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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THURSDAY, FEBRUARY 19, 2015

VOLUME IXX
CLOSING ARGUMENT

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COURTROOM 425
CITY HALL
PHILADELPHIA, PENNSYLVANIA

- - -

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

- - -

REPORTED BY:
JUDITH ANN ROMANO, CRR
CERTIFIED REALTIME REPORTER
OFFICIAL COURT REPORTER

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(Pledger v Janssen, et al.)

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(Hearing is reconvened at 9:38 a.m., and the following transpired in open court out of the hearing of the jury:)

THE COURT: All right, we are waiting for the arrival of a few more jurors, so we are going to address some remaining issues involved with the jury instructions.

I understand there is a new instruction that has been proposed, and also, I have submitted copies of a revised learned intermediary instruction, and I believe we submitted to you a wrong copy of our new causation. So this is a correct copy of the causation. So please disregard the other causation that's been handed out.

Are there any objections to the revised learned intermediary and the revised causation?

MR. MURPHY: Good morning, Your Honor, the learned intermediary that the Court proposes is fine with us. The revised causation charge deletes --

THE COURT: Pardon me?

MR. MURPHY: The revised charge on

causation deletes what you initially had in first: "You must consider."

THE COURT: That was a mistake. We have reviewed the law. We handed you over one that was a mistake. The language that you wish is in Deere versus Gross, 586 South 2nd 196. That does not apply to a jury, that applies to a directed verdict, and we are not using it here for a jury.

MR. MURPHY: But the components that you identify in the paragraph above naturally call for that first paragraph that you took out: "First you must find if an adequate warning had been given."

THE COURT: I am satisfied with the 33.00 causation, as I have said. You certainly may take an exception, but I am satisfied with it.

MR. MURPHY: Understood, Your Honor.

THE COURT: What is the other one?

MR. MURPHY: We understand that there was an instruction handed up just recently regarding life expectancy. First, it appears to be a Pennsylvania charge. I am not aware

of whether there is in fact an Alabama charge on the issue, and we are following Alabama --

THE COURT: Neither of you had requested it up to now. We can look it up.

MR. KLINE: Your Honor, it was strictly an oversight. Obviously, we need the life expectancy charge. I did research Alabama, I do have the case, they do the same thing as Pennsylvania. The citation is Clark V Hudson, I can hand it up to the Court, but basically it says where there is evidence from which there is a reasonable inference that plaintiff's injuries are permanent, the mortality tables are admissible.

I can't believe standing here that this is controversial that we can have a life expectancy charge in a personal injury case with an alleged permanent injury. So I just grabbed the PA standard charge --

THE COURT: Let's put it this way. I don't think this should delay closing arguments. There will be a life expectancy charge, it should be Alabama law, and we will follow that. I don't think there is anything

controversial.

MR. MURPHY: To the extent we are following Alabama law, I think Alabama law is clear that this charge is appropriate where mortality tables are in evidence. There are no mortality tables in evidence in this case.

THE COURT: All right.

MR. KLINE: I have never known mortality tables to be --

THE COURT: In this case every I and T has been requested. As far as I am concerned, counsel, you can make your argument and I will make the instruction. You are talking about a 19-year old boy?

MR. KLINE: Yes.

THE COURT: And you may say you don't know how long he is going to live but you can figure it out for yourselves or estimate for yourselves. But I am not going to charge them. I haven't seen the law. Let me see the law of Alabama. If the evidence is not there, I am not going to permit the instruction.

MR. KLINE: Your Honor, I have tried I don't know how many personal injury cases, I

can tell you that the evidence is almost never there, except when there is a diminished life expectancy. The rule is that the Court takes judicial notice of the official life tables. It's been that way time in-memoriam. It's that way in Alabama. I am entitled to a charge under both Alabama and Pennsylvania law. The Court takes judicial notice.

The only time that there is a controversy is when there is a diminished life expectancy, and a diminished life expectancy -- and frankly, this is to the benefit of the defendant because it gives the average expectancy of all comers.

So I have the case, I have the point --

THE COURT: I will take a look at the cases.

MR. KLINE: -- and I am entitled, frankly, to the point.

THE COURT: I have a lot of time between now and the closing arguments. The jury is here so we will take it under advisement. I don't think it will affect your argument to the jury at this time. I

certainly hope it won't.

MR. KLINE: I will argue as the Court suggested.

THE COURT: My position would be that you can expect no instruction, but we will review it as to judicial notice. And as far as I'm concerned, this is a common sense jury, and the jury can apply their common sense to damages if they get that far.

MR. KLINE: Your Honor, I have one more minor point -- it's a major point but a minor point that I just want to make sure I put on the record. We had never put on the record the Plaintiff had requested that the question of recklessness be submitted to the jury and we take a sealed verdict if the answer to, Was the conduct reckless. We had an informal discussion about it, but I would formally request that there be a question on the verdict slip that asks the question, Was the conduct of the Defendants reckless, which would then, if answered yes, lead to a second deliberation on punitive damages, which I would request be of any sealed verdict.

We had an informal discussion, one of the few that we have had during this trial, and I think I know where the Court stands on this, and I am also cognizant of Judge New's ruling, but I did want to make the request. I am sorry for doing it at this late hour, I just wanted to put it on the record. It doesn't involve a ruling of Your Honor, it involves a ruling of Judge New, frankly.

MR. MURPHY: And we, of course, object to that. We think it is wholly inappropriate. Judge New has ruled regarding punitive damages. There is no room for such --

THE COURT: Let me just put the matter into a more formal construct, and that is the issue has to do with whether or not this Court should include in a verdict sheet an interrogatory, which is really not binding on the verdict itself, sort of like an advisory interrogatory for any potential future punitive damage trial. And the position of this Court, of course, is that we are following New Jersey law as to punitive damages. That matter may or may not be

appealed, but that is the ruling of this Court as far as punitive damages are concerned, so we find that including an irrelevant interrogatory would be confusing for this jury.

