

**In The Matter Of:**

*Pledger v.*

*Janssen*

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*(Jury Trial-Morning Session)*

*XIII*

*February 11, 2015*

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*John J. Kurz, RMR-CRR, Official Court Reporter*

*City of Philadelphia*

*First Judicial District Of Pennsylvania*

*100 South Broad Street, 2nd Floor*

*Philadelphia, PA 19110*

(Jury Trial-Morning Session)XIII - February 11, 2015  
Pledger v. Janssen

1 IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY  
2 FIRST JUDICIAL DISTRICT OF PENNSYLVANIA  
3 CIVIL TRIAL DIVISION  
4 -----  
5 IN RE: RISPERDAL® LITIGATION :  
6 March Term, 2010, No. 296 :  
7 Phillip Pledger, et al., :  
8 Plaintiffs, : APRIL TERM, 2012  
9 v. : NO. 01997  
10 Janssen Pharmaceuticals, Inc., :  
11 Johnson & Johnson Company, :  
12 and Janssen Pharmaceutical :  
13 Research and Development, :  
14 L.L.C. :  
15 Defendants. :  
16 -----  
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13 Marianne Mari, Tipstaff  
14 Cory Smith, Video Technician  
15 Ken Reed, Video Technician  
16 Thomas F. Campion, Esquire  
17 Benita Pledger

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1 - I N D E X -  
2 WITNESSES CROSS REDIRECT  
3 IVO CAERS, Ph.D. (Continued)  
4 By Ms. Sullivan -- --  
5 By Mr. Kline 13 --  
6  
7  
8 E X H I B I T S  
9 NO. PAGE NO.  
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11 P-88A Estimated exposure, risperidone 32  
12 P-89 Handwritten chart on easel 35  
13 P-90 Approvals 42  
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1 (The following transpired in open  
 2 court outside the presence of the jury, at  
 3 9:58 a.m.):  
 4 - - -  
 5 **COURT CRIER:** All rise.  
 6 **THE COURT:** All right. Please be  
 7 seated, everybody.  
 8 **MR. MURPHY:** Good morning, Your  
 9 Honor.  
 10 **MR. KLINE:** Good morning.  
 11 **THE COURT:** Good morning.  
 12 Ms. Brown, you know, I've been  
 13 thinking about you for a while. Were you  
 14 ever in Family Court?  
 15 **MS. BROWN:** Yes.  
 16 **THE COURT:** In front of me, by any  
 17 chance?  
 18 **MS. BROWN:** I volunteer for the  
 19 Support Center for Child Advocates.  
 20 **THE COURT:** Yeah. Were you in front  
 21 of me, though?  
 22 **MS. BROWN:** I think it's possible.  
 23 It's been a couple years.  
 24 **THE COURT:** I think so. Yeah. I've  
 25 been trying to figure this out.

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1 **THE COURT:** I think I know this; the  
 2 answer to this.  
 3 But is there any response?  
 4 **MR. KLINE:** I believe I'm entitled to  
 5 do it, Your Honor.  
 6 **THE COURT:** Okay. Well, in the  
 7 exercise of caution in this matter, we are  
 8 not going to be referring to specific  
 9 monetary figures as to compensation. I think  
 10 the point has been made.  
 11 **MS. BROWN:** Your Honor, should we  
 12 hand up case law?  
 13 **THE COURT:** No. Your motion is  
 14 granted.  
 15 **MS. BROWN:** Thank you, Your Honor.  
 16 **THE COURT:** I mean, the existence of  
 17 stock options, that's fair game. The  
 18 existence of compensation, that's fair game.  
 19 It's just the amounts that are not permitted.  
 20 Am I right?  
 21 **MS. BROWN:** I think that's right.  
 22 Though, as to stock options, they  
 23 certainly moved in limine to exclude any  
 24 reference to their own witnesses' stock  
 25 options in our company or to their experts.

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1 **MS. BROWN:** That's so funny. Yeah,  
 2 of course.  
 3 **THE COURT:** Over at 1801.  
 4 **MS. BROWN:** Yes.  
 5 **THE COURT:** Courtroom E, probably.  
 6 **MS. BROWN:** Yeah. Sure. Go way  
 7 back.  
 8 **THE COURT:** That's a way back, right.  
 9 From here to there.  
 10 Okay. Are there any issues at the  
 11 moment that need to be addressed?  
 12 **MR. KLINE:** Just --  
 13 **MS. BROWN:** Yes, Your Honor.  
 14 We would object to any questioning of  
 15 Dr. Caers regarding compensation or stock  
 16 options. The law is very well settled that  
 17 for a fact witness who is an employee, any  
 18 inquiry into bias, it's sufficient to  
 19 question that you work for the company, and  
 20 anything beyond that is entirely  
 21 inappropriate and serves no purpose; and we  
 22 would object to that.  
 23 **THE COURT:** Any response?  
 24 **MS. BROWN:** And, Your Honor, we have  
 25 some case law.

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1 **THE COURT:** Well, let me see that. I  
 2 don't remember that.  
 3 **MS. BROWN:** I have it, Your Honor,  
 4 I'll hand it up.  
 5 **MR. KLINE:** I don't remember...  
 6 **MS. BROWN:** And I believe that, Your  
 7 Honor, we agreed to that. I don't even think  
 8 that came before you on argument.  
 9 **MR. KLINE:** What does the Judge have  
 10 in front of him? May I have a copy of  
 11 whatever was handed up?  
 12 **MS. BROWN:** Sure.  
 13 **THE COURT:** This is apparently  
 14 Plaintiff's Motion in Limine No. 10, Control  
 15 No. 14062633.  
 16 **MR. KLINE:** Yes. That was a totally  
 17 different issue with an expert witness, not  
 18 with a fact witness who comes from a company.  
 19 And it has to do with the level of  
 20 inquiry to an expert witness, not to a fact  
 21 witness.  
 22 (Pause.)  
 23 **THE COURT:** I don't see -- I'm  
 24 reading this now. There was a motion that  
 25 had been granted which included the

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1 following: This is a Plaintiff's Motion in  
 2 Limine, Paragraph 5: Any comment, inference,  
 3 testimony, or evidence about current or  
 4 former ownership interest by plaintiff's  
 5 counsel, their experts, plaintiffs, or their  
 6 family in the defendant's..., such argument  
 7 is irrelevant, unfairly prejudicial, and  
 8 calculated to mislead and confuse the jury.  
 9 Now, to the extent that so far we've  
 10 had a plaintiff testify and their experts,  
 11 this particular issue was not permitted. I  
 12 don't know whether there was anything  
 13 involving the experts or Mrs. Pledger  
 14 regarding ownership of Johnson & Johnson  
 15 stock.  
 16 Is that what we were talking about?  
 17 **MS. BROWN:** Yes, Your Honor.  
 18 I mean, Your Honor, our position is  
 19 that the inquiry for this witness on bias is  
 20 simply: Are you a full-time current employee  
 21 of --  
 22 **THE COURT:** No. I think stock  
 23 options really does have something to do with  
 24 it, because that's a direct -- theoretically,  
 25 anyway. I don't believe that in our modern

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1 economy that -- even this case is going to  
 2 have more than one or two cents difference on  
 3 the stock market.  
 4 But, theoretically, yes, there's a  
 5 potential impact in his testimony in trying  
 6 to save a company from a judgment, I mean,  
 7 theoretically.  
 8 **MS. BROWN:** Well, Your Honor, they  
 9 made no showing that his compensation is in  
 10 any way tied --  
 11 **THE COURT:** Well, that's part of the  
 12 bias, general credibility factors, that any  
 13 jury would be permitted to consider.  
 14 So I am going to permit the stock  
 15 options and other kind of packages to be  
 16 known to the jury. I think it's certainly  
 17 within factual domain.  
 18 The actual amounts of money involved,  
 19 I think I sustained an objection yesterday  
 20 based on that.  
 21 **MS. BROWN:** Yes, Your Honor.  
 22 **THE COURT:** Such as the attorney's --  
 23 the witness's income. He was saying Belgium  
 24 law. But I don't think that the amount of  
 25 money involved is necessary to make this

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1 point.  
 2 **MS. BROWN:** Thank you, Your Honor.  
 3 **THE COURT:** Anything else?  
 4 **MS. SULLIVAN:** Your Honor, just  
 5 briefly, one point in terms of the  
 6 cross-examination.  
 7 Mr. Kline is right on top of the  
 8 witness, and I would just ask that he has a  
 9 respectful distance.  
 10 **THE COURT:** All right. I was  
 11 wondering about that myself.  
 12 I think, Mr. Kline, if you could  
 13 either from your chair or from behind the --  
 14 **MR. KLINE:** I'll stand right there.  
 15 **THE COURT:** From right there, yeah.  
 16 Anything behind the bar would be preferable.  
 17 **MS. SULLIVAN:** Thank you, Your Honor.  
 18 **MR. KLINE:** Yes.  
 19 **THE COURT:** Thank you.  
 20 All right. Anything else?  
 21 (No response.)  
 22 **THE COURT:** Okay.  
 23 **MR. KLINE:** Your Honor, it's my --  
 24 it's my understanding there are no other live  
 25 witnesses today; that they have videotape

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1 after him.  
 2 **THE COURT:** Okay.  
 3 **MR. KLINE:** So --  
 4 **THE COURT:** That's fine.  
 5 **MR. KLINE:** -- we're not at any time  
 6 crunch.  
 7 **THE COURT:** We will adjourn, just so  
 8 you know, around 12:15 today till about  
 9 quarter of 2:00 anyway. I have a doctor's  
 10 appointment.  
 11 **MR. KLINE:** Okay.  
 12 (Witness took the stand.)  
 13 **THE COURT:** Good morning.  
 14 **COURT CRIER:** All rise as the jury  
 15 enters.  
 16 - - -  
 17 (Whereupon the jury entered the  
 18 courtroom at 10:08 a.m.)  
 19 - - -  
 20 (The following transpired in open  
 21 court in the presence of the jury:)  
 22 - - -  
 23 **THE COURT:** Please be seated,  
 24 everybody. Good morning.  
 25 Good morning, everybody.

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1 **JURY PANEL:** Good morning.  
 2 **THE COURT:** All right. Then,  
 3 Mr. Kline, you're permitted to continue now  
 4 your cross-examination of this witness.  
 5 **MR. KLINE:** Your Honor, thank you.  
 6 Good morning.  
 7 Members of the jury, we all want to  
 8 see what kind of mood you're in and so we  
 9 always say "good morning" and see what  
 10 reaction we get.  
 11 **JURY PANEL:** Good morning.  
 12 **MR. KLINE:** Good morning. Nice to  
 13 see you all. Thank you for coming.  
 14 - - -  
 15 **CROSS-EXAMINATION (Continued)**  
 16 - - -  
 17 **BY MR. KLINE:**  
 18 **Q. And good morning, Dr. Caers.**  
 19 A. Good morning.  
 20 **Q. I'd like to continue your discussion with an**  
 21 **aim towards confirming certain things and seeing if**  
 22 **we can agree on certain things.**  
 23 **Many of my questions will simply be**  
 24 **to confirm information.**  
 25 **A couple of background questions.**

- IVO CAERS, Ph.D. - CROSS - Page 15

1 A. Yeah.  
 2 **Q. Is that correct?**  
 3 A. Yes.  
 4 **Q. Okay. And you had a number of people on your**  
 5 **team, sir, and that would have included a woman**  
 6 **whose name is Carin Binder; would that be correct?**  
 7 A. No.  
 8 **Q. Okay. She was the Director of Medical**  
 9 **Affairs?**  
 10 A. She was -- I'm not sure whether she was  
 11 Director of Medical Affairs, but she was in Medical  
 12 Affairs with Janssen Canada.  
 13 **Q. Janssen Canada, okay.**  
 14 **So that's yet another corporation, to**  
 15 **your understanding?**  
 16 A. I guess so.  
 17 **Q. So there are many different Janssen**  
 18 **corporations worldwide; is that correct?**  
 19 A. There's usually one Janssen commercial  
 20 organization per country. But Janssen R & D is  
 21 obviously not one single country-based organization.  
 22 But legally, I'm an employee of Janssen  
 23 Pharmaceutica, N.V., in Beerse, Belgium.  
 24 **Q. And how much of your time do you actually**  
 25 **spend in Belgium, sir?**

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1 **In the organizational chart at**  
 2 **Janssen and Johnson & Johnson -- first of all, you**  
 3 **are an employee of -- what exact corporation are you**  
 4 **an employee of?**  
 5 A. I'm legally an employee of Janssen  
 6 Pharmaceutica, N.V., which is a Belgium company,  
 7 according to Belgium law.  
 8 **Q. And in your daily business, do you have**  
 9 **interactions with Johnson & Johnson employees?**  
 10 A. With Janssen employees.  
 11 **Q. Janssen employees?**  
 12 A. Yes.  
 13 **Q. Okay. And do you have daily interaction with**  
 14 **Janssen USA employees?**  
 15 A. Yes.  
 16 **Q. And what do you --**  
 17 A. Well, with Janssen R & D US employees.  
 18 **Q. Okay. And let me try to be specific.**  
 19 **Janssen R & D, meaning Research and**  
 20 **Development?**  
 21 A. That is correct.  
 22 **Q. Is there a comma there, to the company?**  
 23 **Janssen R & D...**  
 24 A. LLC or something, whatever that means, yeah.  
 25 **Q. Whatever corporate designation is behind it?**

- IVO CAERS, Ph.D. - CROSS - Page 16

1 A. Oh, my office is in Belgium. I spend 75 --  
 2 75 percent of my time, my working time in Belgium,  
 3 and 25 percent traveling mostly to the US.  
 4 **Q. And as to Risperdal, sir, when you were**  
 5 **working in the period -- and I'm being very**  
 6 **specific -- 2002 through 2006.**  
 7 A. Uh-huh.  
 8 **Q. In fact, let's go 2000 to 2006. You would**  
 9 **have been working primarily in Belgium 75 percent of**  
 10 **the time?**  
 11 A. Ummm, perhaps a little bit less. It was -- it  
 12 might have been -- well, no, 70/30 percent, that  
 13 might have been it, but --  
 14 **Q. Okay.**  
 15 A. Yeah.  
 16 **Q. And you were the -- as I heard you yesterday,**  
 17 **as to, for example, all manuscripts, you said the --**  
 18 **we have a saying from a famous president, "The buck**  
 19 **stops here." That would have been you, correct?**  
 20 A. I'm not familiar with that expression, so...  
 21 **Q. Okay. I understand. Understand.**  
 22 **It was Harry Truman, by the way.**  
 23 A. That's...  
 24 **Q. Okay. But you were the one who was ultimately**  
 25 **responsible; is that correct?**

