

# TO PLAY IN COURT (Played in Cirba on 2/20/15 and 2/23/15)

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**Binder, Carin 07-17-2013**

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**Our Designations 02:25:45**

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**Their Counters 00:02:38**

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**Total Time 02:28:23**



Page/Line

Source

ID

10:12 - 11:1

**Binder, Carin 07-17-2013 (00:00:34)**

10:12 Q. Good morning, Ms. Binder. My  
10:13 name's Chris Gomez. I represent the plaintiffs in  
10:14 this case. We met before the deposition. How are  
10:15 you today?  
10:16 A. Very well, thank you.  
10:17 Q. We're in Toronto, Canada? Correct?  
10:18 A. We are.  
10:19 Q. Okay. Can you tell the jury what  
10:20 you do for a living.  
10:21 A. I work at Janssen Inc. in Canada,  
10:22 and I am in medical affairs.  
10:23 Q. Okay. What is medical affairs?  
10:24 A. Medical affairs is a department,  
10:25 and currently I am in a director role for medical  
11:1 sciences.

21:22 - 22:11

**Binder, Carin 07-17-2013 (00:00:34)**

21:22 BY MR. GOMEZ:  
21:23 Q. Ms. Binder, I've marked as  
21:24 Exhibit 2 to your deposition today, which looks  
21:25 like a copy of your resume or CV. Does that look  
22:1 familiar to you?  
22:2 A. It does.  
22:3 Q. As you see on your copy in front of  
22:4 you, there's two exhibit stickers, and one was  
22:5 from December 6th through an 11, I think of 2011?  
22:6 Do you remember being deposed in Toronto?  
22:7 A. I do.  
22:8 Q. Has your -- to the best of your  
22:9 ability or recollection, has your CV changed in  
22:10 any way since then? And you can take a second to  
22:11 look at it if you need to.

22:12 - 22:24

**Binder, Carin 07-17-2013 (00:00:39)**

22:12 A. Yes, it has changed.  
22:13 Q. In what way?  
22:14 A. The current position --  
22:15 Q. Hm-hmm?  
22:16 A. -- no longer has "immunology" as  
22:17 part of the portfolio, and I have expanded  
22:18 responsibilities.

Page/Line

Source

ID

22:19 Q. And what are those expanded  
22:20 responsibilities?

22:21 A. I now have a medical sciences  
22:22 four-person team that reports in to me.  
22:23 And the company is Janssen Inc.,  
22:24 not "Janssen-Ortho."

23:22 - 24:8

**Binder, Carin 07-17-2013 (00:00:31)**

23:22 Q. Can you briefly tell the jury about  
23:23 what your educational background is?

23:24 A. I have a bachelors of science in  
23:25 human nutrition, and a masters in business  
24:1 administration.

24:2 Q. Where did you get your masters of  
24:3 business administration?

24:4 A. At Concordia University in  
24:5 Montreal.

24:6 Q. And you're talking -- your  
24:7 undergraduate degree was in nutrition?

24:8 A. Correct.

24:16 - 27:1

**Binder, Carin 07-17-2013 (00:03:25)**

24:16 Did you ever work at a hospital? I  
24:17 think on your CV, I'm not trying to trick you or  
24:18 anything, you worked as a nutritionist in a  
24:19 hospital. Correct?

24:20 A. I did.

24:21 Q. Okay. For how long?

24:22 A. Approximately six years.

24:23 Q. And can you tell the jury what you  
24:24 did as a nutritionist in a hospital?

24:25 A. Hmmm. Yes.

25:1 Q. If you can.

25:2 A. Yes. Essentially we would receive  
25:3 printouts of patients that required special diets,  
25:4 or patients who were being asked to consult with a  
25:5 dietitian, such as patients with diabetes or  
25:6 patients with Crones disease.

25:7 And I would go and read the patient  
25:8 charts, review them, and then speak to the  
25:9 patients themselves to get a food history, and  
25:10 design a plan, a sort of food diet plan to help

Page/Line

Source

ID

25:11 mitigate their symptoms or help them control their  
 25:12 blood sugars or whatever is specific to their  
 25:13 medical condition.

25:14 Q. And you worked at the Royal  
 25:15 Victoria Hospital as a nutritionist?

25:16 A. Correct.

25:17 Q. And that was in 1983 to 1989?

25:18 A. Correct.

25:19 Q. And then after that, you went to  
 25:20 work for Eli Lilly Canada?

25:21 A. Correct.

25:22 Q. And what -- and you were a  
 25:23 "Clinical Research Associate"? What is that?

25:24 A. In those days, it was a person who  
 25:25 worked on designing protocols and studies to  
 26:1 investigate certain aspects of medications, both  
 26:2 pre-launch and post-launch.

26:3 Q. Did you work on the compound  
 26:4 Zyprexa?

26:5 A. I touched it briefly.

26:6 Q. After being a "Clinical Research  
 26:7 Associat[ion]" at Eli Lilly Canada, you became a  
 26:8 "Sales Representative." Correct?

26:9 A. I was a clinical research  
 26:10 associate, and then had a two, two-and-a-half year  
 26:11 stint in sales, and then went back in as clinical  
 26:12 research associate.

26:13 Q. Okay. When you were a sales  
 26:14 representative, what drugs did you detail for Eli  
 26:15 Lilly Canada?

26:16 A. Prozac, Ceclor and Oxid.

26:17 Q. In that time frame at Lilly that  
 26:18 we've just talked about, I believe, according to  
 26:19 your CV, 1990 to 1994, did you ever receive any  
 26:20 medical training from them on the issues of  
 26:21 prolactin?

26:22 A. No.

26:23 Q. And then in 1995, you went to work  
 26:24 as a "Senior ... Research" -- "Senior Clinical  
 26:25 Research Associate" at Eli Lilly Canada. Correct?