But moreover, there is another factor at play here, and that is that it was very clear from the outset of this case that recklessness or any element of that sort was not in play as far as evidence the defense had to refute; and so therefore, to put that particular instruction as an interrogatory now is prejudicial to the defense should they ultimately need to prepare for a punitive damage trial in the future.

So that is the ruling of the Court, that motion is denied.

MR. KLINE: Thank you for hearing me. Your Honor, I am handing up the United States Life Expectancy Table which the Court can take judicial notice of, we believe. Thank you.

THE COURT: Okay. We will take a five-minute recess, I will look at that, the jury is here so we will proceed. Is

everything all straightened out between counsel as far as --

MS. SULLIVAN: I understand the Court and Mr. Kline would like me to use the elmo, and I am prepared to do that.

THE COURT: That's fine. The other thing that I would put on the record now is that I am allotting approximately an hour and a half for the arguments of each party. From the Plaintiff's side, that is the entirety. So you need to reserve time for rebuttal out of that one hour and a half. The idea would be to permit the jury to hear the closing arguments all before lunch and then allow this Court to provide them with the jury instructions after lunch. That's the rationale there.

MR. KLINE: It's my current plan to do about an hour and then about a half. That's my goal.

THE COURT: All right, so we will take a recess and we will start in about five to ten minutes.

(A brief recess is taken.)

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THE COURT: All right, please be seated, everybody. We have the jury here, we have ordered lunch for them, so they are not going to be restless about lunch.

I have also reviewed this question of the judicial notice. First of all, Mr. Murphy, you are correct, under Alabama law it needs to be presented during evidence, during the case. However, as this is an evidentiary matter, we are following Pennsylvania law. In Pennsylvania, judicial notice is permitted at any time for certain types of tables, and the question is whether this is a table that is permitted under Pennsylvania law, which according to standard Pennsylvania practice is certain types. So where is this table from?

MR. KLINE: From the Standard Jury Instructions itself.

THE COURT: This should be okay. So we will permit it. We are ready to proceed. I just want to be clear, though, what are you arguing in terms of life expectancy here?

MR. KLINE: We are arguing 56.6

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additional years, according to the table.

THE COURT: So you may use that term if that's what it's calculated to. I don't want any error on those grounds, that's for sure, if you really feel that it is necessary to make that argument.

MR. KLINE: It is.

THE COURT: All right, then we are ready to go.

MR. KLINE: One question was not asked. May we display the verdict slip or not?

THE COURT: That, generally speaking, I do permit that.

MR. KLINE: Okay, so we can put it up?

THE COURT: Yes. That's, of course, with the understanding that I will explain to the jury when they come in that all of counsel's remembrances of the facts and evidence are subject to the jury's recollection and the law as you may discuss it is subject to the Court's jury instructions.

MR. KLINE: Thank you.

(The jury enters the courtroom at 10:12 a.m.)

(Pledger v Janssen, et al.)

THE COURT: Good morning, please be seated. All right, members of the jury, we have made it to this point. We have made it to this point. You are about to hear closing arguments from the Plaintiff's side and from the defense side.

Let me just remind you, first of all, you are permitted to take notes during closing arguments. You will not be permitted to take notes when I give you my final jury charge, but you are permitted to take notes here.

Remember from the outset what I told you, that the arguments at closing are very important, we are giving them time, about an hour and a half each, and we have ordered lunch so we should be okay.

What I wanted to tell you, also, is that the arguments of counsel, this is a reminder, is argument. It is not evidence. So obviously, I expect them to discuss the evidence with you and to explain how they see the evidence in terms of the theories of their case, but remember, the evidence is for you to decide as the fact finders. That's your job.

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The other thing about this is remembering now what the burden of proof is in this case. Remember that the burden of proof in a civil case is preponderance of the evidence. Another term for that is more likely than not. I am going to explain this to you again in my jury charge, but I think it's beneficial for you to think about this now as you hear the arguments.

All right, what are we talking about. I have the scale, I am not going to go over here to move it for you, but basically, the burden of proof is on the Plaintiff and they have to show you more likely than not that their perspective on the case is persuasive to you.

More likely than not can be just a little bit, can be 50.01 percent, or it can be a lot. Just a teeny bit to a lot is more likely than not under the law. However, if they cannot meet that burden, then the verdict goes to defense.

So another way of looking at it is if the evidence you find is in favor of the

defense at 50.01 percent to a lot, the verdict would go to the defense.

Now what happens, ladies and gentlemen, when it's even, when the scales here are even? Well, in that case, the verdict goes to the defense. Why? Because the burden of proof is always on the plaintiff. Okay? So just bear that in mind as you listen now to the evidence that they are going to discuss with you and you have to determine ultimately.

The other thing that I want to say is that, in terms of your own situation in this case, if you have some need to get up or something during this, just let us know, we will stop. Okay? But other than that we are just going to go with a straight flow.

Under the Rules of Civil Procedure, it is the plaintiff that goes first in the argument. So Mr. Kline will go first. And then it will be the defense, we will probably take a break in between, she will go next, and then under the rules we have here in this Court, there will be a brief rebuttal, according to the amount of time reserved by

the plaintiff, and the plaintiff will have an opportunity to speak to you last.

So that's the game plan, and, Mr. Kline, when you are ready you may proceed on behalf of Austin Pledger and the family.

MR. KLINE: Your Honor, thank you very much. It's been an honor and privilege to be in your courtroom.

