrinologists and two psychiatrists when they met in Toronto.

Q So is this changing the rules in the middle of the game?

MS. SULLIVAN: Objection. Argumentative.

MR. KLINE: It's a question.

THE COURT: That's overruled. I am going to ask all jurors to kind of sit up, please.

Thank you. Overruled.

Q Is that changing the rules in the middle of the game?

A I think so. Let me tell you my real concern here. My real concern is you run data and you get a series of results, and that was done in May. And

then you have those results. What you do is you don't change rules after you get those results. Because, I mean for whatever reason, once you get the results, you don't want to come up with different rules after you get the results because if you apply different rules after you get the results, then you have a great chance of introducing bias.

So, I don't like the result, for whatever reason, if I come up with a different set of rules, I have the result, then I go, I am going to change how I am going to do that.

So that's why in clinical trials, in science, you try very hard, not always perfect, but you decide how you are going to run the data. They did that, they ran the data, they got results, and then you don't change the rules.

Q Let's work through this. They had a number of tables in the report and the tables that relate to this are actually all on one page, page 1367, Bates 229. 1367 is the paginated page of the journal article.

MR. KLINE: I believe you have a copy of it, Your Honor, up there.

THE COURT: I have it.

MR. KLINE: Okay, great.

Q Now I would like to first from these tables learn some information and put it on my tablet, my schoolhouse-type tablet here.

And, sir, I know that I have discussed these numbers so they should be up there in your notes as well.

First of all, let's see what these tables are. They have a table here for SHAP(A). SHAP(A) is the run of the data which includes all of the data, the starting data, all of the kids that were in the study ages five to 14. Correct?

A Exactly.

Q And this data here we have -- let's see what they are saying. They had a primary analysis, which is what you focused on, and I believe you have told us what the primary analysis was, correct?

A Yes. That's really the column we should focus on. There are subtle differences between ITT and PA and non-PA, but it's really that column let's focus on. Those are the kids who, I believe, were enrolled and also took one dose.

Q Okay, and then let's go down the column. Let's just for our eyes to focus on it, let's just

yellow the column PA all the way down for now so we are focused.

And in that column, we now know the number of all of the kids in the study is 592, correct?

A Boys and girls.

Q Yes, all, boys and girls.

THE COURT: Counsel, I just want to clarify, does that include all children, all boys and girls from the ages of whatever it is, five to puberty or --

MR. KLINE: Fourteen, yes. We are going to be showing what was shown and what wasn't shown about that.

THE COURT: This column involves all of the kids?

MR. KLINE: Yes. In fact, that matches to the numbers we discussed earlier when they had 500-some kids. Yes is the short answer, Your Honor.

Q So all kids, there are 592, correct?

A Yes.

Q And are we able to tell the number of boys that they have in the study?

A Yes.
Q Is that on the chart, or did you have to count that up yourself?
A I got it from elsewhere but it's accessible. There was 489.
Q So of these, this is not on the chart up on the board, but you know from -- where did you get that information from?
A I got it from the data somewhere. I would have to track it exactly.
Q Okay, there were 489 boys. And that would mean there is 103 girls?
A Exactly.
Q And another thing I'd like to know is of these 592, how many are boys under ten?
A 255, I believe.
Q And since girls under ten weren't eliminated, how many girls would there be? That would remain the same under ten. All girls, since they only eliminated boys under ten, for SHAP(B) would be 103; is that correct?
A Right, so if you want -- the one other number that we probably should have is the number of girls, all girls, and boys under ten and that's 358. And

that will come up later.
Q Yes. So the SHAP(B) totals are 358 kids, correct?
A Yes.
Q And all comers are, when you include the over-tens, are 592, correct?
A Yes.

THE COURT: Again, there is confusion. Try to get this so we can all understand this. There were 592 in this thing, 255 were boys under ten. How many girls under ten were there? So we can simplify it for the rest of us.

MR. KLINE: The reason, they were only excluding boys under ten so girls remained a constant.

THE COURT: So how many are in this group?

MR. KLINE: In SHAP(A) and in SHAP(B), there were 103 girls in both. Because they didn't eliminate girls under ten. They eliminated boys under ten.

THE COURT: So we are talking about, whatever you are looking at, 255 boys under

ten, there were also 103 girls under ten in that group.

MR. KLINE: There are 103 girls period, because they were only eliminating boys under ten. So girls remain a constant over and under. They consistently used girls five to 14.

THE COURT: I don't want to have you testify on this, but I am just saying --

MR. KLINE: Dr. Kessler can explain it.

THE COURT: Go ahead.

MR. KLINE: No, our goal is that everyone understands it.

THE WITNESS: Your Honor, there were --

THE COURT: Talk to the jury.

THE WITNESS: There were boys and girls, that was the first analysis, that's all SHAP(A). Everyone is in that group. Essentially, they took out boys over ten into SHAP(B). They left all the girls.

Sorry for the confusion. But it is important to get to the right percentages, as you will see. That's really the goal, is looking at these numbers and seeing what the

percentage of PRAE or the percentage of gynecomastia are. That's why we are doing this. This is just the basis for this.

And the problem is that when you look at this table, and things happen, I mean this table is somewhat messed up because it doesn't really use the right numbers. But again, the real point, my concern is the lack of statistical association we talked about is not in here. But this table is somewhat messed up, and I would be happy to go through it.

Q That's what I am going to try to do. And when I started out by saying is it complicated but not not understandable, it's all a bunch of arithmetic, correct?
A Yeah, and I guess I may be losing on whether it's understandable or not.
Q Let's try. Let's try to do it in an efficient manner and without burdening this jury.
A Absolutely.
Q We will try. So is it correct that you have 592 SHAP(A), that would be what they used as SHAP(A) in their study, which is all comers, the boys and girl that were in the study to begin with?

A Yes.
Q And then if you strip the boys out under ten, did you end up with 358, because the same girls were included back in?
A Yes.
Q And they call that SHAP(B). That's what I wanted to do. I will mark these all sequentially when I get through with these various things.
Now, let's look up at that board. This is what they refer to as SHAP(A), all kids in the study. And when you looked at all kids in the study, they said that there were 592 kids in the study, correct?
A Yes.
Q We are looking right down this column. Twenty-two had gynecomastia, correct?
A Boys.
Q Boys, yes, 23 males. And it says gynecomastia males, 22?
A Yes.
Q And it says, Reproductive Disorders in Females, and they had -- let's go through them. They had eight total females, correct?
A Yes.