Page/Line

Source

ID

28:12 - 29:15 27:1 A. Yes.  
**Binder, Carin 07-17-2013 (00:01:28)**  
28:12 Q. And then you went to work for  
28:13 Janssen-Ortho Inc. in 1996? Is that right?  
28:14 A. Yes.  
28:15 Q. And your title there was a "Senior  
28:16 Medical Development Associate"?  
28:17 A. Yes.  
28:18 Q. Okay. And in 1997 to January 2000,  
28:19 you were a "Clinical Research Manager" at JRF  
28:20 and -- which is Janssen Research Foundation?  
28:21 Correct?  
28:22 A. Yes.  
28:23 Q. And Janssen-Ortho Inc. here in  
28:24 Canada. Correct?  
28:25 A. Correct.  
29:1 Q. In 19 -- let's talk about this time  
29:2 frame, 1997 to 2000. Was it during this time  
29:3 frame that you first became familiar with the five  
29:4 DBD studies?  
29:5 A. Yes.  
29:6 Q. And the -- what are the five DBD  
29:7 studies?  
29:8 A. RIS CAN 19 and 20, RIS INT 45, and  
29:9 I think there were two U.S. studies, and I don't  
29:10 remember their codes.  
29:11 Q. Were the two U.S. studies RIS USA  
29:12 93 and 97?  
29:13 A. That sounds correct.  
29:14 Q. And you said, "RIS INT 45." I  
29:15 think you meant to say 41. Is that correct?  
29:17 - 30:4 **Binder, Carin 07-17-2013 (00:00:21)**  
29:17 BY MR. GOMEZ:  
29:18 Q. You can tell me if I'm wrong.  
29:19 A. I don't know. I don't remember,  
29:20 Mr. Gomez.  
29:21 Q. Okay.  
29:22 A. But there was an international  
29:23 study with Risperdal in CDD and ODD.  
29:24 Q. Right. And we'll talk about

Page/Line

Source

ID

29:25 that --

30:1 A. Okay.

30:2 Q. -- that later. And I represent to

30:3 you that's RIS INT 41.

30:4 A. Okay.

31:21 - 32:21

**Binder, Carin 07-17-2013 (00:01:38)**

31:21 Q. I'm backing up now to the DBD

31:22 studies. I believe you testified that you

31:23 remember becoming involved with them during that

31:24 time frame.

31:25 What specifically do you remember

32:1 about your involvement?

32:2 A. I started in that department when

32:3 the studies were already underway. There were two

32:4 people working on the study, one of whom - maybe

32:5 one of them worked on the study - one of whom

32:6 quit, and I had to hire someone else to replace

32:7 them.

32:8 And then moving forward, I remember

32:9 having a results meeting with the Canadian

32:10 physicians and being involved with the U.S. team

32:11 in terms of meetings about data, as well as people

32:12 from Janssen around the world.

32:13 Q. The -- would it be fair to say that

32:14 the -- of the DBD studies, during this time frame,

32:15 and we're speaking about 1997 to January 2000, you

32:16 were most involved with the Canadian studies, RIS

32:17 CAN 19 and RIS CAN 20?

32:18 A. That would be correct.

32:19 Q. And would it be fair to say that

32:20 you were working on a manuscript specifically on

32:21 those papers or specifically on RIS CAN 19?

33:3 - 33:10

**Binder, Carin 07-17-2013 (00:00:21)**

33:3 THE WITNESS: Do I remember working on

33:4 RIS CAN 19 as a manuscript? Barely.

33:5 BY MR. GOMEZ:

33:6 Q. What -- I'm sorry, are you

33:7 finished?

33:8 A. Yes. So I do remember that. And I

33:9 also remember on RIS CAN 20, having input into

Page/Line

Source

ID

33:10 that manuscript.

33:11 - 34:11 **Binder, Carin 07-17-2013 (00:01:40)**

33:11 Q. And then in January 2000 to

33:12 May 2000, you were a "Senior Clinical Research

33:13 Manager" at JRF, Janssen-Ortho Inc., according to

33:14 your CV. Correct?

33:15 A. Right.

33:16 Q. And then in May 2000 to

33:17 September 2001, you were "Associate Director -

33:18 CNS, Clinical Affairs." Correct?

33:19 A. Correct.

33:20 Q. What part of Janssen did you work

33:21 for?

33:22 A. Janssen-Ortho Inc.

33:23 Q. And then September 2001 to

33:24 January 2008, you were "Director [of] Medical

33:25 Affairs [in] CNS." Correct?

34:1 A. Correct.

34:2 Q. And you spoke at advisory boards,

34:3 according to your CV?

34:4 A. Correct.

34:5 Q. What's an advisory board?

34:6 A. It is when a group of experts are

34:7 gathered together to provide input in terms of

34:8 what data means to them, in terms of data gaps to

34:9 be identified, and it's generally a way of

34:10 obtaining feedback and input at times on the

34:11 clinical program that the company may have.

34:12 - 34:16 **Binder, Carin 07-17-2013 (00:00:13)**

34:12 Q. When you say, "what data means,"

34:13 are you speaking about Janssen safety data or

34:14 clinical trial data?

34:15 A. It would be data -- clinical trial

34:16 based data.

35:3 - 35:13 **Binder, Carin 07-17-2013 (00:00:36)**

35:3 Q. Would it be fair to say that

35:4 Janssen, meaning Janssen in the United States,

35:5 Janssen in Belgium, Janssen in Canada, when they

35:6 had an advisory board, they would present clinical

35:7 trial data, whether it be safety data or efficacy

Page/Line

Source

ID

35:8 data, to a group of experts invited by those  
 35:9 Janssen entities to the advisory board to solicit  
 35:10 opinions from the experts on the significance of  
 35:11 the data or how to get the word on the data out  
 35:12 through publication or manuscripts? Is that a  
 35:13 fair assessment?