THE COURT: Thank you.

MR. KLINE: Very much so.

Good morning.

JURY: Good morning.

MR. KLINE: One more good morning. You do not have to be scared away by all the papers this time because there is a time limit, and so there can be a false sense of security.

Members of the jury, you have been here a long time, and it is truly, truly remarkable. We don't know each other other than me having the privilege and honor to talk to you, but we are fellow citizens, and in this country we are in this together, and there is nothing that makes this country work

more than the jury system, nothing. The Chief Justice of the United States, a great man, Earl Warren, from 1953 until 1969, he said, Next to putting on the uniform of your country in the time of war, next to putting on a uniform in a time of war, there is no more important duty of citizenship than serving on a jury. And you folks have done the functional equivalent of two tours in Iraq and two tours in Afghanistan. Thank you, however this trial turns out.

It's been a long time, and as you can tell, this is a very important case for Austin Pledger, it's a very important case, and at times tensions are high, at times emotions are high, and I just want to ask you to, with me, go through the evidence. I will show you how the evidence fits together here. I don't plan to do anything but go through the evidence. I don't plan to talk about my opponent and I hope she doesn't talk about me. I hope to talk about the evidence. You have been here day upon day upon day.

The evidence. First of all, legally,

Benita Pledger, a wonderful mom, is actually more than a mom in this case. She is, under Alabama law, the conservator and the guardian of Austin. He can't speak for himself. He can do nothing in this courtroom, he can't testify in this courtroom, other than to exhibit him to you. And you have seen what's important about him. This case is about a young man with female breasts. And you have seen that. But legally, his mom is him. And so he is here through her because the court has appointed her essentially -- not essentially, truly, to be him.

And me, I am a legal representative. People need lawyers in society. And I have been given this task. And in case you haven't noticed it, I have taken it seriously to the interior as far as you can get in my body.

You know a lot about the case. You know about the experts, you know the case is literally awash with money, but I want to focus on the facts and the evidence. You are going to hear that from me now until we leave. I want to spend about an hour now and I hope

to reserve time to finish.

The case involves the period from 2002 until 2006, and during that period of time this drug was not approved for children and adults. That's a start point and an endpoint. The Janssen Pharmaceutical Company can tell you everything they want about the 2006 label, and the 2006 label serves as a benchmark for us, they can try to talk about what happened later, they can brag about the approval they eventually got with many changes in the label; but this case is about what happened between 2002 and 2006, and whether the warning was sufficient to a doctor about a powerful, antipsychotic schizophrenia drug, which was not approved for children in that period of time, not approved, but yet, 1.6 million of these doses were in the bodies of little children, and they knew it. My word, they knew it.

They knew what they were doing, they knew what they were selling. And they knew what was going on when a man by the name of Gilbreath went to visit a doctor by the name

of Mathisen 21 times.

It was a drug that was called by the FDA a chemical straitjacket. It was the drug that when Austin Pledger took it his head was on the table. It's the drug that in the 2006 label, my word, why, it shows that 50-some percent and 40-some percent and 60-some percent of the kids, mentally retarded children, autistic kids, are sleepy, fatigued, and hungry.

Dr. Mathisen told you, That label doesn't tell you what happened in my practice. These kids gained a lot of weight.

Now with all of these prescriptions, and by the way, three quarters of a million, if I recall correctly, three quarters of a million patient years of children and adults, for a drug that's not prescribed for children and adults. And the question is what's the duty of a pharmaceutical company that not only knows it, they bonus and incentivize their salespeople to sell it.

I am going to get to it in a minute. But they drop off in one doctor's office in

Birmingham, Alabama, through their sales representative for an off-label drug, 16,000 of 25-milligram doses of the drug. Why, it's flabbergasting. It's -- I hate to use the word -- it's nearly insane. And they want to tell you because they put in the label gynecomastia and prolactin increase, and they don't tell any doctor in the label, any doctor who is prescribing it off-label, that the drug is worse than any of the other antipsychotics, has a high incidence of gynecomastia, and that in a document they found in their statistics when they pooled the analysis together a statistically significant association between prolactin increase of kids that are on the drug and gynecomastia.

And as I told you how you are similar to those who have put on the uniform of the country, I am going to tell you where you are dissimilar. All you good folks, all of you know something the FDA still doesn't know: That there is a statistically significant association between kids on Risperdal who have increased prolactin that go on to get

gynecomastia. Imagine that. You are the first to know. And you are going to be the first to respond. You have the first opportunity to respond to that knowledge. It's a pretty awesome and important task, if I must say so, very awesome.

Table 21, what's the fuss. I will tell you the fuss. It was never turned over to the FDA. I stood here, and I am sorry, maybe I was out of line when I stood here and I said, when Ivo Caers said that Table was never sent to the FDA, I said, Wow. Now I can say it legally and legitimately, Wow. They knew they had a statistically significant association of the drug by all scientific standards and they didn't do a thing about it.

And by the way, I am just going to talk mostly today, I am not going to parade you back through the documents. This is the time to talk about it, to talk about what this all means. My word.

And then they go about the task, and you saw it, and I will talk about Dr. David Kessler in a moment, a great American, I am

going to talk about him in a moment. But we spent days, and I will never regret bringing him in here, I will never regret bringing the former Commissioner of the Food and Drug Administration to you and paying for it. And for days and days and days, we went through those books and those studies, because we got into their books, and then I got an expert who could show us what happened. I don't see their former Commissioner of the FDA in the courtroom, one of the biggest pharmaceutical companies in the world. He is here on behalf of Austin.