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1 A. Well, there were a few key people who needed  
 2 to review final manuscripts before they were  
 3 submitted for journals; and I was one of them. The  
 4 clinical leader is another one of them. The patent  
 5 lawyer is another one. So they are the last people  
 6 who review and approve manuscripts before they are  
 7 submitted, for example, to journals.  
 8 **Q. Do you remember the question?**  
 9 A. That's an answer to the question.  
 10 **Q. Do you remember it?**  
 11 A. Yeah. Who was reviewing -- whether I'm  
 12 reviewing manuscripts, yeah. I answered.  
 13 **Q. The clinical leader, sir, the clinical leader**  
 14 **at the time of the last draft of the pooled analysis**  
 15 **study, who was the clinical leader?**  
 16 A. I would need to check. I don't know. There  
 17 have been several, so I have to check.  
 18 **Q. Don't know; is that your answer?**  
 19 A. I don't know for sure.  
 20 **Q. And who else would have to --**  
 21 **MS. SULLIVAN:** Your Honor, I'm sorry.  
 22 **BY MR. KLINE:**  
 23 **Q. Who else would have to --**  
 24 **MS. SULLIVAN:** I'm sorry. I hate to  
 25 interrupt, but I'm raising the issue, Your

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1 Honor, about the positioning of counsel that  
 2 the Court had noted.  
 3 **THE COURT:** All right. He's just --  
 4 not much further than where we are. Everyone  
 5 needs, Mr. Kline, some space. Yeah. Thank  
 6 you.  
 7 Go ahead.  
 8 **MR. KLINE:** Okay.  
 9 **BY MR. KLINE:**  
 10 **Q. Yes, sir, the next question. The next**  
 11 **question.**  
 12 A. Yeah. I'm -- I'm with you.  
 13 **Q. Okay. Who is the other person who you**  
 14 **mentioned? What was that designation? Besides the**  
 15 **clinical leader.**  
 16 A. The patent lawyer.  
 17 **Q. I'm sorry?**  
 18 A. The patent. Patent.  
 19 **Q. Oh, the patent lawyer. Oh, okay.**  
 20 A. Yeah.  
 21 **Q. So in addition to whenever an article would be**  
 22 **signed off on, it would be signed off on by you, the**  
 23 **clinical leader, and the lawyer; is that correct?**  
 24 A. Yes. But the mandate of the lawyer is to make  
 25 sure whether in new findings there's no potential

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1 patentability data that might be of value to the  
 2 company as long as it's not brought in the public  
 3 domain.  
 4 **Q. Three people sign off? Just so I get the --**  
 5 A. No. There are the --  
 6 **Q. Just so I get the people.**  
 7 **Now that you had an opportunity to**  
 8 **explain, may I get the three people on the record?**  
 9 **You, the clinical officer, and the**  
 10 **lawyer; do I have it right?**  
 11 A. The clinical leader, yes.  
 12 **Q. Thank you, sir. That's what I needed to know.**  
 13 **Now, I'd like to know -- there are**  
 14 **e-mails that I've seen where you actually correspond**  
 15 **directly with the CEO of Janssen at the time. His**  
 16 **name was Gorski. Do you know that man?**  
 17 A. Yes.  
 18 **Q. And how many rungs on the ladder were there**  
 19 **between you and Mr. Gorski, the CEO of the company?**  
 20 **One or two or three?**  
 21 A. Now or in 2002?  
 22 **Q. Let's take it both. Now.**  
 23 A. Now, there are one -- I think there were four  
 24 people between Mr. Gorski and myself.  
 25 **Q. And then?**

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1 A. Well, at that time I did not report to  
 2 Mr. Gorski because at the time he was marketing and  
 3 sales, up to present, of Janssen US; and I've never  
 4 reported to Janssen US. I reported within Janssen  
 5 R & D.  
 6 **Q. Well, let's take Janssen -- let's take the**  
 7 **company that you're in. Who is your immediate boss?**  
 8 A. My immediate boss is Wayne Drevets. And he is  
 9 based -- he is in Janssen R & D US, and he is based  
 10 here in Titusville, about an hour driving from here.  
 11 **Q. And so you report to a boss who is in Janssen**  
 12 **USA, correct?**  
 13 A. He is in Janssen R & D US, yes.  
 14 **Q. Okay. And I just want to find out, where does**  
 15 **he report?**  
 16 A. He report to his boss.  
 17 **Q. And who's his boss?**  
 18 A. Husseini Manji. And he is head of  
 19 neuroscience within Janssen R & D US.  
 20 **Q. And is he one rung down from the head of**  
 21 **Janssen US?**  
 22 A. No. He is not within Janssen US. He's in  
 23 Janssen R & D US. So Janssen US is, as far as I  
 24 know, a separate company.  
 25 **Q. Okay. And in 2000 and -- between 2000 and**

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1 **2006, sir, how much of your time -- how much of your**  
 2 **professional time at Janssen did you devote to**  
 3 **Risperdal?**  
 4 A. Up to 2006, about -- about all.  
 5 **Q. About all of your time?**  
 6 A. Yes.  
 7 **Q. Okay. All of your time, of which 75 percent**  
 8 **was spent in Belgium; do I have it right?**  
 9 A. Yes.  
 10 **Q. And as to this product, as to the issues**  
 11 **relating to the autism labeling, your role was you**  
 12 **were -- were you in charge of that group?**  
 13 A. Yes; because the compound development team is  
 14 in charge of labels everywhere, not only in the US,  
 15 obviously; everywhere.  
 16 **Q. Yes. That's what I'm trying to figure out.**  
 17 A. Uh-huh.  
 18 **Q. So -- so --**  
 19 A. I'm talking to the jury, okay?  
 20 **Q. Oh. Were you -- were you schooled to do that,**  
 21 **sir?**  
 22 A. No, no, no. I'm just --  
 23 **Q. Did you rehearse?**  
 24 A. Why don't you go like that (indicating).  
 25 **Q. I'm trying to have a discussion with you.**

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1 A. I'm answering your questions.  
 2 **Q. I see.**  
 3 **Would you prefer not to look here?**  
 4 A. I -- do I need to look at you?  
 5 **Q. No. I'm a plaintiff's lawyer, sir. You**  
 6 **wouldn't want to look at me.**  
 7 A. Oh, that doesn't matter.  
 8 **Q. Do you have different customs about when you**  
 9 **talk to people?**  
 10 **MS. SULLIVAN:** Objection, Your Honor.  
 11 **THE WITNESS:** I don't understand that  
 12 question.  
 13 **THE COURT:** Well, I mean --  
 14 **MR. KLINE:** I'll withdraw the  
 15 question.  
 16 **THE COURT:** You can pursue it if you  
 17 want, but --  
 18 **MR. KLINE:** I'll withdraw it.  
 19 **THE COURT:** There is an issue,  
 20 Mr. Kline, as to whether or not the jurors  
 21 can see the witness from the vantage point  
 22 that you seem to prefer.  
 23 **BY MR. KLINE:**  
 24 **Q. Sir, you were the man in charge of -- you were**  
 25 **the man in charge of getting approval to the FDA for**

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1 **this drug for autism use, correct?**  
 2 A. My team, including myself, was responsible for  
 3 having this product in this integration approved in  
 4 the -- worldwide, including US.  
 5 **Q. I asked about you. You, sir, were the one**  
 6 **ultimately who was calling the shots, correct?**  
 7 A. Me and my team, yes.  
 8 **MS. SULLIVAN:** And, Your Honor, again  
 9 on the positioning of the lawyer.  
 10 **THE COURT:** No. I'm satisfied with  
 11 that, I am. I'm satisfied with where he is.  
 12 Can you see the witness, members of  
 13 the jury?  
 14 Yeah.  
 15 As long as they can see the witness  
 16 and we have some space, I'm fine with it.  
 17 And let's move on to a different issue from  
 18 that.  
 19 **MS. SULLIVAN:** Thank you, Your Honor.  
 20 **MR. KLINE:** Yes.  
 21 **BY MR. KLINE:**  
 22 **Q. Now, let's talk about -- let's talk about the**  
 23 **period of time here.**  
 24 **Have you been told anything about**  
 25 **this particular case, sir; the years it involves;**

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1 **the boy that it involves; the circumstances it**  
 2 **involves?**  
 3 A. I've limited information on that, yes.  
 4 **Q. Limited information?**  
 5 A. Uh-huh.  
 6 **Q. Do you know his name?**  
 7 A. Ummm, Pledger or something.  
 8 **Q. Do you know his first name?**  
 9 A. No, I'm afraid not. I was not told.  
 10 **Q. No.**  
 11 **Do you know how long he took your**  
 12 **Risperdal, sir?**  
 13 A. My understanding is he took it for several  
 14 years.  
 15 **Q. Do you know how many years?**  
 16 A. About four or five, something.  
 17 **Q. Do you know for sure?**  
 18 A. No. I was told, so...  
 19 **Q. Do you know if there's an adverse event report**  
 20 **about him?**  
 21 A. That I don't know.  
 22 **Q. You didn't look?**  
 23 A. No, I did not.  
 24 **Q. You have access to the adverse event database,**  
 25 **don't you?**

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1 A. If there is -- if the case had been reported  
 2 to the FDA Adverse Reaction Database, then we would  
 3 have kept it and it would have been included in our  
 4 annual safety report.  
 5 **Q. My question, sir, is do you know if you have**  
 6 **it or not?**  
 7 A. I cannot confirm, neither deny, whether this  
 8 particular case was reported to the FDA database or  
 9 to our adverse event database. If it was, then it  
 10 would have been included. But, obviously, if it was  
 11 not reported, then we can't include it.  
 12 **Q. The kind of answer you just gave me, sir,**  
 13 **right now, is that the kind of an answer when an FDA**  
 14 **official would ask a question, they would get that**  
 15 **answer to that question?**  
 16 A. We --  
 17 **Q. Yes or no, sir?**  
 18 A. No. There is no yes-or-no answer. If the FDA  
 19 asks this question, we will need to dig into our  
 20 files, in our database, to evaluate and answer that  
 21 question later on. That's the way it works.  
 22 **Q. So you would put -- I understand, sir. I**  
 23 **understand.**  
 24 **Okay. Now, the -- if we can put up**  
 25 **DG10.10, just to clean up a few issues that I had at**

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1 **the end of yesterday, if I might, please.**  
 2 **Whoever has access to it, whichever**  
 3 **the operators, I'd be very grateful.**  
 4 **DG10.10.**  
 5 **(Displaying document on the screen.)**  
 6 **BY MR. KLINE:**  
 7 **Q. Sir, I just need to -- I want to fill one**  
 8 **thing in.**  
 9 **The NED, you had said it was a couple**  
 10 **of weeks. And I just wanted to have a full chart.**  
 11 **It was ten weeks. Does that sound about right?**  
 12 A. I don't know this by heart. It may be right.  
 13 Yes.  
 14 **Q. Okay. On the "may be right" answer, I'm just**  
 15 **going to change that to ten weeks so we have a full**  
 16 **chart here. Marking "ten weeks" under NED, Number**  
 17 **9, Exhibit No. P-89.**  
 18 **Thanks. You can take that down.**  
 19 **(Technician complies with request.)**  
 20 **BY MR. KLINE:**  
 21 **Q. Now, the time frame, sir, that I want to**  
 22 **discuss with you is June of 2002 through October of**  
 23 **2006.**  
 24 **Now, do you recall yesterday having**  
 25 **lengthy discussions about an Anderson article --**

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1 **which I will discuss with you -- in 2007? Do you**  
 2 **recall that discussion?**  
 3 A. Yeah.  
 4 **Q. You do not?**  
 5 A. Yeah, yeah, yeah. That's the -- one of the  
 6 publications on the RUPP study.  
 7 **Q. Yes.**  
 8 **And all of the discussion about the**  
 9 **label change which occurred after '06, do you recall**  
 10 **that discussion, generally?**  
 11 A. It occurred in October 2006, yes.  
 12 **Q. I didn't hear you, sir.**  
 13 A. It occurred -- that label change occurred in  
 14 October 2006, indeed.  
 15 **Q. Yes.**  
 16 **During the entire time, from**  
 17 **June 2002 through October 2006, you correct me if**  
 18 **I'm wrong, as to children and adolescents, as to**  
 19 **children and adolescents, in the United States of**  
 20 **America the drug was not approved; is that correct?**  
 21 A. It was not approved for the use in children  
 22 and adolescents, that's correct.  
 23 **Q. And yet, sir, what is a -- when there's a**  
 24 **chart that's shown in patient person years, what are**  
 25 **"person years"?**

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1 A. A person year is one single patient exposed to  
 2 the compound for one full year.  
 3 **Q. Okay. So it would be if someone were -- if we**  
 4 **had a hundred people who were exposed for one year,**  
 5 **it would be a hundred patient years; is that**  
 6 **correct?**  
 7 A. That is correct.  
 8 **Q. And if there were 25 people who were exposed**  
 9 **for four years, it would be 25 times four, it would**  
 10 **be a hundred patient years, correct?**  
 11 A. That is correct, yes.  
 12 **Q. Okay. Now, sir, in this period of time, in**  
 13 **this period of time, from 2001 through 2004, I'm**  
 14 **going to actually go a little before and a little**  
 15 **back because that's the data I have, 2001 to 2004.**  
 16 **Sir, in this drug which was not**  
 17 **approved for children in the United States -- by the**  
 18 **way, was it approved anywhere for its use in**  
 19 **children?**  
 20 A. Yes.  
 21 **Q. But not in the US, correct?**  
 22 A. Not in the US in this time period.  
 23 **Q. And there were 733,454 person years of**  
 24 **children 5 to 17 on the drug. Does that sound about**  
 25 **right?**



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1 A. Well, I would need to evaluate -- go back to  
 2 the documents. I don't know where this figure comes  
 3 from, so... I don't know that by heart.  
 4 **Q. Okay. Does it sound about right?**  
 5 A. I have no clue. But if it is somewhere in our  
 6 safety overview, it must be about right, yes.  
 7 **Q. Okay.**  
 8 A. And I even don't know -- is it US only or  
 9 worldwide? That's --  
 10 **Q. Well, I have a document that says estimated**  
 11 **exposure of oral risperidone in patients 5 to 17**  
 12 **years of age, 2001 to 2004.**  
 13 A. Is that a global safety update?  
 14 **Q. Yes, it is, global.**  
 15 A. Then it's global.  
 16 **Q. Yes.**  
 17 **So there were, can we agree,**  
 18 **something like, in this period of time, three**  
 19 **quarters of a million child years on the drug?**  
 20 **You have some idea of this, sir; can**  
 21 **you agree with that?**  
 22 A. Well, if the figure -- if the 133,000 patient  
 23 years -- is that right? What did you have there?  
 24 **Q. 733,000.**  
 25 A. Oh, seven hundred, okay.