Q And they broke them down into amenorrhea, menorrhea, breast enlargement, nonpuerperal lactation, menstrual disorder, and vaginal hemorrhage; correct?
A Yes.
Q Now let's go a little math if we can so we can get to knowing how much gynecomastia there was in boys. It says here 22 boys had gynecomastia, correct?
A Yes.
Q But we know how many boys were there?
A 489.
Q 489 total boys, correct?
A Yes.
Q And so that is what percent?
A 4.4.
Q Is it a correct statement that 4.4 percent of the boys in the study had gynecomastia?
A According to my math.
Q And, sir, of the total -- look right up there at the top number -- of the total PRAE, what they used to call PRAE, prolactin-related adverse events, they are correct up there, 30 out of 592, is the total number of kids, equals?

A 5.1. That 5.1 is correct.
Q 5.1 percent?
A Yes.
Q 30 out of 592 total children had a PRAE, a prolactin-related adverse event?
A Yes.
Q Equaling 5.1 percent?
A Yes.
Q 22 out of 489 of the total boys had gynecomastia, 4.4 percent?
A Yes.
Q And since we know there are only 103 girls in the whole study, correct?
A Yes.
Q We know that eight out of 103 girls, eight out of 103 girls?
A That's 7.7, according to my math.
Q 7.7 percent of the girls had a PRAE, prolactin-related adverse event.
And by the way, if we trudge back five hours into your testimony and a day or two ago, these girls would show up as PRAE not SHAP, correct?
A Yes.
Q So the numbers I have put on my board here

break down, total PRAE versus total kids, for 5.1 percent. Correct so far?
A Yes.
Q Total boys versus total boys in the study, boys against boys, equaling 4.4 percent; correct?
A Yes.
Q And eight out 103 girls, 7.7 percent are having amenorrhea, menorrhea, breast enlargement, lactation of girls that aren't in puberty, and stuff like that, correct?
A Yes.
Q Now, how we have presented the data, is that to your understanding a correct view of the data?
A Yes.
Q Now this is, and I am going to put it in quotes, "SHAP(A)." I am going to mark it as the next exhibit number, Mr. Gomez, which is number?
MR. GOMEZ: 50.
MR. KLINE: 50 is SHAP(A), blackboard.
(P-50 is marked for identification.)
Q And we will go to their Table 3, SHAP(B). Now, SHAP(B), first of all, sir, do you see their Table 3 says SHAP(B)?
A Yes.

Q Now you know that they eliminated from SHAP(B) all of the kids, we know there is only, for a denominator, for what is going to end up being the denominator, there are only -- and hang with me on this -- there are only 358, correct?
A If you take out the boys over ten.
Q Yes.
A You are left with 358 children.
Q Yes, you are left with 358 total children?
A Boys and girls.
Q And you are left with 255 boys, which I am going to want to focus on, because it's the boys that are having the gynecomastia, by and large; correct?
A Yes.
Q So now let's look at what they have up there in this study, in this Janssen study, and what we see is, let's go down the middle column on the primary analysis.
First of all, sir, they say number.
A The number in SHAP(B) should be 358.
Q That number up there that says 592, should not be 592, should it?
A Not by their definition of SHAP(B).

Q Right. It should be only 358, correct?
A Yes.
Q And where they say number of patients with one SHAP, that's 13, correct?
A Yes.
Q Well, that's not only 2.2 percent, is it?
A No, it comes to 3.6.
Q 13 out of 358 is 3.6 percent, correct?
A According to my math, yes.
Q Let me just check with Corey for one moment.
(Pause.)
Let's go down to the next one, Gynecomastia, Males. Do you see Gynecomastia, Males?
A Yes.
Q Follow along, please, much appreciated. We have five, okay? Now let's go back for a second, sir, before we go forward. Please? Thanks.
If you look here, there were 22 who had gynecomastia when you included all the kids, right?
A Yes.
Q Now, if you eliminate over five, you only have five. Correct?
A Yes. If you eliminate the kids over ten.

Q Yeah, that's going to make the drug look safer, correct?
THE COURT: Wait, I want to be clear. I am confused. Is the elimination, SHAP(B), under ten or over ten?
MR. KLINE: No, this eliminates over ten. They eliminated all kids over ten for SHAP(B).
THE COURT: In other words, you are saying on SHAP(B), that top number there instead of being 592 should have been 358?
MR. KLINE: Yes, because -- their denominator is different because they eliminated a whole bunch of kids.
Can I go on? Okay.
BY MR. KLINE:
Q All right, now, of the five, we are now down to only five kids who have gynecomastia in their study. And they, of course, then in their study report that it's five out of 592, five of 592, for .8 percent, correct?
A No.
Q That's what they say?
A Yes.

Q In this published paper in the *American Journal of Psychiatry*, correct?
A Yes, but you don't have -- that 592 is not what the group is.
Q Right. In the group is gynecomastia males. And in this group --
A Gynecomastia of males under ten in SHAP(B).
Q Yes. Let's highlight Gynecomastia, Males?
THE WITNESS: I think the Judge is about to --
THE COURT: I am with you. I think I understand. I hope the jury is does, too.
MR. KLINE: Me, too, because I am working hard. Let me step back, with the Court's indulgence.
Q They eliminate all the boys -- bear with me -- they eliminated all the boys that are over ten. Correct so far?
A In SHAP(B).
Q That's what constituted SHAP(B). SHAP(B) was all boys over ten are now gone?
A Yes.
Q And so therefore, you no longer have 592 in the study, correct?

A Yes.
Q You have 358 in the study?
A Yes. You get rid of some of those kids, those boys over ten, you are going to have less.
Q Okay, now, you see gynecomastia in males, this SHAP(B) is only males under ten?
A Yes. 255.
Q So I now know they got down to five boys, and we will get to if that's good or bad for them, but we have five boys, and how many boys are in SHAP(B), that is, boys who are under ten, males who are under ten?
A That's 255.
Q 255 is the real number. If you are looking across that table, Gynecomastia, if you want to know the rate of gynecomastia in males in SHAP(B), which is only the ones under ten, you can't start with the numerator for the boys under ten and the denominator for all of them; correct?
A Exactly.
Q And if you were looking at the data properly, it would be five over 255, correct?
A Right.
Q Which is that down to .8?