And what did you see? You saw that they took the data, drafted it five times, found a nauseating amount of gynecomastia, nauseating. As in, I'm nauseated. They have it in Draft one, in Draft two, out of Draft three, told to put it into Draft four or they will be hiding data. They were told that by their own advisors, you will be hiding data, and they take it out.

And this wasn't Moshang and Daneman, the pediatric endocrinology consults, who are

world-qualified and who didn't write that article. You saw who wrote that article, drafted by BrainWorks. Not drafted by Dr. Moshang, drafted by Dr. BrainWorks.

Massaged, manipulated by Janssen, they get rid of Table 21, so they no longer have a statistically significant association.

And by the way, you heard the last witness on behalf of Janssen admit to me that our boy -- she calls him a boy, he is a man -- our young man, he is in SHAP(A). By definition, if you are five to 17 you are a SHAP(A) child. And they took it out and they got to SHAP(B).

And I saw some of you looking when we were going through it, I saw you looking when we were going through all of this math and statistics, and I saw shaking of heads, because it's not complicated once it's explained to you, once you spend days and days and days trying to figure it out. And what we found is that in the second table, Table 20, when they reran the data, reanalyzed it, what did they come up with? They came up with

three times as many. Do you remember, nine versus three, even when you ran the second thing? If you tell me I don't have to put it up I won't, but I think everyone remembers it. Nine versus three? Oh, and it wasn't statistically significant. But then I asked two of their witnesses: That result, even on SHAP(B), even on the five to ten-year olds, why, it is 90 percent certain that the answer is correct, 90 percent certain that it is not by chance.

So in the face of, imagine this, in the face of a finding that increased prolactin levels in kids who take Risperdal, vulnerable, mentally retarded and autistic children who take Risperdal, to a 98 percent certainty, if you have all of the kids, prolactin increase is going to lead to gynecomastia. And if you just take out, if you just take out the kids under ten, it's going to be 90 percent certain. My burden of proof is 50, 50.1.

Now this whole argument about prepubertal gynecomastia, my word. They consulted with, on the one key point, high

level, true pediatric endocrinologists, not this fellow that they dragged up here from Alabama, and what did they tell them? They told them that if you don't report all of it -- there is an E-mail that says it, if I have to drag it out I will -- an E-mail which says that if they don't include all the kids they are hiding data.

Now Ivo Caers confirmed for us Table 21 was never reported to the FDA. And while we were looking at Tables, Austin Pledger's lawyer said, Well, why don't we look behind, who is in the tables. You didn't see anybody else do that. But we know now what's behind the tables: The little girls with the lactating breasts, and the little girls who have amenorrhea, and the little girls who have galactorrhea, and the little boys even under ten who have gynecomastia. My word.

And when Dr. Kessler told us red flag, this isn't "cherrypicking," when a pharmaceutical company acting reasonably and prudently, has this kind of data, they investigate it, they report it, they tell the

FDA, they tell the doctors, they tell the world. They don't just go on selling, selling, selling, selling, selling the drug. And selling the drug.

Oh, and giving it away. In doctor after doctor after doctor's office.

You are going to be given a verdict slip, and here are the questions you are going to need to answer. I am going to display it, His Honor has kindly allowed us to show the verdict slip. If I may.

Question one: Was Janssen negligent by failing to provide an adequate warning to Dr. Mathisen about the risk of gynecomastia to Austin Pledger while taking Risperdal?

Well, of course, they were. Just look at the 2006 label, and honestly, frankly, you can end your discussion. In 2006, folks, 2006, the label changed. Gynecomastia, 2.3 percent. I won't trot out the figures but you know it's higher in the only special attention study, you know it's more like 5 percent. I can go through whether it's 4.6, 3.7, but you know that the one study that they

paid special attention to, you didn't hear Janssen come in here and say that they had some other study.

And by the way, you know that anything that wasn't correct would be challenged, anything that wasn't correct. Anything that, if the comma was missing would be challenged. There is no challenge to that fact. There is no challenge to all of these children who had elevated prolactin levels, when we went underneath the true data and showed that 7-year old boy who profiles out exactly like Austin Pledger. And they say, Oh, you didn't have monitoring of Austin so there wasn't a prolactin level so you can't prove the case. Well, of course, there was no prolactin level. The company didn't tell you to do prolactin levels. They didn't even tell you that the drug was worse than any other antipsychotic, that it had a 2 percent risk of gynecomastia, and a 25 times, 25 times rate of getting increased prolactin, and a statistically significant association of the elevated prolactin with gynecomastia. Not told. Other

than the last point, which was never told in the label on the statistically significant association, all of the rest of that is on the label.

Dr. Mathisen wasn't told. How many times was Mr. Gilbreath, the man, the farmer, how many times was he in Dr. Mathisen's office? Almost twice as many times as Austin Pledger. I think my count was 21 to 11. A salesman for Janssen was there giving out drugs. Every time, every time an opportunity, every time an opportunity to say, Hey, what do we have in the files here? Oh, we have a special attention study, it's showing gynecomastia. Oh, we have known for years, you saw the E-mail, we have known for years that this drug was worse than other drugs in raising prolactin level that are in the same class. Ever told to him? No. Was there ever a Dear Doctor letter sent out? No.

Do you remember what Dr. Kessler told us, the man who ran the FDA. Oh, he ran it 20 years ago; do you think he forgot everything? Twenty years. And do you know what he told

us? The Federal Register tells you a drug company can always warn. He sat in the witness chair and he told you that a drug company has an obligation to warn. And here it's worse. It's with children. It's off-label. It's a powerful drug. It's a schizophrenia drug. It's a chemical alterer. It has a mechanism that they don't even know how it works. They know one thing about it, that it raises prolactin levels, and they never told anybody to monitor.