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1 **Q. Yes. 733,000 patient years, according to a**  
 2 **Janssen document.**  
 3 A. Yeah. Between 2001 and 2004?  
 4 **Q. Yes.**  
 5 A. Yes. Okay.  
 6 **Q. Now, let's mark that as P-88.**  
 7 **MR. GOMEZ:** The chart?  
 8 **MR. KLINE:** I want to mark as P-88  
 9 the document -- the second page of which is  
 10 P-88-A, which contains estimated exposure of  
 11 oral risperidone in patients 5 to 17.  
 12 **MS. SULLIVAN:** Is this the complete  
 13 document?  
 14 **THE COURT:** Let me see that.  
 15 **MR. KLINE:** It's a document, yes.  
 16 **MS. SULLIVAN:** Is that the complete  
 17 document? It doesn't look like it.  
 18 **MR. KLINE:** As far as I know, this is  
 19 a document which I obtained from the  
 20 approximately 3 million documents which were  
 21 produced by Janssen Pharmaceutical. I have a  
 22 high-level representative which I would like  
 23 to ask a question to about it.  
 24 **MS. SULLIVAN:** Well --  
 25 **MR. KLINE:** Which says in black and

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1 white --  
 2 **THE COURT:** Wait. Let's not go into  
 3 what it says before we understand what the  
 4 position is of the defense about this  
 5 document.  
 6 **MS. SULLIVAN:** Yeah. Your Honor, we  
 7 had an agreement that we would show complete  
 8 documents, and this doesn't look like it's a  
 9 complete document.  
 10 **MR. KLINE:** It's the document that I  
 11 have, Your Honor, pulled from our database by  
 12 Priscilla Brandon.  
 13 **THE COURT:** I'm sure you can produce  
 14 on electronic records or something the entire  
 15 document; is that true?  
 16 **MR. KLINE:** I could produce the  
 17 whole -- I could fill the room with the  
 18 documents.  
 19 **THE COURT:** I'm sure you could fill  
 20 the whole room up of the documents for this  
 21 prescription drug.  
 22 **MR. KLINE:** 3 million.  
 23 **MS. SULLIVAN:** I'm just interested in  
 24 the complete document.  
 25 **MR. KLINE:** It has a data point.

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1 **THE COURT:** Well, again, is there an  
 2 objection to the admission of this particular  
 3 document, P-88 and P-88A?  
 4 **MS. SULLIVAN:** Well, Judge, I'm just  
 5 not sure why we can't see the whole document.  
 6 **THE COURT:** Well, you probably have  
 7 it.  
 8 **MS. SULLIVAN:** Yeah. But I don't  
 9 have it here because I didn't know he was  
 10 going to show it.  
 11 **THE COURT:** Well, you're going to  
 12 have a recross, I believe, or a redirect, so  
 13 maybe by then you will -- your team will be  
 14 able to obtain the entire document.  
 15 This is permitted. Go ahead.  
 16 But you have to authenticate it in  
 17 some way and let us know what this is and who  
 18 it's by and what the date is and, you know,  
 19 fundamentally.  
 20 **BY MR. KLINE:**  
 21 **Q. Sir, I'm showing you basic data information on**  
 22 **a table.**  
 23 **MR. KLINE:** May I hand it to the  
 24 witness?  
 25 **THE COURT:** Yes.

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1 **BY MR. KLINE:**  
2 **Q. I'm showing you basic data, which I simply**  
3 **want to establish the fact it says estimated**  
4 **exposure of oral risperidone in patients 5 to 17**  
5 **age, 2001 to 2004. Do you see that, sir?**  
6 A. Yes.  
7 **Q. Does that conform basically with your**  
8 **understanding?**  
9 **We have it as JJRE11115820.**  
10 **VIDEO OPERATOR:** Display it?  
11 **MR. KLINE:** Yes. With the Court's  
12 permission.  
13 (Document displayed.)  
14 **MR. KLINE:** Can you zero in on the  
15 top, please? Just after the numbers. And I  
16 would like to move on, if I'm allowed to.  
17 Just the full '01 to total numbers.  
18 That's what I would just like to do, with the  
19 total.  
20 (Technician complied with request.)  
21 **MR. KLINE:** Okay.  
22 **BY MR. KLINE:**  
23 **Q. Sir, as the person who was in charge of**  
24 **Risperdal R & D in children and adolescents, you had**  
25 **some understanding, did you not, of the number of**

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1 **children who were already using the drug?**  
2 A. Yes. That is common practice on a yearly  
3 basis, yes.  
4 **Q. It's commonly known and reported in a table**  
5 **like this, correct, sir?**  
6 A. Yes, that's pretty common.  
7 **Q. Yes.**  
8 **And you've actually seen this**  
9 **document at some point?**  
10 A. Well, I don't know exactly what this document  
11 is, but if it is a Janssen document and it's an  
12 annual safety review or letter, whatever, then I  
13 likely have seen this, yes.  
14 **Q. Okay. That's good. And I can represent to**  
15 **you and the Court it is. It's produced with a JJRE**  
16 **number, 11115820.**  
17 **I didn't -- I didn't find it on the**  
18 **street, sir.**  
19 A. No, no, no, no. But I hope you appreciate  
20 that based on this code, that there isn't a bell  
21 ringing in my head which document it actually is. I  
22 hope that you don't expect that.  
23 **Q. Now, putting all of that aside, putting all of**  
24 **that aside, in 2001 there were -- the percentage of**  
25 **prescriptions in the 5- to 17-year age range was**

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1 **5 percent, and you see it was 276,611 person years**  
2 **of kids on the drug, correct?**  
3 A. 129,000 -- in 2001 you mean?  
4 **Q. 2001, 276,000 -- or no. It's --**  
5 A. No. That's patient. That's the total  
6 patient. So in the second column for 2001, you have  
7 the total worldwide exposures in patient years.  
8 **Q. Yes.**  
9 A. Of which about 4.7 percent is in the age group  
10 of 5 to 17, meaning 129,889 patient years, in 5 to  
11 17 years old.  
12 **Q. I see. And in 2002, 186,990 patient years in**  
13 **the 5 to 17 patient range, correct?**  
14 A. That is correct.  
15 **Q. And in 2003, 204,830 patient years, correct?**  
16 A. Yes.  
17 **Q. And in the 2004 period, 211,745 patient years.**  
18 **In that period of time, 733,454 patient years of**  
19 **Risperdal for children; is that correct?**  
20 A. That is correct.  
21 **Q. Okay. Just marking my tablet with the 733,000**  
22 **on it as Plaintiff's Exhibit 89.**  
23 - - -  
24 **(Exhibit P-89, handwritten chart on**  
25 **the easel, marked for identification.)**

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1 **BY MR. KLINE:**  
2 **Q. Do you know the numbers off the top of your**  
3 **head broken down in the United States of**  
4 **approximately how many was being used off-label,**  
5 **sir?**  
6 A. No. I don't know this off the top of my head.  
7 **Q. Without taking it out, I can tell you that the**  
8 **jury has seen a figure in 2000 and -- just get that**  
9 **document, and I'll move on.**  
10 **Now, I'd like to talk to you about**  
11 **the approved document, DG6-1.**  
12 **Now, yesterday we saw an exhibit.**  
13 **I'd like to put it up just briefly, DG6-1.**  
14 **THE COURT:** Which one was this?  
15 **COURT CRIER:** It was D-71, Your  
16 Honor.  
17 **THE COURT:** D-71.  
18 **MR. KLINE:** And if we can display it  
19 with the Court's permission, it's the  
20 demonstrative which was shown at the end of  
21 the direct examination.  
22 **THE COURT:** Yes. Yes.  
23 **MR. KLINE:** I'm ready to display it.  
24 **THE COURT:** It's permitted.  
25 **MR. KLINE:** Just display it for a

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1 moment.

2 Thank you so much, team Janssen, for

3 helping me. I much appreciate it, sir.

4 (Document displayed.)

5 **BY MR. KLINE:**

6 **Q. Now, first of all, that document, sir, that**

7 **document, is that accurate as to the approval for**

8 **adults that carried forward after 1993, sir, where**

9 **it says manifestations of psychotic disorders?**

10 A. That was the original approval back in

11 December 1993, yes.

12 **Q. Yeah. That was the approval in December 1993.**

13 **But, sir, that got changed. That got narrowed,**

14 **didn't it?**

15 A. It got changed.

16 **Q. Yeah. How soon after 1993 did that get**

17 **changed and narrowed?**

18 A. I don't know exactly the date. That must be

19 the early 2000s. But I might be wrong. And it was

20 changed into schizophrenia. And this was done for

21 all the second generation antipsychotics approved

22 initially for manifestations of psychosis. It was

23 changed into schizophrenia, I think, somewhere in

24 the early 2000s.

25 **Q. Sir, was it changed or was it -- was the**

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1 **indication for adults narrowed --**

2 A. No; it's changed.

3 **Q. -- to schizophrenia?**

4 A. It's changed.

5 **Q. Did the indication in the US label become for**

6 **schizophrenics? Yes or no?**

7 A. The indication for Risperdal was changed from

8 manifestation of psychotic disorders to

9 schizophrenia.

10 **Q. Yes. It was changed -- the manifestations of**

11 **psychotic disorders is a broader term, correct?**

12 A. I can elaborate a lot on that, but then you

13 need to give me the time. But it's much

14 complicated, much more complicated than it is. And

15 it's not --

16 **Q. The FDA asked you to change it, correct?**

17 A. That's correct.

18 **Q. The FDA asked you to change it, to limit it to**

19 **schizophrenia, correct, sir?**

20 A. The FDA asked it to change into schizophrenia,

21 and they did so for all the, at that time, available

22 second generation antipsychotics.

23 **Q. Regardless of what they asked the other second**

24 **generation antipsychotics to do, as to Risperdal,**

25 **which we're talking about and as to what was**

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1 **displayed to the jury yesterday, which is what I'm**

2 **talking about, the indication was narrowed by the**

3 **FDA to include only schizophrenia, not this general**

4 **category of psychotic disorder; agree?**

5 A. It was changed into schizophrenia, and I'm

6 prepared to explain that.

7 **Q. When was it changed, sir?**

8 A. That, again, I think it's somewhere early

9 2000, but I might be wrong. I don't know for sure.

10 **Q. Bear with me.**

11 **I believe we've marked this document**

12 **previously, the labeling history. Is that correct?**

13 **Exhibit 12.**

14 **MR. GOMEZ:** Exhibit 12.

15 **MR. KLINE:** Exhibit 12, previously

16 marked P-12, Your Honor. It's a document we

17 had a discussion about, but no testimony from

18 Dr. Kessler about the labeling history. I'm

19 using it for a different purpose.

20 I would hand my highlighted document

21 to the witness to confirm this one fact.

22 **THE COURT:** All right. Well, let me

23 hear from the defense about this document.

24 **MS. SULLIVAN:** If he can lay a

25 foundation and Dr. Caers knows what this is,

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1 I have no objection.

2 **BY MR. KLINE:**

3 **Q. It's a document called USPI Labeling History,**

4 **sir. You were the man who was responsible for**

5 **labeling, correct, sir?**

6 A. Yeah.

7 **Q. So you would know the document from the**

8 **Janssen files on the labeling history, correct?**

9 A. I know about that change, yes.

10 **Q. Okay. And -- well, you didn't know the date.**

11 **And what I was trying to do was get the date.**

12 A. Yeah, yeah. Look, I'm sorry, I don't know the

13 date by heart, but I know it happened.

14 **Q. But I'm not asking you to know it by heart. I**

15 **have in my hand -- and I simply want to show you to**

16 **confirm -- with the Court's permission --**

17 **THE COURT:** Yes. You can take a look

18 at that, Dr. Caers, and see if that makes you

19 remember what the date was of the change.

20 **MR. KLINE:** Yes.

21 (Handing document to the witness.)

22 **MR. KLINE:** I've handed the witness

23 P-12.

24 **THE WITNESS:** So in February 2002.