A No.
Q What is that at?
A So I got to check my math, but I get 2 percent.
Q 2 percent. So there is gynecomastia of 2 percent even when they eliminate in the males all of the boys over ten. Correct?
A Yes.
Q And the girls, this would be the next line is Reproductive Disorders of Females, and I am not going to go to all the lines and break them out, but Reproductive Disorders of Females you see as eight?
A That's easy. That should be eight out of a 103 girls, and that should be 7.7 percent. Not 1.4 percent.
Q So these numbers, sir, that are reported under this SHAP(B), is the analysis that we have here the correct numbers as they did SHAP(B)?
A I believe so, yes.
Q And even when you took out all the boys, and even when you got down to only five, you still have five of 255 of 2 percent, right?
A Yes.
Q Of boys under ten getting gynecomastia,

correct?
A Yes.
Q Now next --

THE COURT: May we stop right here for break? I think this is a good time. We are going to take a recess for about ten minutes and come back. Please do remember to not discuss the matter and all the rest, and we will be back later.

(A brief recess is taken.)

(The following transpired in open court:)

THE COURT: All right, doctor, when you are ready, Mr. Kline, when you are ready you may proceed again.

BY MR. KLINE:
Q Let's proceed to just a few more things. Back up on the screen Exhibit 50 -- oh, okay.

MR. KLINE: As we begin, Your Honor, displayed in front of the jury is Exhibit No. 49 on the screen, a portion of it which is Table 3. I am going to take a screen shot of Table 3 and mark it as 49(A), and I am going to take a screen shot of Table 2, we will

display it quickly, and we will mark that as 49(B). And we will put back up the SHAP(B) analysis.

(P-49(A) is marked for identification.)

(P-49(B) is marked for identification.)

BY MR. KLINE:
Q Now as to the Table 3, just to make a note, there is a Footnote A that describes the population which we have been discussing. And if you would put the screen down on the footnote, please, and look at "excluding males ten years or older," just so we know that that's what that's showing.

And that should take us to the next point, which is, let's now -- sir, so as an overall question, before we move on to Table 4, is there anything else significant that went into your opinion to discuss as to Tables 2 and 3, SHAP(A) and SHAP(B).

By the way, as long as we have this, can I screen shot what's up in front of the jury now as 49(C), pulling out "excluding males ten years or older."

(P-49(C) is marked for identification.)

MR. KLINE: And then if you will take

that down so I can have a discussion.
Q I will ask you, as to Tables 2 and 3, is there anything else significant, before we go on to a discussion of the Table 21 versus Table 4 analysis, which I would like to move to?
A No. The only thing that is worth emphasizing really is the 5.1 and the 3.6 percent. That is the overall number that I see in these two tables.
Q By the way, if we go again back to the abstract of the study, and if we can focus in on the front page, the left-hand column where it says, Background Methods Results? If we can take the Conclusion section and put it in front of the jury.

Now we are on the first page of the study. Would this be the abstract, if you will, that short thing that someone who is scanning the journal, a physician scanning the journal would read?
A Yes.
Q And if you notice, it says in the Results section, there is a first sentence about "mean prolactin levels rising," do you see that?
A Yes.
Q There is a sentence that says there was "no

relation between prolactin levels and age." Do you see that?
A Yes.
Q A sentence beginning "females", do you see that?
A Yes.
Q All right, now the next sentence is what, is the last sentence of the results?
A There's two sentences that are key there, sir.
Q And what are those two key sentences?
A So the first sentence, At least one SHAP was reported in 2.2 percent of children, they give 13 of 592. If I were writing this I would want the 5.1 there, certainly. I think that that would reflect all the children.

And again, the most important thing for me is also the next sentence, that I think should talk about the association, not talk about there is no direct correlation, there was a statistically significant finding.
Q Let's hold the "no direct correlation between prolactin" and take it off from being highlighted. I just want to focus on this part.
A So, if you did the analysis by SHAP(A), all

the kids, it would be 5.1 percent. Not 2.2.
Q That's what I want to go through with you very briefly with the jury.

This is the result section of the paper, and by the way, it's right on the first page of the article, right here. I am holding it up in front of me, it's right here, the first page of the article. It's the result section. So you see the article, you see what the results are before you even read the article?
A The results of the abstract.
Q Yes.
A Yes.
Q Yes, the results are the abstract, the results in the abstract section?
A Yes.
Q It's what you see before you even read the article?
A Yes.
Q And let's see what they say and compare it to what we know. And it's going to take a minute to do but I feel obliged.

They said to everyone, At least one SHAP was reported by 13 of 592 patients for

2.2 percent. Okay? Now let's see where that comes from.

First of all, what they are saying is in the SHAP(B), that's the kids where they have eliminated boys over ten, what they did was they took these five and these eight and got 13. Correct?
A Yes.
Q And then they used the denominator for SHAP(A) for all the kids, which is 592, correct?
A Yes.
Q And report in this study as the topline result that it's 2.2 percent, correct?
A Correct.
Q The real fact, sir, if you took the 592 denominator, you would have to put in at least one SHAP was reported by --
A 5.1 percent.
Q By 30 of 592, correct?
A Yes, which is 5.1 percent.
Q So in the either/or category, sir, it's either 592 equaling what percent?
A 5.1.
Q Or if you did their SHAP(B) analysis

themselves, again this is boys and girls with a prolactin-related event, it would be 13 of?
A 358.
Q 358. It's one of those two, correct?
A Yes.
THE COURT: What's the percentage of 13 over 358?
THE WITNESS: 3.6 percent.
Q With the correct numerators and denominators, correct?
A Yes.
Q Am I correct the one thing it's not is 13 out of SHAP(B) out of the denominator of 592?
A That's correct.
Q Would that be misleading, sir?
A Those numbers are not correct. You would look at this and you would think that the incidence was 2.2 percent, and it's more than double. It's a 5.1 percent.
Q Have you seen any documents where Ms. Binder or Mr. Pandina or Dr. De Smedt, Goedel De Smedt who is an author said, Hey, this is wrong, let's change it?
A No, I have not seen it.