And the silliness, I mean silliness about when Austin was diagnosed. Well, who cares if a lawyer sent him there or not. The fact of the matter is that he has gynecomastia. Rock in a sock. That's what they say. Oh, until you ask about a rock in a sock, then it's a pancake. Changed from rock in a sock to a pancake, depending on who is examining him. Silly. Silly. He was never diagnosed. They never took his shirt off. They never took his shirt off, why? They never took his shirt off because they didn't suspect anything, they had no reason to know

that this was any worse than any other drug in the class. They didn't know that in any boy's chest the time bomb could be ticking. He could become female, at least in terms of his breasts.

Gynecomastia, Greek and Latin.

So that's our burden of proof, the adequacy of the Warning. The 2006 label answers the question, actually. And we need to prove that they were unreasonable. You will hear that in the Judge's charge. We don't have to prove that they were reckless, they were this, they were that. Our burden is simply would a reasonably prudent person do this, a person being in this case a corporation, would they really do this to boys like Austin? That's the question, that's the question that you have.

They had info on high rates, they knew it, they understood it, they tried to minimize it. That's what went on here. They knew it from 41. Remember 41? 3.75, 5.7, 5.5. RIS-70, their extension study? Their figure, not mine. You get quibbling about it, but

RIS-70, if I have to put it up when I come back, I will, 12.5 percent. When you extended the same kids for a year you picked up another three.

Why, they did their placebo-controlled studies and they said, oh, the placebo-controlled studies don't show anything. Well, that's nonsense, too. Seven of them are eight weeks or less, some are as little as three weeks. They do one study in '79, takes nine months, Bingo. Three gynecomastias show up.

That's the record that you have here. That's the record.

Now the FDA, they wear like a badge of honor that the FDA approved, FDA approved, FDA approved. The fact of the matter is they were turned down in 1979 for kids, they were turned down in 2005. Oh, they will quibble, it was an informal discussion. They were told no. And they needed it, desperately needed the approval. And you saw a document to the FDA which is so damning. 2005, they want to get that approval. They have done all of this

study with minimizing the risk, they don't tell them about Table 21. The FDA says, and you heard Dr. Kessler say this, We need more information. We are still not sold on safety. And you know what they do? They tell the FDA this, this is in the record. I am only arguing from things you heard in this record. I wouldn't dare do anything else.

Janssen back to the FDA: "A review of the safety information did not show a correlation between prolactin levels and adverse events that are potentially attributable to prolactin." "A review of the safety information did not show a correlation between prolactin levels and adverse events that are potentially attributable to prolactin."

The opposite of Table 21. The opposite. That Table shows an association.

And I guarantee that they are going to quibble and they will say a correlation isn't an association, and there is this and there is that. Why, my word, they knew it. They knew it. That's how they got that drug approved.

The drug was approved by Dr. Kessler and his FDA back in 1993 as a powerful antischizophrenic drug. And he came in and gave you a tour de force, if I must say so. He taught us about drugs, about how these drugs are reviewed, Harvard Medical School, FDA Commissioner under two Presidents of the United States of America, a biostatistician, an epidemiologist. He is the man who fast-tracked HIV drugs and saved lives, put labels on our food cans so we get scared away by doughnuts and sugar drinks -- not really, no one is going to scare us away from them -- fought tobacco. The criticism is he gets paid.

The only reason I went through all of that paid stuff with them is to show you. Dr. Alabama and his 30,000-dollar job, coming up here as a substitute. He basically said that he was the "eyes and ears" of another doctor, a doctor by the name of Braunstein, it's in the record in question and answers. Only Braunstein says that there is an association between Risperdal and

gynecomastia. So you saw the hands and the eyes and the ears, not Dr. Braunstein. That's what you got. That's what was admitted there.

Dr. Kessler told you about the FDA warnings, and he told you about the red flags, and he told you how PRAE became SHAP. Isn't it funny how you can take a word like prolactin-related adverse event -- oh, I am sorry, those are just the statisticians running it, our Ivo Caers told us. You can assess that for its truthfulness. The truth of the matter is that they decided they wanted to soft-pedal it: Symptoms hypothetically related. Why, all their data shows that it's a prolactin-adverse event, which it is, a prolactin-related adverse event, if I might say so.

And we dug through their files with Dr. Kessler, dug through their files. Their strategy -- remember these words -- their strategy: Minimize this, maximize that. One E-mail: "We have known for years that Risperdal elevates prolactin more so than any other second generation antipsychotic." 2006.

They have known for years.

2003: "I don't think it's fair to say that clinical significance of hyperprolactinemia is unknown."

In their documents they are debating whether to say it's unknown. Debating about it. Debating about whether to tell the truth.

"If we can demonstrate the transient rise in prolactin does not result in abnormal maturation, this would be most reassuring."

How about a sentence that reads, if we tell the truth maybe we will sell less of the drug. How about that.

And they even considered monitoring in the E-mails. But there was none.

But we all know as to Austin that there is a, depending on what statistic you want to look at, 25 to one chance, up to 87 percent chance that his prolactin level was raised. Why, my word, that 7-year old boy that was in their study, and I picked him out for a reason, yep, cherrypicked him because he was just like Austin, 7.6 years. Started with a normal prolactin, went up, ended up normal.

And then they say, Oh, he had a normal prolactin level when Dr. Paoletti tested him. Well, of course, their expert admits the prolactin level goes up and down. That's not in controversy here.

Oh, he was still on the drug, they tell us. Well, we spent question after question, he was still on the drug, he was just being tapered, yet his prolactin level was normal. What a disingenuous argument.

They know that Austin was just like Little Boy 7.6 years old. To him, that boy in that study was a number. That boy in that study, like Austin Pledger, who profiles out just like Austin Pledger, has a name, an address, and a Benita Pledger.