35:17 - 35:18

**Binder, Carin 07-17-2013 (00:00:04)**

35:17 THE WITNESS: For the advisory boards  
 35:18 that I participated in, yes.

36:11 - 36:25

**Binder, Carin 07-17-2013 (00:00:39)**

36:11 Q. You are not a medical doctor.

36:12 Correct?

36:13 A. Correct.

36:14 Q. You are not an endocrinologist.

36:15 Correct?

36:16 A. Correct.

36:17 Q. Ever prescribe medications as a --

36:18 you're not a psychiatrist. Right?

36:19 A. Correct.

36:20 Q. Any specific training on prolactin

36:21 and side effects from it? At any time during your

36:22 career.

36:23 A. If the question is have I been

36:24 trained by my local operating company on prolactin

36:25 or side effects, the answer is no.

37:21 - 38:7

**Binder, Carin 07-17-2013 (00:00:34)**

37:21 Q. Have you written more than five

37:22 articles in your career on Risperdal?

37:23 A. I would have to check --

37:24 Q. Please do.

37:25 A. -- the...

38:1 On Risperdal specifically on the

38:2 data, also an article that incorporates Risperdal

38:3 amongst other antipsychotics.

38:4 Q. Specifically as to Risperdal in

38:5 children and adolescents, how many articles have

38:6 you written?

38:7 A. I've been involved as an author.

38:8 - 38:13

**Binder, Carin 07-17-2013 (00:00:13)**

38:8 Six.



Page/Line

Source

ID

38:9 Q. I'm sorry, six?

38:10 A. Six.

38:11 Q. Okay. And that includes the

38:12 Findling 2003 article?

38:13 A. Yes.

38:14 - 38:14

**Binder, Carin 07-17-2013 (00:00:03)**

38:14 MR. GOMEZ: Let me mark as an exhibit 3.

38:15 - 39:10

**Binder, Carin 07-17-2013 (00:00:58)**

38:15 (Whereupon the above-mentioned

38:16 document was marked for

38:17 identification as Exhibit 3.)

38:18 THE WITNESS: Thank you.

38:19 MR. GOMEZ: Sorry, Ken.

38:20 MR. MURPHY: No problem. Thanks.

38:21 BY MR. GOMEZ:

38:22 Q. Okay. Ms. Binder, I've marked as

38:23 Exhibit 3 an article, a journal article entitled,

38:24 "Prolactin Levels During Long-Term Risperidone

38:25 Treatment in Children and Adolescents." Do you

39:1 see that at the top?

39:2 A. Yes.

39:3 Q. Okay. You are listed as an author?

39:4 Correct?

39:5 A. Correct.

39:6 Q. Okay. I'm going to ask you some

39:7 questions about the authors. Who is Robert L.

39:8 Findling, M.D.?

39:9 A. He is a U.S. physician that, if I

39:10 recall correctly, is a child psychiatrist.

39:11 - 39:19

**Binder, Carin 07-17-2013 (00:00:25)**

39:11 Q. Do you respect him?

39:12 A. Yes.

39:13 Q. Did you ever tell him in your

39:14 career, whether on this article or any other

39:15 article, what to write?

39:16 A. No.

39:17 Q. Did you ever find that he was a,

39:18 for lack of a better word, a pushover, that his

39:19 opinions could be swayed?

39:22 - 40:9

**Binder, Carin 07-17-2013 (00:00:32)**

Page/Line

Source

ID

39:22 THE WITNESS: Not in my recollection.

39:23 BY MR. GOMEZ:

39:24 Q. As we sit here before we get into  
39:25 the details of the article, we're going to be  
40:1 talking about a comparison between children with  
40:2 elevated prolactin levels and children with normal  
40:3 prolactin levels and the side effects that they  
40:4 went on to develop during the course of the  
40:5 studies, the five studies that were the basis of  
40:6 this article.

40:7 On that specific issue, do you  
40:8 remember ever telling Dr. Findling to take  
40:9 anything out of the article?

40:12 - 41:1

**Binder, Carin 07-17-2013 (00:00:43)**

40:12 THE WITNESS: I do not.

40:13 BY MR. GOMEZ:

40:14 Q. Do you remember any discussions  
40:15 with Dr. Findling as the lead author on that issue  
40:16 of prolactin elevation and side effects like  
40:17 gynecomastia?

40:18 A. I remember we had discussions as a  
40:19 group.

40:20 Q. Do you remember any discussions as  
40:21 a group specifically with Dr. Findling where the  
40:22 issue -- the data was discussed comparing kids  
40:23 with elevated prolactin levels with normal levels  
40:24 at different time intervals throughout the study,  
40:25 according to the statistical analysis, and any  
41:1 discussions to not include certain comparisons?

41:4 - 41:8

**Binder, Carin 07-17-2013 (00:00:26)**

41:4 THE WITNESS: So I remember discussions  
41:5 about the data, and that there were a lot of  
41:6 requests to analyze the data, looking at different  
41:7 parameters; and as a final outcome, the authors  
41:8 agreed to what was in the publication.

41:19 - 44:11

**Binder, Carin 07-17-2013 (00:04:22)**

41:19 Q. Do you remember in your role as an  
41:20 author of this article prior to publication  
41:21 changing the statistical analysis plan?

41:22 A. I do not.