25 So it's early 2000s, indeed, the label was

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1 changed from manifestations in psychotic  
 2 disorders into schizophrenia, and I see now  
 3 it's February 2002.  
 4 **MR. KLINE:** Okay.  
 5 **BY MR. KLINE:**  
 6 **Q. So in February 2002, sir, this indication,**  
 7 **manifestations of psychotic disorders, gets changed**  
 8 **to -- just to schizophrenia in adults, correct?**  
 9 A. It is changed to schizophrenia.  
 10 **Q. And to be accurate as to adults, sir, the only**  
 11 **thing in the United States that this drug -- and it**  
 12 **was a powerful drug, wasn't it, and still is a**  
 13 **powerful drug?**  
 14 A. It is an effective drug, yes.  
 15 **Q. Yes. I didn't ask about effectiveness. I**  
 16 **asked about power.**  
 17 **Can you agree with me --**  
 18 A. We never talk about -- we never talk about  
 19 power. What -- how do you define powerful drug?  
 20 **Q. When it knocks somebody -- when someone has**  
 21 **their head on the table, would that be a powerful**  
 22 **drug?**  
 23 A. I don't know what you mean by that.  
 24 **Q. You haven't heard about that testimony in this**  
 25 **trial?**

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1 A. No.  
 2 **Q. Okay. Schizophrenia, sir, February 2002, so**  
 3 **since February of 2002, the only indication for this**  
 4 **drug, only indication for this drug is, in adults,**  
 5 **was schizophrenia until 2003 when it became bipolar**  
 6 **mania, correct?**  
 7 A. That is correct.  
 8 **Q. Now, as to all these approvals, sir, as to all**  
 9 **these approvals -- if I can display -- oh. And the**  
 10 **last exhibit I'm marking as P-90.**  
 11 - - -  
 12 **(Exhibit P-90 was marked for**  
 13 **identification.)**  
 14 - - -  
 15 **BY MR. KLINE:**  
 16 **Q. And I'm going to now show you what will become**  
 17 **P-91.**  
 18 **Sir, as to these approvals that we**  
 19 **had up on the board, am I correct that in 1997,**  
 20 **1997, labeling was denied by the FDA -- something**  
 21 **you discussed with Ms. Sullivan yesterday, correct?**  
 22 A. That was a request to the FDA or a proposal to  
 23 add particular text in the label on appropriate  
 24 dosing for Risperdal in pediatric populations.  
 25 **Q. Yes. Denied, correct?**

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1 A. That was denied, indeed.  
 2 **Q. Yes.**  
 3 **And then in 2000, in 2000 you were**  
 4 **back to the FDA, correct?**  
 5 A. We were several times back to the FDA, so...  
 6 **Q. You asked for a label change in 2000, correct,**  
 7 **sir?**  
 8 A. What are you talking about exactly?  
 9 **Q. You asked for a label -- you asked to -- you**  
 10 **went to the FDA and you had discussions with the FDA**  
 11 **as to whether the drug could be approved for**  
 12 **conduct disorder?**  
 13 A. Okay. That's -- no, no. That was a meeting  
 14 with the FDA in which we explored whether the FDA  
 15 will be prepared to review an NDA on Risperdal in  
 16 conduct disorder or disruptive behavior disorders.  
 17 And for a number of reasons, as we discussed  
 18 yesterday, the FDA said that they didn't feel this  
 19 to be an appropriate indication for label. And,  
 20 consequently, we did not submit any NDA. And the  
 21 FDA did not reject it because we never submitted it.  
 22 Why would you do a submission if you know before  
 23 that they would not embrace it?  
 24 Although -- although the FDA made  
 25 also clear at that meeting that they would make this

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1 dependent on a public advisory board, which is often  
 2 part of the review process, where the FDA asks  
 3 experts for their input before they approve it.  
 4 **Q. So it was denied before it was even asked for,**  
 5 **correct?**  
 6 A. That was not denied. That was an exchange of  
 7 ideas, a proposal. And the FDA didn't embrace that  
 8 idea; and, consequently, we did not pursue it.  
 9 **Q. Let's see if we can agree with this. You**  
 10 **exchanged ideas with the FDA?**  
 11 A. Yeah. We came with a proposal.  
 12 **Q. And they said no?**  
 13 A. And they didn't -- they didn't -- they did not  
 14 say --  
 15 **Q. They said no?**  
 16 A. No, no, no, no. They did not say no. They  
 17 said they had several concerns about the concept of  
 18 conduct disorder for different reasons. And they  
 19 said, Hey, guys, if you want to pursue, you will  
 20 need to understand that we need to bring this to the  
 21 public advisory board because we have substantial  
 22 concerns.  
 23 **Q. Did you ever go back and ask for an approval**  
 24 **for conduct disorder?**  
 25 A. No, we did not.

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1 **Q. Conduct disorder -- I'm going to write on my**  
2 **thing -- "discussion." Would that be a fair way to**  
3 **put it?**  
4 A. There was a discussion, that's fair.  
5 **Q. Okay. Let's make sure that we do it.**  
6 **And then in 2005 -- in 2005 there was**  
7 **a formal submission, correct?**  
8 A. Are you talking about --  
9 **Q. For autism.**  
10 A. That was -- I think, as we said yesterday,  
11 that was in December 2003.  
12 **Q. Okay. And when were you told "no"?**  
13 A. Here again, I don't know the dates by heart,  
14 but somewhere in 2004, it was a unapprovable letter.  
15 That's not a "no." That says, Hey, guys, we have  
16 looked at your data and we have additional  
17 questions, can you help us out.  
18 **Q. Well, I'll just have to get the documents out,**  
19 **sir.**  
20 **In fact, let me --**  
21 **THE COURT:** You know what, right  
22 there, I'd like to take a break right here,  
23 if possible, to get the documents and  
24 whatever.  
25 **MR. KLINE:** Yes. And, Your Honor,

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1 I'm just trying to go slow and patient.  
2 **THE COURT:** No; I have no problem  
3 with that. I just want to -- because we're  
4 going to be taking a lunch break around  
5 12:15. So I think right now is the right  
6 time to take our break right here, okay?  
7 **MR. KLINE:** Yes.  
8 **THE COURT:** All right. A ten-minute  
9 recess everybody.  
10 **COURT CRIER:** All rise as the jury  
11 exits.  
12 - - -  
13 (Whereupon the jury exited the  
14 courtroom at 10:54 a.m.)  
15 - - -  
16 **THE COURT:** I'm just going -- Doctor,  
17 I'm just going to ask -- our court reporter  
18 wants to speak to you about the spelling of  
19 some names that you mentioned. I'll permit  
20 that, if there's no objection.  
21 **THE WITNESS:** That's fair.  
22 **MS. SULLIVAN:** No objection.  
23 **THE COURT:** Then we'll come back.  
24 Ten-minute recess.  
25 **MS. SULLIVAN:** Thank you, Your Honor.

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1 - - -  
2 (Whereupon a recess was taken.)  
3 - - -  
4 **COURT CRIER:** Come to order.  
5 **THE COURT:** All right. You may be  
6 seated till the jury comes in.  
7 **COURT CRIER:** All rise as the jury  
8 enters.  
9 - - -  
10 (Whereupon the jury entered the  
11 courtroom at 11:11 a.m.)  
12 - - -  
13 **THE COURT:** All right. Please be  
14 seated, everybody.  
15 You may proceed.  
16 **MR. KLINE:** Thank you.  
17 **BY MR. KLINE:**  
18 **Q. Sir, a definition, sir. What does the word**  
19 **"not approvable" mean?**  
20 A. Well, that basically means that with the  
21 current information provided, that the FDA is not  
22 prepared to approve your application.  
23 **Q. Okay. And in -- and in --**  
24 A. Say again.  
25 **Q. In May 2005, as to autism, the FDA issued a**

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1 **non-approvable letter, correct?**  
2 A. There were different steps: Submission,  
3 approvable, complete response, and you give  
4 additional information, and then we had the  
5 non-approvable in May 2005, yeah.  
6 **Q. Yeah.**  
7 A. It may well be, right.  
8 **Q. May 2005, I'm putting it on my thing, 2005, as**  
9 **to children and adolescents.**  
10 **You use "C and A" a lot, don't you?**  
11 **Children and adolescents; you use that term?**  
12 A. Yeah.  
13 **Q. "Children and adolescents," "not approvable."**  
14 **By the way, in that same month --**  
15 **since you were adding here in this chart all of the**  
16 **things that were approved for adults, in that same**  
17 **month there was something else that was not approved**  
18 **that you tried to get an approval for, a**  
19 **non-approvable. Do you know what that was?**  
20 A. Would that be dementia? Psychosis and  
21 dementia?  
22 **Q. Yeah. Yeah.**  
23 A. 2005. Yeah.  
24 **Q. Psychosis and dementia.**  
25 **That was never approved to this day,**

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1 correct?  
 2 A. That is correct.  
 3 Q. And there was wide off-label use of the drug  
 4 for that as well, correct?  
 5 A. I don't know. I cannot --  
 6 MS. SULLIVAN: Objection, Your Honor.  
 7 THE COURT: That's sustained. That's  
 8 sustained.  
 9 BY MR. KLINE:  
 10 Q. So May 2005 there were non-approvables by the  
 11 FDA for two different -- two different time frames,  
 12 correct? Two different indications.  
 13 A. Yes.  
 14 Q. Autism was non-approvable, and child and  
 15 adolescent irritability of autism non-approvable,  
 16 correct?  
 17 A. No, no. That's the same.  
 18 Q. What's the same?  
 19 A. The two you just mentioned.  
 20 Q. You got two different letters?  
 21 A. Yeah, yeah, yeah. But you mentioned autism  
 22 twice.  
 23 Q. Okay. Well, irritability and autism was not  
 24 approvable?  
 25 A. That was a non-approvable letter, yes.

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1 Q. Yeah. I ran out of room so I just put  
 2 "autism."  
 3 Okay. Next P number is? Pardon me?  
 4 MR. GOMEZ: 91.  
 5 MR. KLINE: P-91, which is the  
 6 plaintiff version of DG6-1.  
 7 (Exhibit P-91 marked for  
 8 identification.)  
 9 BY MR. KLINE:  
 10 Q. Next, moving on to a different topic.  
 11 Sir, picking up a few quick things  
 12 about you. I see from your Curriculum Vitae, which  
 13 was marked in your deposition -- did we mark it for  
 14 this purpose?  
 15 Okay. I see you have not published  
 16 an article in the medical literature since 1991; is  
 17 that correct?  
 18 A. Oh, no, no, that's incorrect.  
 19 Q. When have you last published?  
 20 A. Last month.  
 21 Q. I see.  
 22 In what, sir?  
 23 A. That was an abstract, but the latest article  
 24 was in the British Journal of Psychiatry, a couple  
 25 of months ago.

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1 Q. When was that?  
 2 A. A couple of months ago.  
 3 Q. Okay. And of any of the articles on  
 4 Risperdal, is your name on any of the articles?  
 5 A. Very few; because I leave the authorship to  
 6 particularly the clinical leaders and the  
 7 investigators that really deal with the actual  
 8 study. Because I'm dealing with everything, not  
 9 only clinical, also chem, chem-pharma and --  
 10 Q. My question was only -- here's a question,  
 11 let's see if it can be answered: Is your name on  
 12 any article? Yes or no?  
 13 A. Yes, it is.  
 14 Q. On any Risperdal article?  
 15 A. Yes.  
 16 Q. How many Risperdal articles in the published  
 17 literature is your name on them?  
 18 A. Very few.  
 19 Q. How many is very few?  
 20 A. I don't know that by heart.  
 21 Q. Well, you came here to testify, sir. Is it  
 22 one? Is it three? Is it five? Is it more than  
 23 ten?  
 24 A. It's less than ten.  
 25 Q. Okay. Now, sir, there's a document which -- I

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1 want to establish a couple of things.  
 2 On the Risperdal team is a man by the  
 3 name of Gahan Pandina, correct?  
 4 A. He was not a member of my compound development  
 5 team. He was within the Janssen US Medical Affairs  
 6 organization.  
 7 Q. What's Janssen US Medical Affairs? Is that  
 8 like -- is that a science department?  
 9 A. That is a science department, but in Janssen  
 10 US, that deals with further documentation and  
 11 exploration of what is known about the product and  
 12 scientific affairs, yes.  
 13 Q. Well, did you deal with him on this drug, sir?  
 14 A. Well, he was one of the people dealing with  
 15 Risperdal. So you want to know the way I was  
 16 dealing with --  
 17 Q. My question is, did you deal with him? Yes or  
 18 no?  
 19 A. I had contact with Gahan Pandina, yes.  
 20 Q. Were you on e-mails with Gahan Pandina?  
 21 A. Yes.  
 22 Q. That's the kind of questions I would like to  
 23 ask in the next two hours.  
 24 A. Okay.  
 25 Q. That's what I would like to ask, get a

1 response.

2 Now, you were on e-mails with Gahan

3 Pandina. And you also knew that he was involved in

4 the e-mails regarding the drafting of the Findling

5 article, correct, sir?

6 A. Yes, indeed.

7 Q. As well as this lady Carin -- and, by the way,

8 he wasn't a Medical Doctor?

9 A. He's a psychologist, I think, yeah.

10 Q. Yeah. Psychologist.

11 And psychologists don't prescribe

12 medication, do they?

13 A. I'm not sure whether they are allowed to

14 prescribe certain medications. That I don't know

15 for sure in this country.

16 Q. You just don't know?

17 A. I don't know.

18 Q. And Carin Binder, sir, she also -- you had

19 contact with her. She was on e-mails. Is that

20 correct, sir, regarding the drug, Risperdal?

21 A. Yes.

22 Q. And Carin Binder was with Janssen Canada,

23 correct?

24 A. Yes, correct.

25 Q. And you had various discussions and e-mails

1 controversy that remained about prolactin levels in

2 Risperdal? Yes or no?

3 A. I'm not sure whether there was a controversy.

4 There was different manuscripts' reviews with

5 different positions, and obviously that's the way it

6 works. And that's the way, however, you come to an

7 eventual final manuscript.

8 Q. Well, sir, do you recall being included on an

9 e-mail -- just off the top of your head, before we

10 talk about specific documents, do you recall being

11 on an e-mail in which there was a discussion that

12 the controversy still remains about prolactin? Do

13 you recall that?

14 A. Uhhh...

15 Q. Yes or no. If you recall it, you do. If you

16 don't, you don't.

17 A. I don't recall it literally, but I'm aware of

18 this -- of an e-mail like that, yes.

19 Q. Yeah. Have you reviewed it before coming to

20 the court?

21 A. Uhhh...

22 Q. The lawyers show it to you?

23 A. I think we reviewed this, yes.

24 Q. Yeah.

25 There's a lot of e-mails that you

1 with her as well as Mr. Pandina, correct?

2 A. Yes.

3 Q. This jury has seen many e-mails about them;

4 and some you were copied on and some you were not.