Q I am labeling a document which I just came up with a name for it called abstract numbers, as an exhibit number which is 51.
(P-51 is marked for identification.)
Q By the way, sir, what we have been discussing in this study so far is simply the reporting of the incident rate, correct?
A Yes.
Q Now we are about to turn our attention to this whole issue of Table 21 and whether that ever got reported?
A The association.
Q The association. I am marking as Exhibit 51 my next exhibit number -- my next exhibit number, which is what Mr. Gomez, please?
MR. KLINE: I am marking as 52 the SHAP(B) figures, and I believe for our record I have everything marked.
(P-52 is marked for identification.)?
MR. KLINE: I need one more exhibit number.
(P-53 is marked for identification.)
MR. KLINE: Exhibit 53 is the number of children in the study in the pooled analysis.

Q Thanks for your patience, and let's go to the next thing which is the association.
Now, back to Table 21 for a moment, which is Exhibit No. 34(A). It's being displayed. Straight across the 8 to 12-week row, very quickly. The statistically significant association, correct?
A Yes.
Q And notice, sir, that the statistically significant association is at weeks?
A 8 to 12.
Q 8 to 12. And it's 20?
A Versus seven.
Q It's 20 versus seven, or 7.8 percent, versus 2.9 percent. Correct?
A Yes.
Q And it's at .158?
A The p-value.
Q This is from Table 20 -- bear with me all on the set up, you will see where it goes.
That was from Table 21, and give me the date again? It's real important to me?
A May 15, 2002.
Q May 15, 2002?
A It's when the data was run.

THE COURT: Let's go back for everybody's memory. What test was this run? Wasn't there a number to this test, 41 or something?
MR. KLINE: No, Your Honor, this was the pooled analysis where they took five studies including 41, but it was studies 41.
THE WITNESS: 19, 20, 93, 97, 41.
MR. KLINE: Combined.
THE WITNESS: It was all those tables.
MR. KLINE: And they looked for the association, and this shows they found it.
THE COURT: Memory is a funny thing, you know. So this is all of them combined?
MR. KLINE: Yes, and, Your Honor, I might add, this is a lot of information.
THE COURT: That's why I am trying for everybody's sake. Now this is all of them combined.
MR. KLINE: Yes, the five studies combined, as we have been discussing.
THE COURT: Go ahead.
BY MR. KLINE:
Q Now we have Table 21, May 15, 2002, weeks 8 to

12, 7.8 percent versus 2.9 percent if you had a normal versus an above the limits of normal prolactin level as to when -- if your prolactin level went up at this time interval, there was an statistically significant association with you getting gynecomastia later. Correct?

A All of PRAE, yes.

Q Meaning girls and boys, the things that we have seen?

A That's the way this table was done, yes.

Q Now let's look at Table 20. What was the date of Table 20?

A Have we discussed Table 20?

Q Table 20 --

A I just want to make sure that everybody knows what Table 20 is.

Q I was going to get the date. What's the date of it?

A It's data run on September 27, 2002.

Q September?

A 27th, 2002.

Q This is the table that included --

A Everyone.

Q -- everyone. I am going to say, Included over

tens, and this is the table that Excluded over tens. Okay, so far?

And please tell me, let's go across weeks 8 to 12?

A You had nine findings of PRAE above the upper limit of normal, nine cases, for a percentage of 3.5.

Q And it was at 1.2 percent --

A Was three cases for 1.2 percent if you were in the normal range.

Q Now both sets of information were known to the -- when this article that appears in November 2003, a year and months after both of the data runs, this information was known to the authors, correct?

A Yes.

Q And they presented a table on the comparison of SHAP populations, and I would like to show it now.

Before I show it I want to go back and do one thing. Let me see if I can do one better.

If I can look at Table 21, that is to say, the pooled analysis of five studies table that included all the kids including the over ten boys.

And can we just crib out the prolactin -- just where it says prolactin above normal, Corey, so we can see them?

Now these are the different ranges -- Dr. Kessler went over this with the jury -- pre-dose four to seven weeks, eight to 12 weeks, and what I need to get from you, sir, on Table 21, is the lowest and highest numbers of the normals and the abnormals.

A We are not just talking about weeks 8 to 12?

Q Correct?

A You want across all weeks, for any week.

Q Yes.

A So I see the highest in the above upper limits of 7.8 percent. And I see the lowest of 4.7 percent.

Q I am going to mark that in there because the jury is going to see why in a minute. Highest, lowest is -- tell me again?

A Highest, 7.8. Lowest, 4.7.

Q Is that of any real significance, that number?

A I don't know of any significance. The significance for me was the 8 to 12 weeks, the 7.8, and the 2.9 that's going across. That's the

comparison that's statistically significant.

Q And how about in the normal, what's the highest and the lowest if you pick those numbers out?

A If I pick those out, it's 6.5 and 2.9.

Q And all that tells you what the percentages were high and low, correct?

A Yes.

Q Bear with me, everyone. In Table 20 let's do the same thing. And this number, this highest and lowest, is that called the range?

A Yeah, it's the range, the frequency of PRAE for the upper limit of normal.

Q Now let's go down to Table 20 real quick, and what's the range and the upper limit?

A 1.8 to 3.5.

Q And 3.5, of course, is this number, correct?

A Yes.

Q And then how about down here?

A Within the normal, the range is 1.2 to 3.0.

Q 1.2 to 3.0?

A Yes, sir.

Q Now, of the ranges that we have here, the highest and the lowest on Table 21 are both in weeks

12, 8 to 12, correct? You are comparing the highest to the lowest?
A Yes. That's the way it works out on 21, yes.
Q And by the way, as it turned out, that number was statistically significant, correct?
A Yes.
Q And if you do the same thing for Table 20, the 3.5 compared to the 1.2 range, why that's also in the week 8 to 12 range. Correct?
A Yes.
Q So if one were to display the ranges only, if one were to display the ranges only, would it be telling anyone that we had the lowest and highest ranges in both weeks 8 to 12 in that cohort, meaning those groups?
A Yes. The key is, the paper set out to see whether there was any relationship between prolactin levels and PRAE. They found a relationship at weeks 8 to 12. They don't say it. The way they put the numbers in the paper doesn't show the fact that they found a relationship at those weeks.
Q Now I am about to display what was in Table B, with this in mind. I am going to mark this the Weeks 8 to 12 versus the ranges. Exhibit 54.