Page/Line

Source

ID

41:23 Q. Who is Vivek Kusumakar, M.D.?  
41:24 A. Vivek was a child and adolescent  
41:25 psychiatrist that was located in Canada, and I  
42:1 think he was an investigator on one of the -- RIS  
42:2 CAN 19 study.  
42:3 Q. Okay. Dr. Denis Daneman?  
42:4 A. Is a pediatric endocrinologist in  
42:5 Toronto.  
42:6 Q. Okay. And Thomas Moshang, who is  
42:7 he, Dr. Thomas Moshang?  
42:8 A. A pediatric endocrinologist in the  
42:9 United States.  
42:10 Q. Drs. Daneman and Moshang do not  
42:11 work for Janssen -- did not work for Janssen at  
42:12 any time?  
42:13 A. That is my understanding.  
42:14 Q. Goedele De Smedt, who is she,  
42:15 Dr. Goedele De Smedt?  
42:16 A. She was located in Belgium, and  
42:17 worked on the RIS CAN 19 and potentially other  
42:18 studies.  
42:19 Q. Looking at the document in front of  
42:20 you, the article, the small text to the left in  
42:21 the column on the left, that's the abstract?  
42:22 A. That is the abstract, yes.  
42:23 Q. Okay. And under the "Background,"  
42:24 it says, "This analysis was designed to  
42:25 investigate prolactin levels in children and  
43:1 adolescents on long-term risperidone treatment and  
43:2 explore any relationship with side effects  
43:3 hypothetically attributable to prolactin," and  
43:4 then in parentheses, there's an acronym, "(SHAP)."  
43:5 Do you see that? Did I read that  
43:6 correctly?  
43:7 A. I see it, and you did read it  
43:8 correctly.  
43:9 Q. Okay. When it says, "explore any  
43:10 relationship," what does that mean?  
43:11 A. Based on brainstorming with the  
43:12 clinicians, and their recommendations as to what

Page/Line

Source

ID

43:13 might impact prolactin levels, the statistician  
 43:14 would then develop the analysis to answer their  
 43:15 questions.  
 43:16 Q. The analysis or the questions on  
 43:17 the direct -- I mean on prolactin elevation in  
 43:18 SHAP, that was one relationship that was going to  
 43:19 be looked at in this paper. Correct?  
 43:20 A. That was the hypothesis, was to  
 43:21 look at prolactin and whether or not there was an  
 43:22 association with side effects.  
 43:23 Q. And was there?  
 43:24 A. From what I remember, there did not  
 43:25 appear to be.  
 44:1 Q. Why write this article to look at  
 44:2 the relationship between elevated prolactin levels  
 44:3 and things like gynecomastia?  
 44:4 A. Because the physicians in those  
 44:5 days were very interested in what happens to  
 44:6 prolactin over time.  
 44:7 The studies were designed in a  
 44:8 vulnerable population, which are children and  
 44:9 adolescents. And as part of due diligence, they  
 44:10 wanted to explore what was happening and should  
 44:11 they have a concern.

45:16 - 45:25

**Binder, Carin 07-17-2013 (00:00:25)**

45:16 Q. And one of the reasons why it was  
 45:17 written was to inform clinicians. Correct?  
 45:18 A. The paper was written to inform  
 45:19 clinicians about --  
 45:20 Q. Do you know...  
 45:21 A. ...about whether there is an  
 45:22 association with elevated prolactin and the impact  
 45:23 it might have on children and adolescents.  
 45:24 Q. As you sit here today, was there a  
 45:25 commercial purpose to the paper?

46:3 - 46:3

**Binder, Carin 07-17-2013 (00:00:01)**

46:3 THE WITNESS: There was not.

46:13 - 46:15

**Binder, Carin 07-17-2013 (00:00:12)**

46:13 Q. Should the -- should a manuscript  
 46:14 like the 2003 Findling article ever be written

Page/Line

Source

ID

46:15 with the purpose of helping increase sales?  
 46:17 - 46:19 **Binder, Carin 07-17-2013 (00:00:07)**  
 46:17 THE WITNESS: My viewpoint is that  
 46:18 articles should be written to advance medicine and  
 46:19 science.

46:21 - 46:25 **Binder, Carin 07-17-2013 (00:00:10)**  
 46:21 Q. Sticking with the abstract, you  
 46:22 agree with me that -- you would agree with me that  
 46:23 the abstract is generally the first place -- the  
 46:24 first place a clinician will go when looking at an  
 46:25 article --

47:8 - 48:17 **Binder, Carin 07-17-2013 (00:02:24)**  
 47:8 THE WITNESS: I can't speak to where a  
 47:9 clinician would go in general. They may flip  
 47:10 directly to the "RESULTS" section.  
 47:11 BY MR. GOMEZ:  
 47:12 Q. So some may go to the "RESULTS"  
 47:13 section, some may read the abstract.  
 47:14 A. Some may. Some may read the  
 47:15 discussion.  
 47:16 Q. Who is Miklos Schultz?  
 47:17 A. He is the owner of a company that  
 47:18 provides statistical and data management services,  
 47:19 or he was in those days.  
 47:20 Q. And he worked for Scian in --  
 47:21 A. My understanding is he owned Scian,  
 47:22 he was the founder of Scian.  
 47:23 Q. And Ann Leung, did I pronounce that  
 47:24 correctly?  
 47:25 A. I don't know.  
 48:1 Q. If you look in the top of the  
 48:2 second column, there's a -- the authors thank  
 48:3 Miklos Schultz and Ann Leung.  
 48:4 A. Ann Leung. Okay.  
 48:5 Q. Okay. Did she work for Scian?  
 48:6 A. I don't remember her name; however,  
 48:7 it looks like it.  
 48:8 Q. Who is Brainworks?  
 48:9 A. Brainworks was a company that  
 48:10 provided services; amongst other things, pulling

Page/Line

Source

ID

48:11 together scientific meetings and medical writing.

48:12 Q. How come Brainworks isn't listed

48:13 under the description of the authors in this

48:14 article?

48:15 A. I don't know.