Then there was statistical plans. Remember those statistical plans? We have one plan and another plan. Oh, Mr. Kline, we don't have a plan, until I show them there is an E-mail with the word "plan" in it. Or "protocol" in it. Of course, they had a plan. They ran the statistics, they didn't like the result, they changed the game. I said three

or four times during this case, Did you ever go to high school chemistry? You start the experiment, you live with the results. How dare they call it "exploratory data".

And it takes -- I am not the most patient guy in the world, I admit it, it takes extraordinary patience to sit here and be told it's exploratory data. There is no such thing. He never used that word before, Ivo Caers never used the word, he told us that, he admitted that to me.

Yes, everyone, I had to stand here. Yes, I had to point my finger. Sorry. I wanted to get to the bottom of it. And, yes, he told us, finally, that Table 21 was never submitted to the FDA and the other things that he told us.

That's what we have learned. While these charts, my word, Table 7-8 from RIS-41, I displayed it to you, time after time after time, their trained investigators, with children under ten, and children over ten, show that increased risk. And their own documents: It's definitely related,

prolactin-related, definitely related to gynecomastia.

And then there was a moment in this trial, a moment in this trial, which at least I thought was chilling. The question was asked of the former Commissioner of the FDA, Sir, that statistically significant finding that was in that pooled analysis, at best, that's a misleading statement?

Former Commissioner of the FDA: At best, at best, it's misleading.

I didn't hear any cross examination on that and I didn't hear any refutation of that.

Dr. Mathisen. I have to prove to you the second question. That's the first question, Did they warn? Did Dr. Mathisen know the real facts, the real truth? Assume, assume that he knew that gynecomastia was associated with second generation antipsychotics, assume that he knew that prolactin increased. Because every doctor knew. But did every doctor know it was 5 percent? Did every doctor know that it was 87 percent likely you are going to get a

prolactin level raised? Did every doctor know that statistically significant association or a 90 percent association statistically, and that they have known for years? No.

21 chances to tell him in a doctor's office, 21 chances for the Janssen Pharmaceutical Company to give Mr. Gilbreath information to tell Dr. Mathisen.

Here is the second question in the case. Dr. Mathisen is what's called the learned intermediary. The choice is made by the doctor to inform the patient, and in this case what happened -- and it's a very important part of the case -- in this case what happened is, of course, they are in a child neurologist's office, a child neurologist's office. You've got to literally -- I am going to use figuratively so I don't get in trouble -- you figuratively have to fall over children's furniture to get in to see Dr. Mathisen. What did this child neurologist know? Well, you heard Dr. Robb come in here and say when you are doing it off-label you go by the adult label. You know

what the adult label said. Do you remember what the adult label said? Rare. Less than one in a thousand, which, as you know, she admitted to me, if the real risk is 2.3 percent or 5.5 percent, whichever it was, the risk was understated by either 23 or 55 times. 23 to 55 times the risk really was, compared to what they said in that adult label.

And Dr. Mathisen was asked, here are the questions: "Assuming the evidence will show that there was a study that showed 4.8 percent gynecomastia in children and adults, how would that have affected your prescribing patterns?

And he said, "We would have discussed that with the patient."

"Well, 2.3 in a hundred, sir, compared to less than one in a thousand is what times?" Me to him.

"Twenty-three times.

"Q And assuming, sir, you were told, what would you have done?"

And his answer essentially was, I would

have had a discussion with the patient.

And what does Mom say? Mom says the obvious: If you knew this, would you have allowed your son to be on the drug? She is the one with the autistic boy, folks, she is the one who has to manage him, she is the one who sees him with the towel wrapped around his body to make him happy that his breasts are covered up. If you knew it, would you have allowed your son to be on this drug? No.

And I asked her what I thought was a tough question, just like I try to ask everybody: Can you tell us absolutely and categorially, Benita Pledger, can you tell us, absolutely and categorially, I asked.

Absolutely not.

That's a mom talking. If her doctor knew. And your Question No. 2: Do you find that Janssen's negligent failure to provide an adequate warning was a cause of Austin Pledger's gynecomastia?

Of course. Gilbreath didn't tell them, the label didn't tell them the real risk. He didn't have an opportunity to tell the mom.

And where they rest their case, trust me, is everybody knew about gynecomastia and everybody knew about prolactin, and nobody knew all the rest. Nobody knew all the rest. Nobody. Except the insiders. The Dr. Robbs of the world. Good doctor doing good things at the Children's National Hospital, that's not what's at issue. What's at issue is that she knew. She had the books.

Dr. Robb, did you know? Did you know, ma'am? Did you know?

Yes, I knew.

How did you know?

Well, I was involved in the studies.

Oh, wow, you were involved in the studies, really?

Yeah.

Well, how did a doctor in Birmingham, Alabama know that it was 5 percent in the special attention study? How did he know? How did he know? He didn't know. He didn't know.

What he knew was that he was getting 16,000 samples of the drug. 16,000 samples of

the drug dropped off to one doctor's office. I am going to go further than I went before, it's crazy. Astounding. Sickening. How dare them. And not one warning. Not one warning. Not one, We are doing a special attention study. Not, We have developing evidence. Not, We better be careful. No doctor letter, Dear Doctor: We have developing evidence. They didn't need FDA approval to do that. Nothing.

Why, in 1997, they knew things. That Dr. Robb in 1997 was treating children, not in a study. I put it up on the board. It was staggering. She had little girls who had prolactin-related events. She was just treating them off-label, like an experiment. Holy moly. Like what's that all about? She knew back in '97 that she had it.