(P-54 is marked for identification.)
Q Now with this in mind, let's display Table 3 in the published Findling article. We saw Tables 2 and 3, now we are going to see Table 4. Okay?
A Yes.
Q Now, first of all, I think you already told us but just to be sure, Table 4 does not, correct me if I am wrong, does not show the data in Table 21, correct?
A It does not show the relationship, no, that's correct.
Q And it also doesn't even show the data as presented in Table 20, correct?
A No.
Q What it shows is something completely different, correct?
A Yes. It does it a completely different way.
Q Let's look. It shows these ranges, doesn't it? Instead of showing weeks 8 to 12, it shows these ranges, correct?
A Yes.
Q It shows that in SHAP(A) -- and we are not going to highlight because I am going to pick certain numbers out in a moment -- it shows in

SHAP(A), if you go down the column, it says -- first of all, the title of the table is "Comparison of SHAP Populations (primary analysis populations).
By the way, that's what they focused on, correct?
A Yes. In that table.
Q Yes. And by the way, before we get other information, note that in SHAP(A), the mean age of the boy -- what's "mean"?
A Average.
Q Would you pass a statistic test if mean was an average? Is mean an average?
A For now, so I don't get yelled at by the jury and the Judge.
THE COURT: Why don't you keep it simple.
Q Mean is not exactly an average, is it?
A No, it's not.
Q What is it? Come on, please?
A There is a calculation that goes into the mean.
Q Okay. The mean here is -- the mean age of the boys in SHAP(A) is 11.4, correct?
A Yes.

Q When they got rid of all the boys above ten, the mean age went down to 7.8, correct?
A Yes.
Q The mean age of the girls in the study stayed the same?
A Yes, because they didn't eliminate the girls.
Q Exactly. And if you go down here, they show ranges. They show Patients with SHAP and Prolactin Levels above the Upper Limits of Normal during any time. And you see they say -- we don't have to highlight -- they say 4.7 to 7.8 percent?
A Yes.
Q That's telling us, not weeks 8 to 12, or whoever is reading it, it's just telling them that the highest and lowest percentage in the whole study was within those two limits. Correct?
A And those numbers are those numbers.
Q And the same thing if you go over and look at the Normals, it tells you that the range is 2.9 to 6.5, correct?
A Yes. Again, those are the numbers.
Q Did you ever hear, since we are headed into the Super Bowl, head on head? Head on head competition?

A If you wanted to do head on head, right, you would take that 7.8, and you can highlight it.
Q 7.8.
A And the 2.9.
Q 2.9?
A That's head on head. If you look at Table 21, just put that back, if you don't mind, and look at the 8 to 12 weeks, you will see the head on head is the 7.8 and the 2.9. That's the statistically significant head on head.
Q And by the way, would you also say in the paper it's statistically significant, it's a statistically significant finding?
A You have to because the purpose of the paper is to look for any relationship, and that's a relationship.
Q So let's go back to what they reported. Let's go down SHAP(B). That's their other thing.

Now there, they say that the range for patients who have above the limits of normal, above the limits of normal, the range is 1.8 to 3.5. Do you see that?
A Yes.
Q Is that at all a meaningful number?

A That is the range that it is but head on head.
Q Yes?
A Please, highlight the 3.5, and the 1.2. And if you do me a favor and go to Table 20, and you look at the 8 to 12 weeks, you will see that's the comparison. Or if you can't, it's the same thing, if you want to do the head on head --

THE COURT: Patience, patience. Is this Table 20?

MR. KLINE: Yes.

Q There is the 3.5 against the 1.2, correct?
A Yes.
Q And let's go back to the table that they showed in the Findling study. In the Findling study --
A The pooled analysis.
Q The pooled analysis, yes, the Janssen pooled analysis, this table here. Does this table here tell the medical community, tell doctors, tell prescribers the problem that they found in Table 21 back a year ago?
A No.
Q Now, in addition to this, they write it up. Because there is a Discussion section in the

article. Correct?
A Yes.
Q And let's look at the Discussion section. On page Bates number 229, for those who have the article in front of them including the Court, it's page 1367 of the article, right under Table 4. Right under it.

So before we get there, before we do the pull-out, am I correct, sir, that if someone is reading this article would see Table 4, and then right under the Table 4 there would be a discussion of what the authors are telling us. Is that correct?
A That was, in fact, if you looked at the draft four it had that. And it had the table and it had the statistical association in draft four, yes. In the text, too.
Q Okay, now let's see what they say in this article. Starting with, "The percentage of patients with SHAP," okay? Do you see it there?
A Yes.
Q Again, SHAP is nothing other than PRAE?
A Yes.
Q "The percentage of patients with SHAP was

assessed for SHAP(B) patients with prolactin levels above the upper limits of normal versus patients with prolactin levels within the normal range at the various analysis time periods."
A Yes.
Q Do you see that? Let me stop. First of all, the various analysis time periods included weeks 8 to 12. Correct, sir?
A Sure.
Q And when it says here the percentage of patients with SHAP was assessed for SHAP(B)?
A Taking out the boys greater than ten.
Q You are only now talking about the study that takes out the boys over ten, correct?
A Yes.
Q And look what they report: Can we highlight it?

"There was no statistical difference in the percentage of patients who reported SHAP for any analysis time period, whether or not prolactin levels were normal or above the upper limits of normal (range, 1.8 to 3.5 percent with SHAP)."

Do you see that?
A Yes.

Q Now let's go back. Right here, what they are reporting is a range of -- actually, it's 1.2 to 3.5, not 1.8. Correct?
A Yes, I believe that is correct, yes.
Q So that happens to be an error?
A Yes.
Q Right. Because the range is 1.2 to 3.5?
A Yes.
Q Overlooking that error, just overlooking that error, is the real story told here that there was no statistical difference in the percentage of patients who reported SHAP for any analysis time period?
A That's a correct statement if you are only looking at SHAP(B). It's not a correct statement if you are looking at all the children.
Q And what did their outside advisors tell them back in 2002?
A Look at all the children.
Q And, sir, would you expect all of the children to be reported?
A I would expect if there were a relationship, there was a statistically significant relationship, that that would be in the paper. That said we are going to investigate whether there was any

relationship. It should have been in the paper.
Q And if I can go down on page 1368, which is the next page, which we already talked about briefly, the statement "no correlation was found." "No correlation was found between" -- you can highlight that sentence -- "between SHAP and prolactin levels, even when male gynecomastia during puberty was included." Would that be the over-tens?
A Yes.
Q And so would this statement be a correct one?
A It should have included the association that was statistically significant. That's what it should have said.
Q Yes, but my question is a different one. Is this statement a correct one as stated there?
A It's misleading.
Q And, sir, then if you go down to the bottom of the page, this paper which includes two Janssen authors and is Janssen data, if I can get to this paragraph here, it talks about the clinical implications of the -- can I highlight this -- "novel findings." Do you see that? The novel findings of this study? What was the novel finding of this study, sir?