48:16 Q. What did you write as a part of

48:17 this -- being an author in this article?

48:20 - 49:12

**Binder, Carin 07-17-2013 (00:00:57)**

48:20 THE WITNESS: It's like 12 or 13 years

48:21 ago. I don't recall what I wrote specifically.

48:22 However, I would have checked it from an editorial  
48:23 perspective.

48:24 BY MR. GOMEZ:

48:25 Q. When you say, "from an editorial

49:1 perspective" --

49:2 A. Hm-hmm.

49:3 Q. -- can you explain that?

49:4 A. Typos, double checking the stats

49:5 tables, prepositions, does the sentence -- is the

49:6 sentence clear, does it convey what the authors

49:7 want it to convey.

49:8 Q. Would it be fair to say that

49:9 Janssen and Johnson & Johnson wanted this article

49:10 to convey that there was no direct correlation

49:11 between prolactin elevation and SHAP before it was

49:12 written?

49:15 - 49:25

**Binder, Carin 07-17-2013 (00:00:42)**

49:15 THE WITNESS: What happened is that the

49:16 Canadian physicians were asking about the data,

49:17 and that I undertook to see if we could answer

49:18 their questions.

49:19 BY MR. GOMEZ:

49:20 Q. Okay. I don't think you answered

49:21 my question.

49:22 MR. GOMEZ: Can you read the question

49:23 back, please?

49:24 (The record was read back by the reporter.)

49:25 BY MR. GOMEZ:

50:4 - 50:19

**Binder, Carin 07-17-2013 (00:01:02)**

50:4 THE WITNESS: This paper was not

Page/Line

Source

ID

50:5 conceived and driven by Janssen Canada or Janssen  
50:6 or Johnson & Johnson.

50:7 BY MR. GOMEZ:

50:8 Q. Who conceived or drove the article?

50:9 A. The concept was conceived by the  
50:10 clinicians.

50:11 Q. Which ones?

50:12 A. It started off with Richard Snyder,  
50:13 Atilla Turgay, various other physicians that have  
50:14 participated in the studies, Dr. Findling, Stan  
50:15 Kutcher, Vivek Kusumakar. So a plethora of  
50:16 physicians asked the question.

50:17 Q. Asked what question?

50:18 A. What happens to children who have  
50:19 an elevated prolactin level.

50:20 - 51:4

**Binder, Carin 07-17-2013 (00:00:32)**

50:20 Q. In the abstract, the sentence in  
50:21 the last section of the "Results" section, "There  
50:22 was no direct correlation between prolactin  
50:23 elevation and SHAP." Do you see that?  
50:24 A. I do.

50:25 Q. Is that an accurate statement?

51:1 A. I would have to reread the article.  
51:2 However, if this is what was written, it was the  
51:3 authors deciding that based on their data review,  
51:4 this is accurate.

52:1 - 52:5

**Binder, Carin 07-17-2013 (00:00:13)**

52:1 get a clean question. Were you aware that in  
52:2 December 2012, Dr. Daneman testified that the  
52:3 statement in the abstract that "There was no  
52:4 direct correlation between prolactin elevation and  
52:5 SHAP" is inaccurate?

52:18 - 52:18

**Binder, Carin 07-17-2013 (00:00:01)**

52:18 A. No.

54:4 - 54:19

**Binder, Carin 07-17-2013 (00:00:53)**

54:4 Q. Let's go to page 1364. I have a  
54:5 brief question.  
54:6 Under the section "Outcome  
54:7 Measures," in the second paragraph, last sentence,  
54:8 it reads, "The normal ranges used by Quest

Page/Line

Source

ID

54:9 Diagnostics were used to define the upper limit of  
54:10 normal (ULN) for male and female patients in this  
54:11 analysis. For males, the ULN for serum prolactin  
54:12 was 18 ng/mL, and for females, it was 30 ng/mL."

54:13 Did I read that correctly?

54:14 A. Yes.

54:15 Q. Do you -- as we sit here and

54:16 looking at the final published version of this

54:17 paper, do you have any memory of the threshold for

54:18 abnormal in boys changing in terms of the

54:19 statistical analysis?

54:22 - 55:9

**Binder, Carin 07-17-2013 (00:00:35)**

54:22 THE WITNESS: No.

54:23 BY MR. GOMEZ:

54:24 Q. Specifically you do not remember

54:25 being informed that instead of using 30 as a

55:1 cutoff for normal versus abnormal, you were going

55:2 to use 18 in boys.

55:3 A. I do not recall that.

55:4 Q. Do you recall ever telling the

55:5 authors in an e-mail that you had -- the

55:6 statistical analysis had been rerun using 18 as a

55:7 normal in boys, and that the analysis had not

55:8 changed in terms of the issue of any correlation

55:9 between elevated prolactin levels and SHAP?

55:13 - 55:13

**Binder, Carin 07-17-2013 (00:00:01)**

55:13 THE WITNESS: I do not.

55:23 - 56:6

**Binder, Carin 07-17-2013 (00:00:24)**

55:23 BY MR. GOMEZ:

55:24 Q. Ms. Binder, we're back from the

55:25 break and we're talking about the final published

56:1 version of the 2003 Findling article. Okay? I

56:2 asked you about the normal thresholds for

56:3 prolactin earlier.

56:4 Do you know what type of tests were

56:5 used to compare elevated prolactin and side

56:6 effects like gynecomastia?

56:9 - 56:14

**Binder, Carin 07-17-2013 (00:00:15)**

56:9 THE WITNESS: No.

56:10 BY MR. GOMEZ:



Page/Line

Source

ID

56:11 Q. The relationship between elevated  
56:12 prolactin and gynecomastia, or "SHAP" as the  
56:13 article calls it, what test was used to examine  
56:14 that relationship?