And then they do post-pharmacovigilance. And they come in here, and they have Dr. Coppola, she has been here the whole trial, and the one thing they don't ask her, the one thing they don't ask her is how about PRRs. It was late in the

day, it is tiring, it is exhausting, it is frustrating. I have to count to ten. My mom told me to do that. I still do it. Sometimes to 20. She was a good lady. Good lady.

And Dr. Robb, the pharmacovigilance, the PRR -- lost my train of thought -- the PRR, why it's staggeringly high. When you compare -- this is a little confusing but it's pretty easy when you get it -- when you compare the number of adverse events in one category like gynecomastia to the total adverse events, in one age group and compared it to all the others, why, it was four and five to one. Kids were getting gynecomastia. And she quibbled about it but it's a safety signal.

And that was back in the mid-2000s, and they did nothing there, even though they had the clinical studies, they had all of this information.

And what were we asking them to do, by the way? Were we asking them to pull the drug off the market? No. The case is about the failure to warn. The failure to warn. That's

what the case is about.

Oh, and about the failure to warn, it's just staggering. Why, remember they had in 2004, things got a little dicey, and they were told you have got to qualify the doctor to make absolutely sure that he qualifies, that you are no longer going in and -- sorry for using this word -- hustling the drug to children's doctors, getting incentivized for it. So they had a qualifying doctor program. And Mr. Gilbreath disappeared. 10-18-04 to 10-30-06, bye-bye, no samples, not coming, not allowed.

Then they show back up, remember, there is a new label? New label. And the leave-behind. We were here late in the day then, too. A leave-behind. Hyperprolactinemia, they bring the label to Dr. Mathisen in 2006. They bring the label to him. Oh, congratulations, Janssen, for bringing him the label. And they bring the summary, one page, two pages, new indication. You know what it says?

"As with other drugs that antagonize

dopamine, Risperdal elevates prolactin levels and the elevation persists."

Even then, the leave-behind doesn't tell the truth. And you know why? Because that is what they are told to do, and what they are told to do is to tell the exact opposite information, the old information. That's what they were actually told to do. I did a call-out for it. They were told to tell the doctors the clinical symptoms related to hyperprolactinemia occurred infrequently. In 2006, their sales reps were told by Janssen to tell the doctors that. My word.

Cause and effect: Dr. Solomon. They don't want to talk about the facts of the case like I have talked about with you. They want to talk about, Oh, the penis enlargement doctor. Oh, yeah. He is a plastic surgeon, oh, yeah, we can all giggle. This ain't the day to giggle. Pardon me, giggling is over. Yes, he does that procedure, and he does breast enhancement, breast reductions and, my word, he has on his website about gynecomastia. And, oh, yes, he was expensive,

and oh, yes, I thought he was important to bring in here, somebody who actually knows the breast. And I don't apologize for doing it, for bringing in a real doctor who reconstructs breasts, who knows breast tissue, who showed you the pathology of the breast under a microscope, who talked about the breast, and who did everything that you would want to know about the breast, and told you the logical conclusion, that this boy had gynecomastia, he had true gynecomastia, he lost weight, there is some tissue hanging there, connective tissue, adipose tissue, might have some fat in it, of course.

How about that other opinion you heard yesterday, how about that. A guy who doesn't take a note about pseudogynecomastia comes in here and tries to tell you there is 5 centimeters of pseudogynecomastia, a fellow that is here to say and argue everything down to the last point.

I like to test people, I admit it. And so I asked him the question at the end. I went real low, real low, and I said, Doctor,

Table 21, that's something that you as a doctor would want to know, want to have submitted to the FDA? Oh, no. Oh, no. Oh, no. God forbid, the FDA should know the true facts. That would be bad.

Dr. Solomon told you the obvious. You have a boy who came out of a pool, you have a picture of him with the breasts. Today you feel the breasts, they have true gynecomastia. He connects three dots, three dots, like a straight line, dot, dot, dot. Started with nipple enlargement -- this doctor yesterday didn't even admit that he heard about nipple enlargement -- started with nipple enlargement, Mom tells us, why, by the time he is 11 or 12 he has fully formed women's breasts. And by the end you see what happened, he had full breasts. Yes, some from his weight gain in 2012, very full, pendulous women's breasts, and today, after losing some weight, has the rock in the sock. Size 46 double D breasts. And you are asked to use your common sense. I guess they developed in puberty. Tell me anybody in your life that

has size 46 double D women's breasts, any boy that you know who has size 46 double D women's breasts that he got from puberty.

How about a different obvious answer. How about a different answer.

Now, I have a lot more but I want to talk about Mom, I want to talk about her boy. Mom, I hope I did okay. I am not a corporate lawyer, but I think Mom has a right to be proud. I just do. I think moms have a right to be proud. And God only knows she loves that boy. Yeah, I just met her, I just met her when this trial started. I am a courtroom lawyer, I confess, 37 years here, City Hall, William Penn, him and me, I guess, and the Judge has been around a long time. I have never seen a mom like her. Why, that little boy, that man, she and her husband, they love him, they care for him, they respect him. They respect him. They protect him. They don't parade unnecessary photos of him showing him fat. I have heard that called bullying.

She stuck with this. Her husband didn't -- she was scared that her husband

would find out that she went to a lawyer. The lawyer led her to a doctor, the doctor led her to a diagnosis, the diagnosis led her to a courtroom, and here we are. Blame her for bringing her boy's case.

She noticed the breasts, she wouldn't think anything was wrong, she wasn't told anything was wrong. Unlike any other mother, at least that I have ever heard of, she called Janssen. Holy cow, what a great mom. She called the company. Do you remember the question? I remember the question. Do you remember the question? The Question: What are the dangers of the drug?

What is the failure to warn? A failure to warn is not telling someone something about a danger. Even she called and asked them.