A The statistically significant association at 8 to 12 weeks.
Q Okay, now --
A But it's not in there.

MS. SULLIVAN: Your Honor, that's about the tenth time that we heard that. I am objecting to it.

THE COURT: Just one second. For all of us, you are now looking at portions of P-49, which was the Findling article, "Prolactin Levels During Long-Term Risperdal Treatment in Children and Adolescents," and I think we described that as coming from the *Journal of Clinical Psychiatry* or something?

MR. KLINE: Yes, sir, and if I can step back for a moment, I think that when we were -- yes, and I believe it's well identified in the record because I consistently talked about the pages.

THE COURT: You are going back and forth in different tables. All of us are trying to follow you.

MR. KLINE: I understand.

BY MR. KLINE:
Q So we are now going to pass November of 2003 with this study. Oh, by the way, I will ask you this question. I think I covered what I wanted to, but as to your opinion, which you expressed quite awhile ago, is there anything else about the study which I may have missed which comes to mind as being important in discussion with the jury?
A There is.
Q Okay, so what is it?
A So if you go to the last paragraph of the article ending in 231, and if you just kindly highlight the phrase -- the sentence that begins, "If a highly distressing symptom hypothetically attributable to prolactin," and then that includes "substantial breast enlargement, especially in males, develops, clinicians must balance the risk-benefit." I think this paper gets it right, that these are conditions that are highly distressing. And if there are these symptoms this all has to be information that's important to physicians.
Q Yes, but then two sentences lower they say, "Although in some cases prolactin levels did remain

--

MS. SULLIVAN: Objection, Your Honor, Mr. Kline is just testifying now.

MR. KLINE: I am reading a sentence and asking him a question about it.

Q Is there a sentence below that which says, "Although in some cases prolactin levels did remain above those seen prior to the initiation of risperidone therapy, there is no evidence that untoward effects related to prolactin are likely to be seen at these dosing levels"?

A That's correct.

Q Is that a correct statement?

A It doesn't reflect the statistically significant association.

MR. KLINE: I want to do a couple of screen shots so we have a record. This is 49(D).

(P-49(D) is marked for identification.)

MR. KLINE: I need two or three screen shots, Your Honor.

THE COURT: We are going to recess soon. Will we close the direct examination before 12:30?

MR. KLINE: I will be close but I don't know if I can be done.

THE COURT: You said you would have the direct examination concluded before lunch.

MR. KLINE: I think I can do that. If you step back and take this Table 23 as a screen shot. I think I can get there. I have precious few documents left.

I want to do Table 3 as 49(E). P-49(E) will be that screen shot.

(P-49(E) is marked for identification.)

BY MR. KLINE:

Q Sir, very quickly, let's see if we can cover this in a heartbeat, I hope. And maybe even without documents.

I am going at your Tab 26 relating to Janssen going to the FDA?

A Yes.

Q Now Janssen was doing these studies so that they could try to get approval for the use of the drug in autism, correct?

A Sure.

Q And they applied to the FDA for approval, correct, sir?

A Yes.

Q And in May of 2005, did the FDA approve it or turn them down?

A They turned them down. They said it was inadequate at that point in time.

Q Okay, they said that the information was inadequate; is that correct?

A That's correct.

Q And did the FDA tell Janssen that there were deficiencies?

A Yes.

Q And did the FDA tell Janssen that one of the concerns was the sequelae of prolonged increase prolactin?

A Yes.

Q And by the way, what is a sequelae, one or two words?

A The effects.

Q And did the FDA give Janssen a chance in May of 2005 to add information so that the drug could be approved?

A Give more information for the safety profile of the drug, yes.

Q And as Commissioner of the FDA, former

Commissioner of the FDA, is that anything usual, saying you still haven't given us enough, we would like more information?

A No, that should be done.

Q Okay, and did Janssen Pharmaceuticals then provide more information to the FDA?

A It did.

Q And we all know eventually, in October of 2006, they got approval; correct?

A Yes.

Q When they responded to the FDA's denial of the drug in -- am I correct, in May 2005?

A August 2005.

Q Thank you. I correct the record, August of 2005. When they responded on August 16, 2005 in a document entitled, "Response to FDA Action Letter For Autism and Requesting a Meeting."

A Yes.

Q By the way, anything unusual or untoward or bad about that, a drug company trying to provide additional information, get its drug approved?

A No.

Q I would like you to look at the document, which is August 16, 2005?

A Yes.
Q JJRE 11084197?
A Yes.
Q And Janssen in that document told the FDA certain things -- it's not a document, it's really a letter?
A That's correct.
Q It's Bates numbers 197 through 206. And in that letter, sir, which we are going to mark, this is a Johnson & Johnson Pharmaceutical Research and Development LLC letter to Thomas P. Laughren, Acting Director, Division of Psychiatric Products, Center for Drug Evaluation and Research of the Food and Drug Administration in Beltsville, Maryland.

MR. KLINE: I have marked the document as Exhibit 55, Your Honor.

(P-55 is marked for identification.)

Q I would like you to look at page six?
A I am there.
Q After the FDA told Johnson & Johnson and Janssen no, Janssen's letter in response -- can we display Exhibit 55, page six of the letter, bottom of the page? I am going to go to the first page, actually.

The first page, the Bates number is JJRE 11084197. Please display the first page.

Johnson and Johnson Pharmaceutical Research and Development LLC is at the top, and the addressee in at the top, addressing it to him, as you would expect in a letter, regarding Risperdal, with the NDA number, and entitled, Response to FDA Action Letter for Autism and Request for Meeting.

Now let's see what Janssen said on page six of the letter.

A I am there.
Q Bottom of the page?
A Yes.
Q They talk about the DBD studies, correct?
A I would highlight, Mr. Kline, where it says long-term safety. That's really the section that this is referring to. This is about long-term safety.
Q Yes, let's go back up if we can. Was one of the things that the FDA was still concerned about prior to approval of the drug long-term safety?
A Exactly.
Q And is long-term safety including everything we have been talking about for two days about this

prolactin issue?
A Yes.
Q And rather than me telling the jury and you confirming, please tell the jury what's important in this paragraph that they told to the FDA?
A There is a sentence, if I can ask you to highlight, it's mid sentence. And again, you are correct that it's referring to -- let's actually start with the first sentence.