5 But ultimately, you were the one who was running the

6 show as to getting the label changed, correct?

7 A. Well, running the show is some word -- I'm not

8 sure what you mean by that. I'm not running a show.

9 I'm running a product. And --

10 Q. All right. Running a project.

11 A. I'm running a label review, yes, but I don't

12 call this a "show."

13 Q. Never heard that expression?

14 A. I don't like the word "show" for drug

15 development.

16 Q. Well, sir, let's look at -- I want to get to

17 some documents.

18 First of all, each one we'll put in

19 some perspective.

20 THE COURT: There's some kind of

21 feedback there, Mr. Gomez and Mr. Kline.

22 BY MR. KLINE:

23 Q. Sir, I'd like to focus on -- I'd like to focus

24 on April or thereabouts of 2003. And in April of

25 2003, sir, would you agree with me there was a

1 reviewed before coming to court, correct, sir?

2 A. Hardly any.

3 Q. There's one that includes the words "hiding

4 data." You saw that e-mail, correct?

5 A. I don't think so.

6 Q. No?

7 A. No.

8 Q. Okay. There's one e-mail saying there's a

9 nauseating amount of information about gynecomastia.

10 Did you --

11 A. No.

12 Q. Did you see that e-mail?

13 A. No. No.

14 Q. No?

15 Have you ever seen that e-mail?

16 A. I don't know -- really I haven't -- I haven't

17 seen that in the last -- no.

18 Q. Do you know what "nauseating" means?

19 A. Nauseating amount, no.

20 Q. You don't?

21 A. I know nausea, yeah.

22 Q. It's a side effect of a lot of drugs.

23 A. That's not -- no, that's not --

24 Q. Did you ever --

25 A. That's not correct. Nausea is not the side

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1 effect of many drugs.  
 2 **Q. No?**  
 3 A. No.  
 4 **Q. TV ads I see they say it.**  
 5 **But how about the -- sitting here**  
 6 **today, you've never seen either an e-mail talking**  
 7 **about hiding data nor an e-mail regarding Risperdal**  
 8 **that talks about there being a nauseating amount**  
 9 **of info; is that correct?**  
 10 A. No, I don't -- it doesn't ring a bell to me,  
 11 no.

12 **Q. If that's the way the drug were being talked**  
 13 **about at the time it was being developed, would you**  
 14 **expect to have seen those e-mails, sir?**  
 15 A. Say that again.  
 16 **Q. Okay. Now, back to something else in 2003, in**  
 17 **April of 2003. There was always an attempt, sir,**  
 18 **with the drug, with Risperdal, as it applied to**  
 19 **adolescents and children, there was always a message**  
 20 **that you and your group were looking to convey; can**  
 21 **we agree, a message?**  
 22 A. That's an interpretation. I'm not aware of  
 23 that particular objective.  
 24 **Q. Did you ever see the word not once but many**  
 25 **times in e-mails regarding messaging, "message**

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1 **emphasis is important"? Did you ever see that kind**  
 2 **of e-mail, sir?**  
 3 A. No, it doesn't ring a bell to me, to be  
 4 honest.  
 5 **Q. No?**  
 6 A. No.  
 7 **Q. And in fact Risperdal -- Consta, what was**  
 8 **Consta, by the way, sir?**  
 9 A. This drug Consta is a trademark for a  
 10 long-acting injectable formulation for risperidone  
 11 so that you can inject the patients so that they  
 12 don't need to take pills.  
 13 **Q. Yeah. And when did that become approved?**  
 14 A. Was that 2003?  
 15 **Q. Is that on -- is that on the chart? We'll**  
 16 **take a look.**  
 17 **I have oral solution and**  
 18 **disintegrating tablet was on the chart.**  
 19 **Do you have a sense of it? You're**  
 20 **the guy who knows a lot about this.**  
 21 A. Yeah. I think our first approval for  
 22 Risperdal Consta, this was in 2003 or something like  
 23 that, yeah.  
 24 **Q. All right. Thereabouts. Early on.**  
 25 **And that was just an injectable form.**

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1 **It was a form of Risperdal. There was Risperdal**  
 2 **pills; Risperdal liquid; Risperdal dissolvable?**  
 3 A. (Nodding.)  
 4 **Q. You could get your Risperdal almost any way**  
 5 **you could get it down, correct?**  
 6 A. Oh, no, no, no, no. There are many more ways  
 7 you can get a product in a body.  
 8 **Q. Are you working on it?**  
 9 A. Uhhh, no. But those are the ones we  
 10 developed. But there are many more ways that you  
 11 can -- you could use, yes.  
 12 **Q. Okay. But anyway, anyway, Risperdal,**  
 13 **Risperdal was the franchise?**  
 14 A. No, no, no, no.  
 15 **Q. No. Did you ever see -- here's my question,**  
 16 **just simple straight up yes or no.**  
 17 **Did you ever see Risperdal in an**  
 18 **e-mail that you were involved in, someone sent you,**  
 19 **calling it the Franchise? Capital F, the Franchise.**  
 20 A. That may be, but I would never call this a  
 21 "franchise."  
 22 **Q. By the way, the documents show that in the**  
 23 **early 2000s it was a two-billion-dollar drug in**  
 24 **sales.**  
 25 **MS. SULLIVAN: Objection, Your Honor.**

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1 This violates -- blatant violation of an in  
 2 limine motion. And I guess we can talk about  
 3 how much money it costs to develop this drug.  
 4 This is a blatant violation of Your Honor's  
 5 ruling.  
 6 **THE COURT:** Well, I'll hold that  
 7 under advisement.  
 8 Can you just move on --  
 9 **MR. KLINE:** Yes, we'll move on.  
 10 **THE COURT:** -- to other areas other  
 11 than franchise.  
 12 Do you have some documents?  
 13 **MR. KLINE:** I do.  
 14 **THE COURT:** If you have some  
 15 documents that refresh his memory, whatever  
 16 you want to do.  
 17 **MR. KLINE:** Okay. I will do it. Let  
 18 me show a document.  
 19 Let me show you a document, one of  
 20 many I have here, April 14, 2003.  
 21 P-92, for the Court.  
 22 (Exhibit P-92 marked for  
 23 identification.)  
 24 **MR. KLINE:** And I'm referring, Your  
 25 Honor, to the bottom of the page where this



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1 witness -- this witness is a recipient.  
 2 It is from -- well, I'll identify it  
 3 and I'll have the Court look at it, and I'll  
 4 have Ms. Sullivan look at it. Dr. Caers is a  
 5 recipient, and I would ask to display it to  
 6 the jury.  
 7 **THE COURT:** What you're talking about  
 8 now -- the bottom one?  
 9 **MR. KLINE:** Yes, the bottom one,  
 10 going into the next page.  
 11 **THE COURT:** Oh, okay. Just one  
 12 second.  
 13 **MR. KLINE:** Yeah. It's from Reyes.  
 14 **THE COURT:** April 13, 2003?  
 15 **MR. KLINE:** Yes.  
 16 **THE COURT:** 11:54 a.m.?  
 17 **MR. KLINE:** Yes.  
 18 **MS. SULLIVAN:** And, Your Honor, this  
 19 I would object because it relates to a  
 20 different drug, Consta, which is not at  
 21 issue.  
 22 **THE COURT:** That's overruled. That  
 23 objection is overruled. We just determined  
 24 that Consta is a form of Risperdal.  
 25 **MR. KLINE:** Yes.

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1 **THE COURT:** All right. You can be  
 2 permitted to use that.  
 3 **MR. KLINE:** Thank you, Your Honor.  
 4 **THE COURT:** In other words, all I  
 5 want on the screen -- no; I don't want that.  
 6 Take that down.  
 7 **MR. KLINE:** Take that down. Just  
 8 need the bottom.  
 9 **THE COURT:** Just the part that has to  
 10 do with original message of April 13, 2003,  
 11 through the next page.  
 12 **MR. KLINE:** Yes.  
 13 I'm not going to display the first  
 14 part, Your Honor. He has to show it with --  
 15 you couldn't see it from the juror box.  
 16 **THE COURT:** That's fine.  
 17 **BY MR. KLINE:**  
 18 **Q. But can we agree, sir, that the e-mail is from**  
 19 **Magall, M-A-G-A-L-L [sic], with a hyphenated last**  
 20 **name, Reyes-Harde, R-E-Y-E-S hyphen H-A-R-D-E?**  
 21 A. Yes.  
 22 **Q. Who is "Magall" Reyes-Harde?**  
 23 A. Magali. Magali Reyes-Harde was in 2003, I  
 24 think, also in Medical Affairs.  
 25 **Q. Medical Affairs in USA?**

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1 A. Yes, US, yes.  
 2 **Q. And you see there are a lot of people on this**  
 3 **e-mail, including Ivo Caers, PRDBE. Do you see**  
 4 **that?**  
 5 A. I see that.  
 6 **Q. PRDBE meaning?**  
 7 A. That's Pharmaceutical Research and  
 8 Development, and the BE stands for Belgium.  
 9 **Q. Thank you.**  
 10 **Now, let's quickly go to the e-mail.**  
 11 **The e-mail says on the first -- on**  
 12 **the second paragraph, "However."**  
 13 **Yes.**  
 14 **(Document displayed.)**  
 15 **MR. KLINE:** Okay. We can stretch it  
 16 as large as we can.  
 17 Okay. Viewable.  
 18 **BY MR. KLINE:**  
 19 **Q. Sir, do you see it in front of you on your**  
 20 **screen?**  
 21 A. Okay.  
 22 **Q. Yes?**  
 23 **We both have the document. And I**  
 24 **think it's called out on the screen as well for your**  
 25 **convenience.**

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1 A. Yeah, yeah, yeah.  
 2 **Q. It says, "However, the controversy remains.**  
 3 **Should we be emphasizing prolactin levels per se or**  
 4 **their so-called consequences? All of the prolactin**  
 5 **literature in pediatrics and with oral RIS in adults**  
 6 **suggests there is no correlation of levels to AEs."**  
 7 **Do you see that?**  
 8 A. Yes.  
 9 **Q. "Further, most patients see an increase in**  
 10 **prolactin levels, but FEW ever see so-called related**  
 11 **symptoms."**  
 12 **Do you see that?**  
 13 A. Yes.  
 14 **Q. Next paragraph, let's put that one down and**  
 15 **put the next paragraph up.**  
 16 **[Reading]: "The Global Prolactin**  
 17 **Task Force research efforts being led by Gahan."**  
 18 Let me stop there for a minute.  
 19 Were the Prolactin Task Force  
 20 research efforts, were they being led by Gahan  
 21 Pandina?  
 22 A. Yes.  
 23 **Q. [Reading]: "Will start to provide some**  
 24 **definitive data, but not seen enough to resolve the**  
 25 **issue for APA."**

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1 **What's APA?**  
 2 A. APA is the American Psychiatry of --  
 3 Association. American Psychiatry Association.  
 4 **Q. [Reading]: "We are meeting with an expert in**  
 5 **endocrinology from Harvard, Dr. Klibanski."**  
 6 A. Klibanski.  
 7 **Q. "Klibanski on May 8th but, again" -- and if we**  
 8 **can highlight this part, till the end of the**  
 9 **sentence to talk about -- "this will not help us**  
 10 **resolve the appropriate message emphasis in time."**  
 11 **Do you see that?**  
 12 A. Yes.  
 13 **Q. Were you aware of this e-mail? Did you**  
 14 **receive this e-mail?**  
 15 A. Well, I must have received it because I was on  
 16 the copy list.  
 17 **Q. Okay. And does that document talk about a**  
 18 **"message emphasis," sir?**  
 19 A. That talks about a message emphasis, yes.  
 20 **Q. Okay. And also the next sentence, if we pull**  
 21 **that down and pull the next sentence up.**  
 22 Do you see the sentence [reading]:  
 23 "This is very" -- all caps -- "important poster for  
 24 both Consta and" -- and let's highlight -- "the  
 25 future of the franchise."

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1 A. Yes.  
 2 **Q. See that?**  
 3 **You received this e-mail, correct?**  
 4 A. Yes.  
 5 **Q. Do you recall responding to it, sir?**  
 6 A. That I don't recall, no.  
 7 **Q. Okay.**  
 8 A. But here now I understand what you mean by  
 9 "franchise," which is not what you've said.  
 10 **Q. Sir, "this is very important for the future of**  
 11 **the franchise." Do you see that?**  
 12 A. So that's not the Risperdal franchise.  
 13 **Q. What franchise is that?**  
 14 A. Franchise is a cluster of -- of products, not  
 15 only risperidone, but also paliperidone, for  
 16 example, and potential future other antipsychotics.  
 17 So that's a group of products in psychiatry. So a  
 18 psychiatry franchise has several products. It has  
 19 Risperdal, Invega, Concerta.  
 20 Now I understand what you mean and  
 21 what this "franchise" means, yes.  
 22 **Q. Paliperidone, that's Invega, which is a form**  
 23 **of risperidone, correct?**  
 24 A. It's not a form of risperidone, no. It's a  
 25 separate molecule.