56:17 - 57:13

**Binder, Carin 07-17-2013 (00:01:02)**

56:17 THE WITNESS: It was a statistical  
56:18 analysis.

56:19 BY MR. GOMEZ:

56:20 Q. Okay. What type of statistical  
56:21 analysis?

56:22 A. I don't remember.

56:23 Q. Was it a correlation test?

56:24 A. I don't -- I don't know.

56:25 Q. What are descriptive statistics?

57:1 A. Descriptive statistics just usually  
57:2 describe percentages or numbers. They do not draw  
57:3 an inference as to whether it is clinically or  
57:4 statistically significant.

57:5 Q. A chi-squared analysis, was that  
57:6 test for an association or a relationship and  
57:7 assign to it statistical significance, if there?

57:8 A. I am not a statistician. I don't  
57:9 know.

57:10 Q. Before your deposition today, did  
57:11 you go back and look at any of the statistical  
57:12 manuscript support for this article and look at  
57:13 the statistics?

57:16 - 57:19

**Binder, Carin 07-17-2013 (00:00:05)**

57:16 THE WITNESS: No.

57:17 BY MR. GOMEZ:

57:18 Q. Do you know Gahan Pandina?

57:19 A. I know -- I used to know him, yes.

58:18 - 58:25

**Binder, Carin 07-17-2013 (00:00:32)**

58:18 Q. What is "SHAP(A)" and "SHAP(B)"?

58:19 A. One group included all sorts of  
58:20 sort of side effects that potentially could be  
58:21 attributed to prolactin, as well as other things,  
58:22 such as puberty; and the other group tried to  
58:23 narrow that down to side effects that potentially  
58:24 may be associated or correlated to the prolactin

Page/Line

Source

ID

58:25 elevation.

59:7 - 59:8 **Binder, Carin 07-17-2013 (00:00:05)**

59:7 Q. Is one of the purposes of this

59:8 final paper to compare SHAP(A) and SHAP(B)?

59:11 - 59:14 **Binder, Carin 07-17-2013 (00:00:20)**

59:11 THE WITNESS: I would have to reread the

59:12 paper. The purpose of the data analysis was to

59:13 try to tease out if there was a prolactin

59:14 association to some of these side effects.

60:1 - 61:6 **Binder, Carin 07-17-2013 (00:01:46)**

60:1 Q. The first paragraph, sorry. Can

60:2 you read that sentence to the jury?

60:3 A. "The percentage of patients with

60:4 SHAP was assessed for SHAP(B) patients with

60:5 prolactin levels above the [upper limit of normal

60:6 or] ULN versus patients with prolactin levels

60:7 within the normal range at the various analysis

60:8 time periods."

60:9 Q. Can you read the next sentence,

60:10 please, to end the paragraph.

60:11 A. "There [were] no statistical

60:12 difference..." "There was no," sorry, "was no

60:13 statistical difference in the percentage of

60:14 patients who reported SHAP for any analysis time

60:15 period, whether or not prolactin levels were

60:16 normal or above the [upper limit of normal]

60:17 (range, 1.8%-3.5% with SHAP)."

60:18 Q. The sentence -- the two sentences

60:19 you just read talk about a relationship analysis

60:20 on SHAP(B) patients. Correct?

60:21 A. Correct.

60:22 Q. And according to the paragraph we

60:23 read over there earlier, "SHAP(B), excluded

60:24 additional symptoms that the pediatric

60:25 [endocrinologists] (T.M. and D.D.) attributed to

61:1 puberty." Do you see that?

61:2 A. I do.

61:3 Q. And then it said, "SHAP(A) included

61:4 gynecomastia irrespective of age." Did I read

61:5 that right?

Page/Line

Source

ID

61:6 A. Correct.

69:15 - 70:16 **Binder, Carin 07-17-2013 (00:01:11)**

69:15 Let me ask you to go to

69:16 1368. Are you there?

69:17 A. I am.

69:18 Q. Over in the second column, first

69:19 full paragraph, beginning "Only 13 [of] 592," do

69:20 you see that?

69:21 A. I do.

69:22 Q. Okay. It reads, "Only 13 [of] 592

69:23 (2.2%) of children and adolescents developed

69:24 symptoms hypothetically attributable to prolactin

69:25 (SHAP), with 9 of the 13 showing resolution of

70:1 these symptoms at study end." Did I read that

70:2 correctly?

70:3 A. You did.

70:4 Q. The next sentence reads, "No

70:5 correlation was found between SHAP and prolactin

70:6 levels, even when male gynecomastia during puberty

70:7 was included." Did I read that correctly?

70:8 A. Yes.

70:9 Q. Okay. Is that sentence that I just

70:10 read inaccurate?

70:11 MR. MURPHY: Is that inaccurate?

70:12 MR. GOMEZ: Yes.

70:13 THE WITNESS: Based on the data in here

70:14 and based on what the authors concluded, it's

70:15 accurate.

70:16 BY MR. GOMEZ:

89:2 - 90:24 **Binder, Carin 07-17-2013 (00:02:02)**

89:2 Q. Ms. Binder, I've put in front of

89:3 you Exhibit No. 6, which is an e-mail string.

89:4 Have you seen this e-mail? Did you review this

89:5 e-mail before today?

89:6 A. No, not that I recall.

89:7 Q. If you could go to the e-mail at

89:8 the -- your e-mail dated August 29th, 2001 at the

89:9 bottom, beginning at the bottom on page 1, going

89:10 into page 2?

89:11 A. Yes.