"A detailed review of prolactin in children with DBD treated for up to 12 weeks." So those are the studies.

Q Up to 12 months. You said weeks?
A I am sorry. Twelve months. That's the reference and those are, in fact, the DBD studies that were pooled together. But it's the sentence --
Q That's the pooled analysis of the five studies we have been talking about for the last day?
A Exactly. That's the pooled analysis. And it's the subject of that paper that we spent a lot of time talking about. If you highlight the sentence that says, "A review of the safety information."
Q This is Janssen telling the FDA?

A Right, in 2005. "A review of the safety information did not show a correlation between prolactin levels and adverse events that are potentially attributable to prolactin."

That's my concern.

Q Tell us about the concern, sir?
A It was a statistically significant finding that was the result of that pooled analysis. At best, that's a misleading statement.
Q At best?
A At best.
Q I won't ask you at worst.

MS. SULLIVAN: Objection, Your Honor, that's argument.

MR. KLINE: I completed my direct examination, Your Honor, as the Court requested.

THE COURT: All right, then we will adjourn right now for lunch. Please be back by 1:30. Again, please wear the yellow badges, do not discuss it with each other, keep an open mind, we will hear the cross examination after lunch. Please do not talk to anyone about this case. Nobody.

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All right, thank you very much.

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

THE COURT: There are some other issues I think maybe we should address.

MS. SULLIVAN: Your Honor, at this time we moved to strike Dr. Kessler's testimony. It's untethered to any Regulatory opinion. He is giving sort of his gut opinion, not citing any regulations and instructing the jury on common law, and we would object under the Frye standard here, and also on 403 grounds.

His report was clear he was going to give a labeling opinion, that we violated regulations. He didn't give that opinion. He has now completely changed it because he knows the FDA has disagreed with him on the labeling opinion, and that was our pre-emption motion, Judge.

THE COURT: You have got a lot of different points in that one statement. The one I want to see for the moment is the one involving the expert report. Everyone please

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be seated.

I am very comfortable with Dr. Kessler's qualifications as he was presented and the fields he was presented with as to his testimony in this case. I do want to see, however, whether there were any issues that go beyond the scope of the expert report and whether those are a surprise in any way to the defendant prior to cross examination.

MS. SULLIVAN: Your Honor, the specific objection is nowhere in his expert report -- the word Dear Doctor letter is not in his expert report.

THE COURT: That's not what we are talking about.

MS. SULLIVAN: I have Warning --

THE COURT: These are all, you know, he testified for three days. So I doubt that there was a verbatim translation of the expert report. Otherwise why would we have the trial testimony itself.

MS. SULLIVAN: But the core of his opinion, in his report anyway, is that we violated the labeling regulations.

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THE COURT: Let me see that.

MS. SULLIVAN: He has now not given that opinion.

THE COURT: Let me see that. The expert opinion that I heard was that there was an inadequate warning on this particular label.

MS. SULLIVAN: On the label.

THE COURT: As to this particular label. Let's see what he says as to his opinion on his expert report.

MS. SULLIVAN: I am handing up page 67 of Dr. Kessler's report. Paragraph 258 and 259 on page 67 is among the many places where Dr. Kessler talks about the fact that we violated Federal statute regulation and agency policy by not having a warning in the Warnings section of our label. He didn't give that opinion, instead, he has morphed into a common law expert, instructing the jury on the law, and we submit that's improper.

THE COURT: I am looking at paragraph 260 in his expert report: "In my opinion Janssen failed to adequately warn physicians

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about the risk of gynecomastia."

That is in essence his opinion, it's right there, paragraph 260. So therefore, your motion is denied.

MS. SULLIVAN: I understand Your Honor's ruling, but in his report at least it was tethered to the regulations. Here, it is just instructing the jury on his common law gut feelings.

THE COURT: Motion denied.

MS. SULLIVAN: Thank you, Your Honor.

THE COURT: Anything else?

MR. KLINE: Just to mark as part of the record, I know it's denied and I know it usually violates good practice to add when you have won, but there was a deposition taken of him. Contrary to the custom and practice in our Pennsylvania courts, these experts are all deposed in pharma cases under our Mass Tort protocol, and he was specifically asked questions about all of these things.

He told a lawyer for Janssen, "It's the best way to do it. I mean there are other ways, you can do Dear Doctor letters, but I

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certainly wouldn't want, blah, blah, blah, he goes on.

Every issues was talked about. He talked about Dear Doctor letters, he talked about notifying the sales rep --

MS. SULLIVAN: It's a different case, Your Honor, it's a Texas case.

MR. KLINE: May I please? Okay, it's been denied, I am sorry I talked.

THE COURT: There is no surprise that can be identified to the defense. That motion is denied, and I am very comfortable with the doctor's qualifications to render that opinion.

MR. KLINE: I have two matters.

THE COURT: Anything else?

MR. KLINE: I don't think we need to argue, I have two matters to hand up, I know the Court likes to be alerted ahead if we think an issue is going to arise.

There are two issues, one of which I gave to the Court already, I don't want to stand here and argue it, but it has to do with, to the extent, I think we have already

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covered this issue with money in qualifications. Ms. Sullivan didn't cross-examine on it and I wouldn't expect to hear about it again since that was her opportunity.

MS. SULLIVAN: Money doesn't go to qualifications.

MR. KLINE: To the extent she does try to go to it and wants to go to it and the Court allows her, I handed up case law that's very specific in Pennsylvania that has to do with the proper scope of cross examination. I gave these to you.

THE COURT: I read those.

MR. KLINE: Proper scope of cross examination.

THE COURT: You want that ruling on that issue now?

MR. KLINE: I just want to make sure Court is aware.

THE COURT: I am aware. However, there are some nuances in this area. It is not appropriate to discuss the fees in other cases, but it is quite common in Pennsylvania

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to discuss overall earnings from expert fees in total part of a consulting or reporting or expert report practice. That's very common.

MR. KLINE: I believe that that is specifically in these cases that says that an expert witness does not under Pennsylvania law need to "turn his pockets inside out." It says so in the cases I gave the Court. And that doesn't go to his bias because he has a relationship with.

THE COURT: Hold on one second.