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1 **Q. The fact of the matter is, the "Franchise," by**  
 2 **your definition, is the antipsychotic franchise of**  
 3 **Janssen, correct?**  
 4 A. In this case, that is, but I --  
 5 **Q. Is that correct?**  
 6 A. Yeah, this is the antipsychotic franchise, you  
 7 would call it like this.  
 8 **Q. Right. Right. Capital F, correct? That's**  
 9 **how it's written there?**  
 10 A. What the capital F means, I'll leave that up  
 11 to the writer. I haven't written this, huh.  
 12 **Q. Yeah. It's written to you, correct?**  
 13 A. It was written to a range of people, including  
 14 myself, yes.  
 15 **Q. Okay. Now, sir, let's move back in time.**  
 16 **By the way, sir, Risperdal is not a**  
 17 **wonder drug, correct?**  
 18 A. It's not a one-year drug?  
 19 **Q. Wonder drug. Wonder drug.**  
 20 A. I don't call any drug a "wonder drug."  
 21 **Q. Yeah, that's right. And you've said so in**  
 22 **writing, correct?**  
 23 A. I'm not sure whether I said it in writing, but  
 24 I would be surprised if I ever had used that word.  
 25 **Q. Okay. You would be surprised if you ever used**

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1 **the word?**  
 2 A. Say again.  
 3 **Q. You would be surprised if you ever used the**  
 4 **word?**  
 5 A. Yeah. I wouldn't -- you know, I wouldn't be  
 6 inclined to use that word, but...  
 7 **Q. Okay. Well, let's look at exhibit -- let's**  
 8 **mark the next exhibit. When you say you're not**  
 9 **inclined to use the word -- P-93.**  
 10 **THE COURT:** One second, Mr. Kline.  
 11 Just for the record, the actual  
 12 content of that e-mail that you asked  
 13 Dr. Caers a question on, that's going to be  
 14 marked P-92-A.  
 15 **MR. KLINE:** Okay. Thank you, Your  
 16 Honor.  
 17 - - -  
 18 (Exhibits P-92-A and P-93 marked for  
 19 identification.)  
 20 - - -  
 21 (Pause.)  
 22 - - -  
 23 **MR. KLINE:** We're just getting the  
 24 document, Your Honor.  
 25 Did we hand one to the witness?

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1 **THE COURT:** I have P-93.  
 2 **MR. KLINE:** Yes. P-93.  
 3 **THE COURT:** One second, please.  
 4 **MS. SULLIVAN:** And, Your Honor, this  
 5 is the subject of the manuscript discussion,  
 6 which I think Your Honor has ruled on.  
 7 **THE COURT:** Well --  
 8 **MR. KLINE:** It just goes to the  
 9 question --  
 10 **THE COURT:** Who wrote this article?  
 11 Who wrote this e-mail?  
 12 **MR. KLINE:** Caers, Ivo Caers. And he  
 13 said he doesn't use the word "wonder drugs,"  
 14 and I simply wanted to point it out to him  
 15 that he used it.  
 16 **THE COURT:** All right. It's  
 17 permitted. P-93 is permitted.  
 18 **MR. KLINE:** It's the only purpose of  
 19 it.  
 20 **THE COURT:** For that purpose.  
 21 **BY MR. KLINE:**  
 22 **Q. Sir, do you see the drug -- we don't need to**  
 23 **display it. Do you see the e-mail?**  
 24 A. I think what you -- I think I know what you  
 25 refer to. But just to have the real text, I would

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1 need to see it, you know.  
 2 **COURT CRIER:** He doesn't have it.  
 3 **BY MR. KLINE:**  
 4 **Q. My question is simply: In the e-mail, did you**  
 5 **say antipsychotics are not wonder drugs? Yes or no,**  
 6 **sir?**  
 7 A. I write here, indeed, that atypical  
 8 antipsychotics are not wonder drugs. And --  
 9 **Q. That's my question. Do they say -- the**  
 10 **dialogue we had was about whether you used the word**  
 11 **"wonder drugs." You said that's not words that you**  
 12 **use.**  
 13 A. But this is now an exact example of how you  
 14 tweak --  
 15 **Q. I have a question pending.**  
 16 A. No, no, no -- how you tweak the truth. I --  
 17 we --  
 18 **MR. KLINE:** Your Honor, may I --  
 19 **THE COURT:** No. He's allowed to  
 20 answer.  
 21 **THE WITNESS:** How you see it --  
 22 **BY MR. KLINE:**  
 23 **Q. Okay. We'll talk about the truth, sir.**  
 24 A. You bring up a document and I can't comment on  
 25 it? Okay.

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1 So what I say here, guys, the way  
 2 this manuscript is written sounds like two -- and I  
 3 used the words: It lacks fair balance and a  
 4 critical view. It sounds rather like a sales piece.  
 5 Atypical antipsychotics are not wonder drugs.  
 6 And what you try to make the jury  
 7 understand --  
 8 **Q. No, sir.**  
 9 A. -- is that I used the word "wonder drug" for  
 10 antipsychotics. I just said they are not wonder  
 11 drugs.  
 12 **Q. That's --**  
 13 A. Unfortunately -- unfortunately, they should  
 14 always be used with caution.  
 15 That's the truth, okay? Now we can  
 16 continue.  
 17 **Q. That's the point that I was going to make with**  
 18 **you, sir.**  
 19 A. Well --  
 20 **Q. The point was --**  
 21 A. No.  
 22 **Q. -- you don't know what point I was going to**  
 23 **make.**  
 24 A. Well, I hope you know that I'm making --  
 25 **THE COURT:** No, no.

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1 **MS. SULLIVAN:** Your Honor, this is  
 2 argument. Objection.  
 3 **THE COURT:** Overruled.  
 4 **BY MR. KLINE:**  
 5 **Q. Sir, when you were in front of the FDA -- when**  
 6 **you were in front of the FDA, were you a partisan**  
 7 **like you are in this courtroom? Yes or no?**  
 8 **MS. SULLIVAN:** Objection. Objection,  
 9 Your Honor.  
 10 **THE COURT:** Overruled. Overruled.  
 11 **BY MR. KLINE:**  
 12 **Q. Yes or no. When you're in front of the FDA,**  
 13 **are you a partisan like you are in this courtroom?**  
 14 **Yes or no?**  
 15 A. That's -- that's more a discussion between  
 16 scientists.  
 17 **Q. Are you -- that's not my question.**  
 18 A. No.  
 19 **Q. Are you a partisan; that is, you are for the**  
 20 **drug and you're going to convince the FDA --**  
 21 A. That's not how it works.  
 22 **Q. Okay. Let me show this right up to the jury,**  
 23 **okay?**  
 24 A. Yeah, show it. You should really do that.  
 25 **Q. Let's look at P-93. P-93, and many more --**

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1 A. Sure.

2 **Q. -- about wonder drugs.**

3 **Sir, the fact of the matter is -- the**

4 **fact of the matter is, on this document, on this**

5 **particular document, you, Ivo Caers, was criticizing**

6 **one of your people who had written a manuscript,**

7 **correct?**

8 A. I was making comments, yes.

9 **Q. You were making?**

10 A. Comments.

11 **Q. Comments.**

12 A. Yes.

13 **Q. Yes.**

14 **Well, you were criticizing them?**

15 A. Yes.

16 **Q. You were criticizing them because -- and this**

17 **is a point I wanted to get to -- you were**

18 **criticizing them because you said that the**

19 **manuscript -- a manuscript is a --**

20 A. That's --

21 **Q. No. I didn't ask a question yet. I had a**

22 **pause. I had a pause.**

23 **Do you have something to say before**

24 **the question?**

25 A. (No response.)

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1 **Q. If so, say it.**

2 A. Go ahead.

3 **Q. You view this, sir, as a battle, don't you?**

4 A. Oh, not at all.

5 **MS. SULLIVAN:** Objection, Your Honor.

6 Objection. This is argumentative.

7 **THE COURT:** All right. That's

8 sustained.

9 **MS. SULLIVAN:** And --

10 **THE COURT:** That's sustained.

11 Mr. Kline, why don't you just -- a

12 little bit to the side and behind.

13 **MS. SULLIVAN:** Thank you, Your Honor.

14 **THE COURT:** Unless -- you want to put

15 up P-93, you can.

16 **MR. KLINE:** Not yet. Not yet.

17 **THE COURT:** All right.

18 **BY MR. KLINE:**

19 **Q. You were criticizing -- see if you can agree**

20 **with a word -- you were criticizing a manuscript,**

21 **what was supposed to be or look like an academic**

22 **manuscript; correct so far?**

23 A. Yes.

24 **MS. SULLIVAN:** Objection, Your Honor.

25 You just asked him --

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1 **BY MR. KLINE:**

2 **Q. And you were telling --**

3 **THE COURT:** Overruled.

4 **MS. SULLIVAN:** Your Honor, you just

5 asked Mr. Kline to step back and he's back

6 where --

7 **MR. KLINE:** I was told I can stand

8 here.

9 **THE COURT:** He can stay right where

10 you're supposed to be, or behind.

11 **BY MR. KLINE:**

12 **Q. Sir, you don't know the questions that are in**

13 **my head, do you?**

14 A. I -- I would be surprised.

15 **Q. The fact of the matter is that you, sir, were**

16 **appropriately being critical of someone who made a**

17 **manuscript, an academic manuscript, look like a**

18 **sales pitch, correct?**

19 A. That is exactly what this mail says.

20 **Q. And that's because someone on the team was**

21 **overzealous and was trying to make the drug look**

22 **better than you thought it was, correct?**

23 A. Overzealous, I don't know that word, but

24 basically that's it, yes.

25 **Q. Yes. You don't know that word, but that's it.**

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1 **Now, the fact of the matter is, you**

2 **thought -- you thought -- if I could get my question**

3 **out -- that the person was trying to make it look**

4 **like a wonder drug, correct?**

5 A. Yes.

6 **Q. And you said antipsychotics aren't wonder**

7 **drugs, correct?**

8 A. That's what I apparently said, yes.

9 **Q. And that's because there is an incentive**

10 **sometimes for people to want to make things look**

11 **better than they are, and that's what you were**

12 **criticizing here, correct?**

13 A. Yes. Whether that's an incentive for people

14 making things better than they are, that's

15 debatable.

16 **Q. And now what you said -- if I can have an**

17 **opportunity to show you the document and the jury**

18 **the document and conduct an examination like we do**

19 **in courtrooms --**

20 **MS. SULLIVAN:** Objection, Your Honor,

21 to the argument.

22 **MR. KLINE:** Here's what --

23 **THE COURT:** Well --

24 **MR. KLINE:** Here's what it said.

25 **MS. SULLIVAN:** Objection.

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1 **THE COURT:** You know what, that's  
 2 sustained. But, you know, obviously we are  
 3 in a courtroom. We are not in a science lab.  
 4 That's true.  
 5 **MR. KLINE:** Thank you, Your Honor.  
 6 **BY MR. KLINE:**  
 7 **Q.** Now, let's put it up. Now let's see what it  
 8 says, like I planned to do.  
 9 **Bates -- it's P-93 -- JJRE01991724.**  
 10 **(Document displayed.)**  
 11 **BY MR. KLINE:**  
 12 **Q.** Now, first of all, you sent the e-mail to this  
 13 person Nynke, N-Y-N-K-E, correct?  
 14 A. Yeah.  
 15 **Q.** Please find my comments attached. You say  
 16 Dear Nynke, N-Y-N-K-E?  
 17 A. Yes.  
 18 **Q.** Who is Nynke?  
 19 A. That's a medical writer.  
 20 **Q.** Medical writer. Not even in the company,  
 21 correct?  
 22 A. No. It's an agency that serves -- that does  
 23 medical writing for companies.  
 24 **Q.** Yeah. Some of these articles, like the one  
 25 that was being written here, aren't even written by

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1 **Janssen, correct?**  
 2 A. They are written in -- in -- how do you call  
 3 that? Well, they are agencies hired by Janssen to  
 4 write.  
 5 **Q.** What do you call them usually, sir? You call  
 6 them something writers. What do you call them?  
 7 A. Medical writing agencies.  
 8 **Q.** Medical writing agencies, I see.  
 9 **And the medical writing agencies**  
 10 **write some of these articles, correct?**  
 11 A. They write -- they do the writing, yes.  
 12 **Q.** Yeah.  
 13 **The scientists at Janssen don't even**  
 14 **write the articles. They're written by outside**  
 15 **medical writing agencies, correct?**  
 16 A. Yeah. But they are written under the  
 17 supervision and subject to the final approval of the  
 18 Janssen scientists, obviously.  
 19 **Q.** My question wasn't that, sir. My question  
 20 was: They're written and drafted by outside  
 21 companies, correct?  
 22 A. By outside medical writers, yes.  
 23 **Q.** And here -- do you know this lady? Is it a  
 24 lady or a man, by the way? Maybe I'm making a  
 25 presumption. Nynke.

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1 A. I wouldn't know whether it's a lady or not. I  
 2 don't know.  
 3 **Q.** "Please find my comments attached."  
 4 "This manuscript lacks fair balance  
 5 and critical view. Sounds rather like a sales  
 6 piece," correct?  
 7 A. Yes.  
 8 **Q.** And this was something called the pediatric  
 9 positioning paper, correct?  
 10 A. That I don't remember exactly on what this --  
 11 I think it was a review article rather than a  
 12 pediatric positioning paper, but --  
 13 **Q.** Sir, look right below. "Dear Team, please  
 14 find the first draft of the so-called pediatric  
 15 positioning paper."  
 16 A. Okay. That's an internal terminology, then,  
 17 yes.  
 18 **Q.** All you had to do was look right below to know  
 19 what it was, correct?  
 20 A. Okay.  
 21 **Q.** If they say it, then you'd agree with it,  
 22 correct?  
 23 **MS. SULLIVAN:** Objection, Your Honor.  
 24 That's argument.  
 25 **BY MR. KLINE:**

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1 **Q.** If your own team says the words, then you  
 2 agree, correct? Yes or no?  
 3 A. That's --  
 4 **THE COURT:** The objection is  
 5 overruled. You may answer that.  
 6 **THE WITNESS:** That's an internal name  
 7 given for that planned manuscript.  
 8 **BY MR. KLINE:**  
 9 **Q.** Okay. So we can call it that, correct?  
 10 A. That's fair.  
 11 **Q.** You wouldn't criticize me for calling it that?  
 12 A. No; that's fair.  
 13 **Q.** A positioning paper?  
 14 A. Yep.  
 15 **Q.** It positions the drug to get approved,  
 16 correct?  
 17 A. Well, products don't get approved based on a  
 18 positioning paper, huh.  
 19 **Q.** Sir, a positioning paper is one of the steps  
 20 that's taken to get the drug approved, correct? Yes  
 21 or no?  
 22 A. Not correct.  
 23 **Q.** Now, what you say here is "sounds like a sales  
 24 piece."  
 25 A. Yes.