Page/Line

Source

ID

89:12 Q. It's dated August 29th, 2001. That  
89:13 is your e-mail? Correct?  
89:14 A. It has my name on it --  
89:15 Q. Yeah.  
89:16 A. -- correct.  
89:17 Q. And you sent it to Ivo Caers, among  
89:18 others?  
89:19 A. Correct.  
89:20 Q. Okay. Vincent Nys, they're both in  
89:21 Belgium?  
89:22 A. They were.  
89:23 Q. And then you sent it to numerous  
89:24 other Janssen employees. Do you see that?  
89:25 A. I do.  
90:1 Q. Okay? You CCed Dr. Albert Derivan,  
90:2 among others?  
90:3 A. Yes.  
90:4 Q. And the "Subject" was the  
90:5 "prolactin analysis."  
90:6 A. Yes.  
90:7 Q. Do you remember, prior to  
90:8 August 29th, 2001, meeting with Dr. Daneman?  
90:9 A. I don't.  
90:10 Q. Okay. If you can go... You write  
90:11 in the e-mail, "A quick update regarding the  
90:12 prolactin analysis. Rosanna and I met with  
90:13 Dr. Denis Daneman who is a peer of Tom Moshang and  
90:14 a pediatric endocrinologist." Did I read that  
90:15 right?  
90:16 A. Yes.  
90:17 Q. Okay. "Our reasons for meeting  
90:18 with Dr. Daneman were to review the analysis plan  
90:19 and obtain additional validation that the areas  
90:20 Dr. Moshang wished to focus on had a broad appeal  
90:21 not just to ped endos but to answer questions from  
90:22 pediatricians, GPs, etc." Did I read that  
90:23 correctly?  
90:24 A. Yes.

93:25 - 94:3 **Binder, Carin 07-17-2013 (00:00:14)**  
93:25 Q. Do you remember showing

Page/Line	Source	ID
94:4 - 94:7	<p>94:1 Dr. Daneman, prior to August 29th, 2001, "the 16 94:2 cases with gynecomastia etc.," referred to in the 94:3 next paragraph, if you want to take a look at it?</p> <p><b>Binder, Carin 07-17-2013 (00:00:06)</b></p>	<p>*****07172013_PA_02</p>
94:4 - 94:7	<p>94:4 A. And the question is do I remember 94:5 showing him these 16 cases? 94:6 Q. Yes. 94:7 A. I do not.</p>	<p>*****07172013_PA_02</p>
94:10 - 94:12	<p><b>Binder, Carin 07-17-2013 (00:00:06)</b></p> <p>94:10 Do you know what "the 16 cases of 94:11 gynecomastia, etc.," what clinical trial those 94:12 came from?</p>	<p>*****07172013_PA_02</p>
94:15 - 94:20	<p><b>Binder, Carin 07-17-2013 (00:00:18)</b></p> <p>94:15 THE WITNESS: It would be from the trials 94:16 within the databases that we had. I couldn't tell 94:17 you specifically which ones. 94:18 BY MR. GOMEZ: 94:19 Q. Do you remember why you showed 94:20 Dr. Daneman "16 cases with gynecomastia, etc."?</p>	<p>*****07172013_PA_02</p>
94:23 - 95:9	<p><b>Binder, Carin 07-17-2013 (00:00:36)</b></p> <p>94:23 THE WITNESS: In order to get his 94:24 clinical opinion. 94:25 BY MR. GOMEZ: 95:1 Q. The clinical opinion on what? 95:2 A. His clinical opinion in terms of 95:3 what is part of normal puberty and what one would 95:4 expect to see. 95:5 Q. Were you looking for an alternative 95:6 explanation to the "gynecomastia, etc.," other 95:7 than Risperdal? 95:8 A. It was the intent was to show the 95:9 data and get his feedback.</p>	<p>*****07172013_PA_02</p>
95:10 - 95:23	<p><b>Binder, Carin 07-17-2013 (00:00:33)</b></p> <p>95:10 Q. At the bottom of the e-mail, it 95:11 reads, "NEXT STEPS." Okay. "revise stats 95:12 analysis plan and send to statistician (M. Schultz 95:13 in Canada) and obtain raw tables." Did I read 95:14 that right? 95:15 A. Yes. 95:16 Q. "run the data by internal JRF</p>	<p>*****07172013_PA_02</p>

Page/Line

Source

ID

95:17 people and Dr. Daneman for interpretation and  
95:18 approval." Did I read that right?

95:19 A. Yes.

95:20 Q. When you say, "run the data by

95:21 internal JRF people," who are you referring to?

95:22 A. Internal people working for Janssen

95:23 Research Foundation.

96:14 - 96:24

**Binder, Carin 07-17-2013 (00:00:24)**

96:14 BY MR. GOMEZ:

96:15 Q. It says, "If JRF OK with data and

96:16 wishes to publish, hold meeting with Daneman,

96:17 Moshang and child psych to interpret data and

96:18 write up the article. Regards, Carin."

96:19 A. Hm-hmm.

96:20 Q. Did I read that correctly?

96:21 A. You did.

96:22 Q. Does this refresh your recollection

96:23 about, for lack of a better word, the genesis of

96:24 the Findling article, like... Does that help you?

97:2 - 97:2

**Binder, Carin 07-17-2013 (00:00:01)**

97:2 THE WITNESS: No.

97:15 - 98:7

**Binder, Carin 07-17-2013 (00:00:35)**

97:15 Q. Ms. Binder, one quick exhibit and

97:16 then we'll take a break for lunch. This is an

97:17 e-mail that I've marked as Exhibit 7 dated

97:18 December 5th, 2001. Do you see that at the top?

97:19 A. Yes.

97:20 Q. Is that your e-mail?

97:21 A. Yes.

97:22 Q. Okay. And you're sending it to

97:23 Gahan Pandina?

97:24 A. Yes.

97:25 Q. Okay. And Magali Reyes-Harde.

98:1 Correct?

98:2 A. Correct.

98:3 Q. And Vincent Nys is carbon copied?