When Dr. Mathisen called and asked, did he get back RIS-41? No. Did he get back the interim results? No. The final results? No. The topline reports? No. The pooled analysis? No. Table 21? No. You know what he got back? A bunch of studies showing how great the drug was in treating autism. That's

what he got back.

So she gets a diagnosis. Now here is her Austin. Here is her Austin, P-39. There is Austin. Phillip, after his dad, Austin Pledger. Age 20. You are not going to know he has female breasts in that photo, because his mom protects him. He knows it when he takes a shower. He grew a beard. Do you know why he grew a beard? To be like a man. To be like a man. Do you know what his alternative is? Disfiguring, scarring surgery. Rock and a hard place. Unfair. Wrong. Really wrong.

Well, you are about to hear an hour and a half of this, that, and the other thing. It's wrong. We could all stand up and say one word and be right: Wrong.

Why, this young man shouldn't have that condition. He has enough problems.

He recognizes you, you heard the testimony, (clapping hands) Hi, Mr. Tom. But yet he knows. He smashed the breasts on the table, he covers them up when he can, he knows that they are there, and he can't even speak for himself, caused by a powerful

antipsychotic drug not even for children. And Dr. Mathisen didn't manufacture the drug, and Mrs. Pledger didn't manufacture the drug.

Here are the elements of damages, third question: Did they negligently fail to warn? Yes. Was the failure to warn a cause? Yes. And I am asking you for monetary damages. I can't suggest a figure, not the rules. I wouldn't want you to listen to me anyway. You know what's going on in this courtroom, you have all watched it. It's really important to compensate Austin Pledger, it's really important, really important to give him a real award that compensates him for what they did to him. They knew and they didn't do the right thing, and now look at him. Now look at him. Behind that beautiful smile -- I debated but I am going to do it -- behind that beautiful smile is the remnants of this horrible drug. All they had to do was tell the truth, the full truth, and nothing but the truth. Like when you put your hand on the Bible. It's so sad and so unfair, so tragic, when all they had to do was the right thing.

I have used up barely my hour, and I am going to have another half to talk to you at the end. This is my time to ask you to do right in this case.

You are going to hear a lot coming up. You are going to hear a lot of stuff about a lot of stuff about a lot of stuff. You keep track of the number of times that they are not talking about the things I am talking about, all the times that you hear about Mr. Kline, all the times that you hear about the Plaintiff's lawyers, and all the times that you hear about the first time it was ever diagnosed, that you hear about the time when he was obese, he gained all that weight, and that weight was pseudogynecomastia, and you hear about all of those things.

My word, he had breast buds, they developed into women's breasts, they are there today, their own doctor admits it. The only thing he changed his opinion on was the diameter. The only thing he changed was the diameter on us, the volume of the diameter, I should say.

So please, please, please, recognize that it's really, really, really important in this case for Austin, through Benita, and I have just been the person who has had the good grace to be the one to argue to you. Thank you.

THE COURT: All right, thank you, Mr. Kline. We will have a recess here for about ten minutes, and then we will hear from Ms. Sullivan.

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

THE COURT: Before we adjourn and take a recess, I would like to know if there is there are any objections.

MS. SULLIVAN: Yes, Your Honor, there were a couple. One, not a punitive damage case.

THE COURT: Actually, what is that?

MS. SULLIVAN: This is not a punitive damage case, as the Court made clear, and there was over-the-top inflammatory language: Insane, crazy, flabbergasted.

Also, he talked about the mother and

our obligation to warn the mother when she called Janssen. Clearly, not the law, improper, and I would ask for an instruction on that point.

THE COURT: All right, anything else?

MS. SULLIVAN: No, Your Honor.

THE COURT: All right, I do not find that the language used was over the top. It doesn't matter whether it's punitive or not, he is discussing the negligent conduct. I don't find that's prejudicial in the sense of being over the top requiring a cautionary.

Regarding the other issue, as far as I'm concerned, I will be instructing the jury as to learned intermediary rule at the end and this is not the time to issue any cautionary instructions, given the fact that the jury has been advised that I will be giving the law and not Mr. Kline and not you.

All right, so we will take a recess for about ten minutes.

(A brief recess is taken and the following transpired in open court:)

MR. MURPHY: If I may, Your Honor,

before the jury comes in, there were comments made by Mr. Kline in his closing related to other children, other injuries sustained by other children which were inappropriate, that were contrary to certain in limine rulings the Court made. We would ask the jury be instructed appropriately not to consider other children and other injuries as they are not an issue in this litigation.

THE COURT: We will alert the jury to that when I give them the general instructions.

MR. MURPHY: Those comments, Your Honor, are also consistent with certain running commentary that this Court has heard during the course of this trial. They are inappropriate, also outside the bounds of in limine rulings that were made; and on that basis, we have filed a motion for mistrial early this morning.

THE COURT: That's the first I heard of a mistrial motion early this morning.

MR. MURPHY: It was filed earlier today, Your Honor.

THE COURT: Normally, it's done in open court.

MS. SULLIVAN: Your Honor, there is a collection of the running commentary from beginning to the end of the trial to outline the prejudice.

THE COURT: I can't respond to it because I haven't seen it. Don't let me forget about it before jury instructions. All right, ready?

Are you telling me that you filed downstairs a written mistrial motion, Mr. Murphy?

MR. MURPHY: Your Honor, I believe it has been filed, yes.

THE COURT: Normally, you would have the courtesy of serving those to the other party and to this Court. We will look at them over lunch.

MR. MURPHY: Fair enough.

MR. KLINE: For the record --

THE COURT: Have you been served with those?

MR. KLINE: No, I haven't seen it.