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1 **Q. "Atypical antipsychotics are not wonder drugs**  
2 **in this population and should always be used with**  
3 **some caution." Do you see that?**  
4 A. Yes.  
5 **Q. Antipsychotic drugs in children should not**  
6 **only be used with some caution, sir, they should be**  
7 **used with great caution. Can you and I agree on**  
8 **that?**  
9 A. Well, that's a matter of terminology. It's  
10 important --  
11 **Q. Can we agree to that terminology?**  
12 A. Well, this is my language. It should be used  
13 with some caution.  
14 **Q. Okay. And you even go further to criticize.**  
15 **"The description of the studies is very sloppy." Do**  
16 **you see that?**  
17 A. Yes.  
18 **Q. "Substantial changes are needed." Do you see**  
19 **that?**  
20 A. Yes.  
21 **Q. "Best regards"?**  
22 A. Yes.  
23 **Q. "Ivo."**  
24 **Now, let's look at -- now, sir, I**  
25 **want to jump ahead to an e-mail from January 29,**

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1 **2004, okay.**  
2 **You remember seeing the term about**  
3 **messaging before in an e-mail, sir?**  
4 A. That may be, yeah.  
5 **Q. There were discussions all the time back and**  
6 **forth with you and your team about the key messages,**  
7 **correct?**  
8 A. That may be, yes.  
9 **Q. Because the key message is important to**  
10 **getting approval, correct?**  
11 A. No. Key messages has nothing to do with  
12 approval.  
13 **Q. Key message is important to making sure that**  
14 **the drug is well accepted, correct?**  
15 A. Key messages are what are the key messages on  
16 this product in this area. Has nothing to do with  
17 approvals.  
18 **Q. Oh, it's an advocacy statement; can we agree?**  
19 A. No. It's an as-fair-as-possible summary on  
20 what this product really stands for.  
21 **Q. What does the word "message" mean in English,**  
22 **sir?**  
23 A. Message means that --  
24 **Q. A message?**  
25 A. -- that is something that I want to bring over

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1 to another person.  
2 **Q. Now, you were involved with the -- you were**  
3 **involved in the period around January of 2004,**  
4 **correct, sir?**  
5 A. Involved in what?  
6 **Q. Let me show you an e-mail, sir.**  
7 **January 29, 2004. Let's talk about**  
8 **this e-mail.**  
9 **Let's just go to documents. See if**  
10 **you agree or disagree.**  
11 **COURT CRIER: It's 94. P-94.**  
12 **MR. KLINE: Yes. P-94.**  
13 **THE COURT: Is there an objection to**  
14 **this?**  
15 **MS. SULLIVAN: I'm sorry, no**  
16 **objection.**  
17 **THE COURT: Okay.**  
18 **MR. KLINE: Okay.**  
19 - - -  
20 (Whereupon Exhibit P-94 was marked  
21 for identification.)  
22 - - -  
23 **BY MR. KLINE:**  
24 **Q. It's an e-mail. Let's discuss it before we**  
25 **display it, sir.**

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1 A. That's fine.  
2 **Q. I had a smile.**  
3 **THE COURT: Have you had a chance to**  
4 **read it?**  
5 **THE WITNESS: Yes. I now --**  
6 **BY MR. KLINE:**  
7 **Q. Did you review it before you came to court?**  
8 **Is this one of the documents they showed you?**  
9 A. No.  
10 **Q. No?**  
11 A. (Shaking head.)  
12 **Q. By the way, sir, how many times have you**  
13 **testified in this litigation so far?**  
14 A. This testifying in court or all depositions?  
15 **Q. Depositions, too.**  
16 A. Five.  
17 **Q. Five?**  
18 A. Yeah, plus ones in court.  
19 **Q. And what states, sir?**  
20 A. South Carolina.  
21 **Q. Yeah. Where else?**  
22 A. Depositions, that was not for particular  
23 states, as far as I remember.  
24 **Q. Did lawyers fly over to Belgium to even take**  
25 **your deposition?**

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1 A. I think I've been over here three times in  
 2 Philadelphia, perhaps even four. And once they flew  
 3 over to Limburg for the deposition, yes.  
 4 **Q. Now, sir, you state here -- this is an e-mail**  
 5 **from Greg Panico.**  
 6 **Who's Greg Panico?**  
 7 A. Greg Panico is, I think, at that time within  
 8 Janssen US responsible for public relations.  
 9 **Q. Public relations, hmm.**  
 10 **And you're on the e-mail, correct?**  
 11 A. Yes, I am.  
 12 **Q. Public relations are people in the company; do**  
 13 **you interact with them often?**  
 14 A. Not very often.  
 15 **Q. But sometimes?**  
 16 A. Yes.  
 17 **Q. Like here?**  
 18 A. Yes.  
 19 **Q. Now, let's see, what was going on in January**  
 20 **of 2004? Just give me, if you would, a sentence or**  
 21 **two, what was going on?**  
 22 A. That was during the review process of the FDA,  
 23 the review process of the autism submission. And as  
 24 I said yesterday, I think, one of the steps in an  
 25 approval process by the FDA is sometimes a public

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1 advisory board where the FDA asks experts in the  
 2 field to come together to review with them all data  
 3 and to advise them on whether they would advise the  
 4 FDA to, yes or no, approve this compound. So, in  
 5 other words, whether the compound would be safe and  
 6 effective in the proposed indication.  
 7 **Q. All I'm --**  
 8 A. That --  
 9 **Q. All I'm asking you is what was going on, sir,**  
 10 **in a sentence or two. That was the question.**  
 11 **THE COURT:** Well, that was the  
 12 answer, Mr. Kline.  
 13 You may move on, please.  
 14 **THE WITNESS:** And there's one --  
 15 **MR. KLINE:** One more thing?  
 16 **THE WITNESS:** One additional.  
 17 **MR. KLINE:** Oh, okay. Go ahead. One  
 18 more thing.  
 19 **THE WITNESS:** These advisory panels  
 20 are in the public domain and capture a lot of  
 21 press coverage. So, consequently, we needed  
 22 to be prepared for questions from journalists  
 23 and press in order to -- and who would attend  
 24 that advisory committee and who would raise  
 25 questions to the company. And that's what

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1 this is about.  
 2 **BY MR. KLINE:**  
 3 **Q. Anything else it was about?**  
 4 A. Not to my knowledge, because it --  
 5 **Q. Whenever -- whenever you're -- whenever I can,**  
 6 **I will then ask you about the e-mail.**  
 7 **All right. Now, so the PR people are**  
 8 **talking about what the key messages should be at**  
 9 **this public meeting, correct? That's what this is**  
 10 **all about?**  
 11 A. No, no, no. No, no, no.  
 12 This is -- these are the anticipated  
 13 issues that following the advisory panel, which,  
 14 once again, is in the public domain, that  
 15 journalists may bring up and raise questions on.  
 16 **Q. Yes. Okay.**  
 17 **And here were the key issues. It**  
 18 **says -- let's get the document up. JJRE0109688.**  
 19 **(Document displayed.)**  
 20 **BY MR. KLINE:**  
 21 **Q. And it says here on November 21, we had a very**  
 22 **productive session.**  
 23 **Simple question, sir, which will take**  
 24 **a yes or a no: Were you at that session?**  
 25 A. I don't know.

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1 **Q. [Reading]: To lay out the various public**  
 2 **issues that are likely to be associated with the**  
 3 **autism finding [sic].**  
 4 **As a follow-up to that meeting, we**  
 5 **will be organizing a session to anticipate -- first**  
 6 **of all, it says J&J PRDs.**  
 7 **What's J&J PRDs?**  
 8 A. At that moment the research organization was  
 9 called Johnson & Johnson Pharmaceutical Research and  
 10 Development.  
 11 **Q. And Janssen top-line position. What does he**  
 12 **mean by top-line position, if you know, as you**  
 13 **understood it then?**  
 14 A. Well, that means that -- those are our company  
 15 positions on a whole range of things that  
 16 journalists may raise.  
 17 **Q. And here are anticipated issues. Let's block**  
 18 **out the anticipated issues here.**  
 19 **One of the anticipated issues at the**  
 20 **advisory committee meeting was side effects,**  
 21 **immediate and long term. Do you see that, sir?**  
 22 A. Yes.  
 23 **Q. And a second thing that would be raised was**  
 24 **chemical straitjacket. Do you see that?**  
 25 A. Yes.

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1 **Q. That's because you knew that the FDA**  
 2 **previously used that language, "chemical**  
 3 **straitjacket," as it pertained to Risperdal,**  
 4 **correct?**  
 5 A. Yes; but not for autism.  
 6 **Q. It used the term "chemical straitjacket" in**  
 7 **connection with the drug, correct?**  
 8 A. Yes.  
 9 **Q. Thank you.**  
 10 A. And this is not in anticipation of the FDA  
 11 using this. This is in anticipation of journalists  
 12 using this term.  
 13 **Q. Yeah, journalists.**  
 14 **Well, journalists would have to get**  
 15 **their knowledge from someplace, correct?**  
 16 A. Well, they attend a meeting and then they pick  
 17 up a whole range of things.  
 18 **Q. Yeah.**  
 19 A. And they may have questions.  
 20 **Q. And you thought that one thing they might pick**  
 21 **up at that meeting is the word "chemical**  
 22 **straitjacket" might come up, correct?**  
 23 A. That might come up, but that might also come  
 24 up in the question of the journalist without it  
 25 being used during the advisory committee, obviously.

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1 Because this is not -- the FDA has not a monopoly on  
 2 the straitjacket. That's an old concept. That is  
 3 in the literature for many, many, many years now.  
 4 **Q. Yes. Chemical straitjacket is a term that's**  
 5 **in the medical literature for many years. But I was**  
 6 **only asking you about whether it had been used with**  
 7 **respect to the drug Risperdal. Yes or no, sir?**  
 8 A. Well, it --  
 9 **Q. Yes or no?**  
 10 A. No. No. It has been used for many years  
 11 regarding antipsychotics in general. And since  
 12 Risperdal is an antipsychotic, it could be used when  
 13 you talk about Risperdal, that's fair.  
 14 **Q. '97, the FDA used the term as it applied,**  
 15 **correct?**  
 16 A. That was in the feedback on conduct disorder,  
 17 as we discussed yesterday, yes.  
 18 **Q. Right.**  
 19 **The kid has -- by the way, you're**  
 20 **really familiar with this drug, correct?**  
 21 A. (No response.)  
 22 **Q. You're very familiar with the drug, correct?**  
 23 A. Well, I better be.  
 24 **Q. Yeah.**  
 25 **If a kid takes the drug and then has**

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1 **his head on the table, just like head on the table,**  
 2 **is that a chemical straitjacket, sir?**  
 3 A. No.  
 4 **Q. Yes or no?**  
 5 A. No.  
 6 **Q. No?**  
 7 A. No.  
 8 **Q. Hmm.**  
 9 **Okay. And then you knew that there**  
 10 **would be objections. And one of the objections --**  
 11 **it's right here -- as far as you knew, that some of**  
 12 **the problems were prolactin levels; do you see that?**  
 13 A. Yes.  
 14 **Q. And gynecomastia, correct?**  
 15 A. Yes.  
 16 **Q. Yeah.**  
 17 **Now let me go to another document.**  
 18 **This is the same time period, only a**  
 19 **little earlier.**  
 20 **And, by the way, sir, as far as**  
 21 **Janssen Pharmaceuticals went, your goal, correct me**  
 22 **if I'm wrong, from 2003 to 2005, if there were an**  
 23 **ultimate goal, it was to get the drug approved by**  
 24 **the FDA, correct?**  
 25 A. It was the objective to get the drug approved

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1 for autism with the FDA --  
 2 **Q. Yes.**  
 3 A. -- because it was already approved.  
 4 **Q. I know that. It was to get the drug**  
 5 **approved -- let me ask a question that is formulated**  
 6 **correctly, maybe even scientifically.**  
 7 **It was a -- it was the goal of**  
 8 **Janssen to get the drug approved by the FDA for the**  
 9 **indication of irritability in autism; can we agree?**  
 10 A. In children and adolescents with autism.  
 11 **Q. Now, there's an e-mail in January 2004.**  
 12 **And, by the way, during this entire**  
 13 **time period, every time that it was being used in a**  
 14 **child or an adolescent, every time it was being used**  
 15 **off-label, correct?**  
 16 A. Correct, in this country, yes.  
 17 **Q. Yes. That's all that this trial is about --**  
 18 A. Sure.  
 19 **Q. -- this country and the warning in this**  
 20 **country.**  
 21 A. Yeah.  
 22 **Q. And, by the way, what you displayed earlier,**  
 23 **let's see if I can do a half an hour in two minutes**  
 24 **or one minute.**  
 25 **In 2006 the label said -- let's see**



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1 if we can just basically agree on three points.  
 2 In 2006 the label said --  
 3 October 2006, the label said that the gynecomastia  
 4 rate was 2.3 percent, correct? Yes or no?  
 5 A. Yes; in children and adolescents.  
 6 Q. Thanks; in children and adolescents.  
 7 Prior to that time, that information  
 8 was not in the label; can we agree?  
 9 A. That's correct.  
 10 Q. In 2006 the label said that there was a study  
 11 that showed that prolactin levels increased  
 12 49 percent versus 2 percent in a placebo, that is to  
 13 say, 25 times to one. That was in the label in  
 14 2006, correct, sir?  
 15 A. That I need to check. I am not sure.  
 16 Q. All right. Then we'll have to make a note and  
 17 we'll come back to that after lunch.  
 18 That was not in the label prior to  
 19 2006; that much you know, correct?  
 20 A. I -- I agree, yes.  
 21 Q. And in 2006, sir, there's a statement that  
 22 prolactin levels increase in this drug at a greater  
 23 rate than any of the other antipsychotics. That  
 24 statement is in the 2006 label, correct?  
 25 A. "A greater rate," I don't think that's the

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1 language.  
 2 Q. Then I'll go to the exact language. We'll  
 3 take the half hour rather than two minutes. I'll go  
 4 back after lunch.  
 5 Now, let's talk about January 8,  
 6 2004.  
 7 On January 8, 2004, sir, you received  
 8 an e-mail from Susan Mallows. Who is Susan Mallows,  
 9 before I display the e-mail?  
 10 A. Susan Mallows at the time was my project  
 11 manager in the team.  
 12 Q. Project manager in the team, okay.  
 13 Were there various project managers  
 14 over the years for Risperdal for child and  
 15 adolescent?  
 16 A. No, no. There was only one program -- project  
 17 manager in the team, but there were various  
 18 different people all over the years.  
 19 Q. Is the project manager of the team the number  
 20 two?  
 21 A. Well, we don't count in teams in that way. A  
 22 team is a team. And it is -- yes.  
 23 Q. Did she report directly to you, sir? And was  
 24 she the second person?  
 25 A. That has been -- no, she is not the second

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1 person. She -- but to answer your question, there  
 2 had been years that they reported to me in a adult  
 3 line. There had been years that they reported to me  
 4 in a full line. And there had been years that they  
 5 did not report to me at all.  
 6 Q. How about here in 2004?  
 7 A. That I should -- I need to check that.  
 8 Q. Where would you need to go to check that?  
 9 A. That's a good question.  
 10 Q. Now, this is right about the time -- this is  
 11 about the time that you're going -- you're going to  
 12 have this meeting that we described, correct?  
 13 A. Which meeting do you refer to?  
 14 Q. This is January of 2004.  
 15 A. Which meeting do you refer to? This meeting  
 16 or --  
 17 Q. Let's show the e-mail. Let's show the e-mail.  
 18 THE COURT: We may be getting tired  
 19 at this point, everybody here. So a few more  
 20 minutes and we'll --  
 21 MR. KLINE: Yes.  
 22 THE COURT: I think we were looking  
 23 at P-95 to remind the witness as to what  
 24 meeting we're talking about; is that the  
 25 right document?

