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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FRIDAY, JANUARY 30, 2015

VOLUME V
MORNING SESSION

- - -

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:
JUDITH ANN ROMANO, CRR
CERTIFIED REALTIME REPORTER
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I N D E X

(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.)

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DIRECT EXAMINATION

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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.

(Kessler - Direct)

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.

(Kessler - Direct)

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

(Kessler - Direct)

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.

(Kessler - Direct)

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.

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

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.

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

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

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

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

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.

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?

(Pledger v Janssen, et al.)

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

(Pledger v Janssen, et al.)

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

(Pledger v Janssen, et al.)

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.

- - -

(A luncheon recess is taken at 12:40 p.m.)

- - -

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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