MS. SULLIVAN: Your Honor, the argument is twofold on that. First, I am not sure Mr. Kline read the cases he handed the Court, but the cases make clear --

MR. KLINE: Of course, I read them.

MS. SULLIVAN: Including the Coward V Owens Corning case, that testimony against the same industry goes directly to bias and is permissible. And also, Your Honor, Mr. Kline opens the door by spending about a half hour asking Dr. Kessler about his testifying and money, and it's clearly proper.

MR. KLINE: Not money. Not money.

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THE COURT: One second. What is your take, Mr. Kline, on the law in Mohen versus Hahnemann that Judge Rau decided awhile ago, regarding this issue as to what is permitted regarding money?

MR. KLINE: My understanding of Pennsylvania law is it's very clear: Money is different from whether he testified against the industry. I think it's fair game to be asked whether, under these cases, collectively, whether the expert has testified before in pharma cases against pharma companies, whether he shows up every other week to testify, whether he testifies more for the plaintiff than for the pharma company in these cases. That's all fair game.

What is not fair game is to suggest as she did in her opening, this man has made "millions testifying against pharma." That is clearly unequivocally prohibited. The other is all fair game.

What is permitted as to money --

MS. SULLIVAN: Your Honor --

MR. KLINE: Again, may I please?

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THE COURT: Ms. Sullivan, let him finish.

MS. SULLIVAN: I am sorry.

MR. KLINE: As to money, there is a very famous Bob Dylan song from the 60s called *Brownsville Girl* where the line is, "She changed the subject every time money came up." That's just a 60's reference.

The fact of the matter is on money, she can go to town on how much I paid him, how much Mr. Sheller has paid him, and by the way, I would agree how much he has been paid in the Risperdal litigation.

THE COURT: We already talked about that. It was a quarter of million dollars, so far.

MR. KLINE: It only goes to show you the stakes. We just would love everybody to know what the stakes are here. But the -- my last point is, that's the distinction. The distinction is she cannot, and it will be error, suggest to this jury that he has made millions, paid by someone else.

For example, he was paid a significant

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amount of money, we all know this, in a case called Actos. Actos was a single plaintiff, a case in Texas, a company after he testified was -- the plaintiff was awarded $9 billion.

So I guess we get that in if she gets into money. She can't get to the money that another lawyer paid.

THE COURT: There is a lot of danger in your posture. There is a lot of negativity about your client that has been kept out of this trial. If we go into this who said what against who for what purpose and which case, you never know what ends up being permissible in this trial.

MS. SULLIVAN: Your Honor, just on the subject of money and fees, and Mr. Kline's threat that it's reversible error, it clearly is not. The very case Mr. Kline handed you, the Coward versus Owens Corning, it was held that the cross-examination of the expert witness regarding the amount of the fees he was paid to testify against other asbestos defendants over the 20 years was allowed because it goes to potential bias in favor of

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the parties litigating the claims.

THE COURT: We will look at them again, but what these cases stand for is that there is some, as in virtually any evidentiary ruling, a balancing between probativity and prejudice. So we will look at it with that in mind and give you your instructions before cross examination.

MR. KLINE: By the way, on that, asbestos: Product. Risperdal: Product. It's not industry. That was the distinction made there.

Very briefly, Your Honor --

THE COURT: I do think defense should bear in mind that the opening up of other matters in this case has the potential of widening the door as to other prior acts by the defendants.

MS. SULLIVAN: Well, Your Honor, one is proper evidence and one is not, I would submit. Clearly, under the case law.

THE COURT: It depends on what purpose -- it all depends on the posture of the evidence that's being presented. And I am

(Pledger v Janssen, et al.)

just cautioning you that you never know. You just never know what you have opened up.

MS. SULLIVAN: One is bias and fair game, one is prior bad acts.

THE COURT: Again, you can argue evidence later, but I am just warning you that these kind of issues will be considered. I will give you some parameters. If you wish to break them, then do so.

MS. SULLIVAN: Thank you.

MR. KLINE: The other issue, Your Honor, if I may hand up a brief bench memo, and I know that defense counsel is going to want to discuss FDA and FDA documents.

MS. SULLIVAN: You put them in evidence, counsel.

MR. KLINE: I have not.

MS. SULLIVAN: You put the FDA contact report in and you read from the --

THE COURT: Ms. Sullivan, let the gentleman finish. Whatever is in evidence is already in evidence. He can't take it back and there it is. So what's the issue?

MR. KLINE: The issue is, Your Honor, I

am handing up a bench memo, rather than arguing and taking our lunchtime, I will hand it you to. It's a couple of pages. It says what I would say if I were standing here arguing, even if I were arguing uninterrupted.

It basically says that there are rules as to what can come in from the FDA and not. Pennsylvania law is different than Federal Rule of Evidence 803(6), in that opinions are not allowed, and our official records doctrine in Pennsylvania, which is 42 Pa.C.S. 6104, has an exception for Commonwealth documents, not Federal documents. So I just would like the Court to take that into consideration.

THE COURT: I will review that, but again, our practice in this Court, FDA documents and the nature of the relationship between the FDA and their requirements and state law is not preempted in evidence.

MR. KLINE: FDA --

THE COURT: Otherwise we wouldn't be having this trial.

MR. KLINE: Here is the distinction, yes, Your Honor, here is the distinction: FDA

actions are not preempted. FDA opinions are hearsay under the current law in Pennsylvania, and that is the bench memo I gave Your Honor, respectfully, for consideration.

MS. SULLIVAN: Your Honor, we weren't provided with a copy.

MR. KLINE: I just gave it to you.

MS. SULLIVAN: Our argument would be twofold. First, as part of approval package, the FDA documents come to Janssen, they maintain them in the ordinary court of business. We will have witnesses --

THE COURT: The difficulty I have is the timing of this particular motion. It really should have come in before the trial. It's a little bit of sabotage here in the posture right before cross examination. So it may have been waived up until now. So we will take a recess now.

MR. KLINE: Your Honor, respectfully, you cannot waive a correct or incorrect legal ruling. And I am calling the Court's attention to what I believe to be the law. That's all I am doing.

THE COURT: The law will be reviewed, but I do believe this has been waived for the purposes of fairness at trial, and that has the overall -- that is the most important thing that the appellate courts care about, what is fair at a trial.

MR. KLINE: I gave you the law, Your Honor. The law is the law.

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(A luncheon recess is taken at 12:40 p.m.)

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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

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