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1 MR. KLINE: Your Honor, I'm going to  
 2 withdraw asking him about the meeting because  
 3 I just am tired out.  
 4 THE COURT: All right.  
 5 MR. KLINE: I'm just not going to ask  
 6 him. I'm going to go to a document. I got a  
 7 lot to do here. I'm just tired out.  
 8 THE COURT: All right. So why don't  
 9 we -- well, go ahead, then, for a few more  
 10 minutes, please.  
 11 MR. KLINE: Please. I'd appreciate  
 12 it. I'd appreciate it very much.  
 13 THE COURT: Well, which subject do  
 14 you want to go back to with the documents?  
 15 MR. KLINE: I'm going to P-95.  
 16 Did we mark it?  
 17 MR. GOMEZ: We did.  
 18 MR. KLINE: Did we put it in front of  
 19 him?  
 20 MS. SULLIVAN: Do you have a copy for  
 21 me?  
 22 MR. KLINE: Please put a copy in  
 23 front of him. He's on the e-mail. Let's see  
 24 if there's an objection. I'll ask him some  
 25 questions.

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1 (Exhibit P-95 marked for  
2 identification.)  
3 (Handing document to the witness.)  
4 **BY MR. KLINE:**  
5 **Q. This is an e-mail. It follows another e-mail.**  
6 **It's forwarding an e-mail with an attachment is**  
7 **what's going on here.**  
8 A. Uh-huh. Yes.  
9 **Q. So you would have seen this document, sir --**  
10 A. Yes.  
11 **Q. -- correct?**  
12 A. Yes.  
13 **Q. What is an issues management workshop?**  
14 **Let's -- let's look at the document.**  
15 A. Yes. So that's --  
16 **Q. I don't have a question, sir. I don't have a**  
17 **question, honestly.**  
18 A. So what question do you have?  
19 **Q. I would like to look at the document and ask**  
20 **you specific questions, most of which can be**  
21 **answered yes or no.**  
22 **THE COURT:** All right. So, Doctor,  
23 why don't you look at this document, read it  
24 over.  
25 Both pages or just one page? Is it a

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1 two-page document?  
2 **MR. KLINE:** No. I don't need the  
3 first page because he's acknowledged that he  
4 received the e-mail and the attachment. I'd  
5 now like to look at the attachment, which is  
6 JJRE04242471.  
7 **THE COURT:** All right. So we're  
8 going to mark that particular page as P-95-A.  
9 And I'm going to ask our witness to take a  
10 look at that, and then put the page over and  
11 ask any questions. If you don't remember it,  
12 then you can look back on this page.  
13 **MR. KLINE:** Okay. I'd like to  
14 display the page.  
15 **THE COURT:** All right. 95-A. Go  
16 ahead.  
17 **MR. KLINE:** Thank you, Your Honor.  
18 **BY MR. KLINE:**  
19 **Q. Do you see the issues management workshop,**  
20 **sir?**  
21 A. Yes.  
22 **Q. Question, yes or no, was there an issues**  
23 **management workshop? Yes or no?**  
24 A. Yes.  
25 **Q. Okay. Was the date November 21, 2003?**

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1 A. Yes.  
2 **Q. Is there a subject line there "objections"?**  
3 A. Yes.  
4 **MR. KLINE:** Oh, it's not displayed,  
5 I'm sorry. JJRE04242471.  
6 Do you have it, Cory? Yes or no?  
7 **VIDEO OPERATOR:** Not at this point.  
8 **MR. KLINE:** You don't have it?  
9 Can you display it on the ELMO for  
10 me?  
11 You think you have it.  
12 Okay.  
13 **BY MR. KLINE:**  
14 **Q. What, sir, without giving a treatise, is the**  
15 **issues management workshop?**  
16 **MS. SULLIVAN:** Objection. Objection,  
17 Your Honor.  
18 **THE COURT:** Objection? That's  
19 sustained. But --  
20 **BY MR. KLINE:**  
21 **Q. In two sentences, tell me what the issue**  
22 **management workshop was.**  
23 A. It's a workshop to prepare the company for  
24 journalist questions following a potential public  
25 advisory board on the autism indication organized by

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1 the FDA.  
2 **Q. And this document came to you, correct?**  
3 A. This came -- I was copied on this, yes.  
4 **Q. Did you attend that workshop?**  
5 A. Once again, I'm not sure. I may have or it  
6 may also have been a telephone conference.  
7 Obviously, we do daily telephone conferences.  
8 **Q. This lists the objections to the drug that**  
9 **were being anticipated, correct, sir? Yes or no?**  
10 A. Yes.  
11 **Q. And one of the objections to the drug was**  
12 **prolactin levels, correct?**  
13 A. Yes.  
14 **Q. And one of the objections to the drug was**  
15 **gynecomastia, correct?**  
16 A. Yes.  
17 **Q. And the anticipated issues, sir, were, among**  
18 **others, chemical straitjacket, correct?**  
19 A. Yes.  
20 **Q. And another thing anticipated, same as the**  
21 **other document, was side effects, immediate and long**  
22 **term, correct, sir?**  
23 A. Yes.  
24 **Q. And then there's a list of allies and**  
25 **adversaries. Do you see that?**

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1 A. Yes.

2 **Q. Do you describe people who might have an**

3 **objection to the drug as an adversary, sir?**

4 A. Well, that's what is done here, yes.

5 **Q. And among the adversaries were some parents,**

6 **correct?**

7 A. Where what?

8 **Q. Parents.**

9 A. Yes.

10 **Q. It says adversaries, parents?**

11 A. Yes.

12 **Q. Adversaries, there were pediatricians who were**

13 **adversaries, correct?**

14 A. Yes.

15 **Q. There were psychologists who were adversaries,**

16 **correct?**

17 A. This is all potential adversaries, obviously.

18 **Q. And there were allies?**

19 A. Yeah.

20 **Q. Parents, psychologists, neurologists,**

21 **pediatricians, teachers, psychologists, correct?**

22 A. Yes.

23 **Q. You could anticipate people on both sides,**

24 **being for and against this drug, correct?**

25 A. Not necessarily for or against this particular

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1 drug, but overall against using drugs in children

2 even.

3 **Q. Yes.**

4 **And in particular a drug which**

5 **someone might say is a chemical straitjacket,**

6 **correct?**

7 A. That is correct.

8 **Q. And a drug that someone might say causes too**

9 **high of a rate of gynecomastia, correct?**

10 A. That might be one of the adversaries'

11 positions, yes.

12 **Q. And a drug that might cause too high levels of**

13 **prolactin, correct?**

14 A. That might be one of the arguments used by the

15 adversaries, yes.

16 **Q. And the people who were against you, the**

17 **people who were against the Janssen Pharmaceutical**

18 **company was, sir -- if we can highlight that word on**

19 **the top -- they would be adversaries, correct?**

20 A. Yes.

21 **MR. KLINE:** Did you want 12:15, Your

22 Honor? It's a good time for me.

23 **THE COURT:** You ready?

24 **MR. KLINE:** I'm ready.

25 **THE COURT:** All right. We'll take a

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1 break right here, okay?

2 So we are in recess till about 1:30.

3 I do have an appointment. So we're going to

4 start no later than quarter of 2:00, but

5 between 1:30 and quarter of 2:00. It's a

6 little later, okay?

7 Same instructions: Yellow badges; do

8 not discuss; open mind; no investigation.

9 And just enjoy lunch, okay?

10 **COURT CRIER:** All rise as the jury

11 exits.

12 - - -

13 (Whereupon the jury exited the

14 courtroom at 12:13 p.m.)

15 - - -

16 (The following transpired in open

17 court outside the presence of the jury:)

18 - - -

19 **THE COURT:** All right. Then just as

20 yesterday, don't talk about this with the

21 lawyers.

22 **THE WITNESS:** Can I ask you one

23 question? Can I talk with some of our people

24 about hotel reservations and things?

25 **THE COURT:** Yes.

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1 **THE WITNESS:** Because I may need to

2 make some changes.

3 **THE COURT:** Yes, of course.

4 **MS. SULLIVAN:** And, Your Honor, I'm

5 going to renew our motion for a mistrial in

6 light of the blatant and intentional

7 violation of the in limine motion on the

8 numbers.

9 **THE COURT:** Is the door closed?

10 **COURT CRIER:** Yes.

11 **MS. SULLIVAN:** The billions of

12 dollars in sales on the drug. That was a

13 blatant and knowing violation of this Court's

14 in limine motion in terms of the sales

15 numbers.

16 **MR. KLINE:** Your Honor, my

17 understanding --

18 **THE COURT:** I don't know. I think I

19 sustained the objection, didn't I?

20 **MR. KLINE:** Yes.

21 **MS. SULLIVAN:** But he said --

22 **MR. KLINE:** But my understanding --

23 **THE COURT:** You want a cautionary?

24 **MS. SULLIVAN:** No, I don't want a

25 cautionary.

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1           **THE COURT:** The difficulty you have  
2           on that point is that Johnson & Johnson is a  
3           known company to the public. So, you know,  
4           it's known as a Fortune 500 company, so  
5           what's the prejudice?  
6           **MS. SULLIVAN:** Your Honor, you had a  
7           specific order, given that there was no  
8           punitive damages in the case and no fraud  
9           claim, about the numbers of dollars in sales  
10          for this medicine. You ruled that that  
11          should be out of this case. It was a knowing  
12          and intentional violation of the Court's in  
13          limine motion.  
14          **THE COURT:** Well, I sustained the  
15          objection.  
16          **MR. KLINE:** Your Honor, may I be  
17          heard for one moment?  
18          **THE COURT:** Yes.  
19          **MR. KLINE:** That is absolutely not  
20          true, and she knows it.  
21          **MS. SULLIVAN:** So --  
22          **MR. KLINE:** This Court specifically  
23          said as to marketing documents, sales and  
24          numbers, and the record will reflect it;  
25          that if the correct witness was there, that

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1           I'd be able to ask questions. And certainly  
2           they have the correct witness here.  
3           And he should be out of the room, by  
4           the way, because he's not part of this.  
5           **THE COURT:** All right. Well, Doctor,  
6           why don't you ask about your hotel situation  
7           in just a couple minutes, one second.  
8           **MR. KLINE:** And in any event, the  
9           objection was sustained.  
10          **THE COURT:** I agree, it was  
11          sustained.  
12          **MR. KLINE:** But the fact of the  
13          matter is it, of course, is relevant. It's,  
14          of course, relevant. They're working on a  
15          billion-dollar franchise drug.  
16          **MS. SULLIVAN:** And, Your Honor --  
17          **MR. KLINE:** And my hands are tied by  
18          not being able to show that all of this  
19          conduct is motivated by them and what they  
20          see and what they know about the use of the  
21          drug, the numbers of kids on the drug and the  
22          like.  
23          **THE COURT:** Well, what -- if we're  
24          going to be getting -- I'd like to resolve  
25          this issue once and for all. So what motion

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1           are we talking about here?  
2           **MS. SULLIVAN:** We'll pull it for Your  
3           Honor, and we'll pull the argument.  
4           **THE COURT:** Okay.  
5           **MS. SULLIVAN:** It was clear.  
6           **THE COURT:** So we'll review it after  
7           lunch.  
8           **MS. SULLIVAN:** Thank you.  
9           **THE COURT:** I know that I sustained  
10          the objection. And I don't see the prejudice  
11          for the reasons I've just stated. Johnson &  
12          Johnson is known to the public as a large  
13          corporation. So I'm not sure what prejudice  
14          yet.  
15          Okay. So we will be in recess  
16          between 1:30, 1:45. 1:45 is what we're  
17          looking for.  
18          **MS. SULLIVAN:** Thank you, Your Honor.  
19          **MR. GOMEZ:** Thank you, Your Honor.  
20          - - -  
21          (Morning session concluded.)  
22          - - -  
23          (Whereupon the Afternoon Session was  
24          reported and transcribed by Judith Ann  
25          Romano, CRR, Official Court Reporter.)

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1           - - -  
2           (Whereupon Exhibits P-96, P-97 and  
3           P-98, handwritten charts on the easel, were  
4           marked for identification by the Court  
5           Crier.)  
6           - - -  
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1 CERTIFICATION

2  
3 I hereby certify that the proceedings  
4 and evidence are contained fully and  
5 accurately in the notes taken by me on the  
6 trial of the above cause, and that this copy  
7 is a correct transcript of the same.

8 I further certify that I am not a  
9 relative or employee of any attorney or  
10 counsel employed in this case.

11  
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21 transcript does not apply to any reproduction  
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**(Jury Trial-Morning Session) - XIII - February 11, 2015  
Pledger v. Janssen**

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