98:4 A. Yes.

98:5 Q. Okay. Who did you report to in

98:6 this time frame? Like who was your boss?

98:7 A. Fiona Dunbar.

Page/Line

Source

ID

98:22 - 99:6

**Binder, Carin 07-17-2013 (00:00:24)**

98:22 Q. The "Subject" of this e-mail is  
 98:23 "Pediatric prolactin potential meeting."  
 98:24 Just so the jury understands, in  
 98:25 December 2001, was Risperdal indicated to treat  
 99:1 child and adolescents in the United States?  
 99:2 A. I don't know.  
 99:3 Q. Do you know when Risperdal was  
 99:4 first approved to treat children in the United  
 99:5 States?  
 99:6 A. I do not.

99:12 - 99:19

**Binder, Carin 07-17-2013 (00:00:22)**

99:12 Q. If I told you that in late 2006,  
 99:13 Risperdal was approved to treat the symptoms of  
 99:14 irritability associated with autism, does that  
 99:15 refresh your recollection as to when it was first  
 99:16 approved for children in the United States?  
 99:17 A. No.  
 99:18 Q. You worked a lot with the DBD  
 99:19 studies. Correct?

99:22 - 100:8

**Binder, Carin 07-17-2013 (00:00:36)**

99:22 THE WITNESS: Yes.  
 99:23 BY MR. GOMEZ:  
 99:24 Q. Were you aware that Janssen in the  
 99:25 United States was exploring an indication for DBD  
 100:1 or conduct disorder in the spring of 2000?  
 100:2 A. I was aware that Janssen U.S. was  
 100:3 running these registration studies in the hopes of  
 100:4 having a submission to FDA, yes.  
 100:5 Q. Were you aware that in December of  
 100:6 2001, Janssen in the United States already knew  
 100:7 that there wasn't going to be an indication for  
 100:8 conduct disorder or DBD?

100:11 - 100:23

**Binder, Carin 07-17-2013 (00:00:28)**

100:11 THE WITNESS: Not aware. Didn't know.  
 100:12 BY MR. GOMEZ:  
 100:13 Q. You write, "Dear All, Canada is  
 100:14 taking the lead on generating a post hoc  
 100:15 exploratory analysis on the entire pediatric  
 100:16 registration database." Did I read that right?

Page/Line

Source

ID

100:17 A. Yes.

100:18 Q. Okay. Do you -- what is a "post

100:19 hoc exploratory analysis," number one; and number

100:20 who, who told you to do that?

100:21 MR. MURPHY: Who told her to do what?

100:22 MR. GOMEZ: The "post hoc exploratory

100:23 analysis."

101:2 - 101:8

**Binder, Carin 07-17-2013 (00:00:29)**

101:2 THE WITNESS: A post hoc is something

101:3 that happens after the fact. So in this case,

101:4 "post hoc" means after the core analyses are run

101:5 on each individual study.

101:6 "exploratory" means it's hypothesis

101:7 generating. So you have a few hypothesis that

101:8 you're trying to explore by looking at the data.

101:9 - 101:20

**Binder, Carin 07-17-2013 (00:00:26)**

101:9 BY MR. GOMEZ:

101:10 Q. You wrote, "As such in conjunction

101:11 with the global commercial leader Vincent." Is

101:12 that referring to Vincent Nys?

101:13 A. I assume so.

101:14 Q. "we have generated a first draft

101:15 analysis which we wish 2 endos to comment on."

101:16 Did I read that correctly?

101:17 A. Yes.

101:18 Q. Would it be fair to say that when

101:19 you say, "we," you're talking about Janssen in

101:20 Canada and Janssen in the United States?

101:23 - 101:23

**Binder, Carin 07-17-2013 (00:00:01)**

101:23 THE WITNESS: Yes.

102:5 - 103:13

**Binder, Carin 07-17-2013 (00:01:34)**

102:5 Q. Going down one e-mail in the chain,

102:6 Gahan Pandina sent to you on December 4th, 2001,

102:7 along with Magali Reyes-Harde and two others, on

102:8 the "Subject" of "Pediatric prolactin potential

102:9 meeting." Do you see that?

102:10 A. Yes.

102:11 Q. Okay. There's no reason to believe

102:12 you didn't receive this e-mail, based on the fact

102:13 that you are listed as a recipient?



Page/Line

Source

ID

102:14 A. Correct.

102:15 Q. And you most likely read it? Yes?

102:16 A. I would hope so, yes.

102:17 Q. And Dr. Pandina writes, "Megali,"

102:18 "Dear Megali, I was not aware of this meeting.

102:19 [Can] you give me some more information? I am

102:20 happy to support activities in pediatrics, and

102:21 this certainly seems like an appropriate

102:22 opportunity to fund pediatric activities. This

102:23 re-analysis planning is a crucial step for the

102:24 coming year, and I would appreciate being brought

102:25 on board (at least to be made aware of activities)

103:1 so that I can best give feedback (should this be

103:2 desirable)."

103:3 And then he says he will approve

103:4 funding for the attendance of Dr. Moshang in

103:5 reference to the meeting that you were planning.

103:6 Correct?

103:7 A. Yes.

103:8 Q. Okay. Now, why is -- do you know

103:9 what Dr. Pandina means when he wrote to you that

103:10 "This re-analysis," meaning the prolactin

103:11 reanalysis, "planning is a crucial step for the

103:12 coming year"?

103:13 A. No, I don't remember.

104:9 - 104:18

**Binder, Carin 07-17-2013 (00:00:29)**

104:9 Q. Okay. Before we start talking

104:10 about some specific exhibits as to the Findling

104:11 article as we move through the afternoon, I wanted

104:12 to see if you agree with me on a few points

104:13 that... Regarding medical literature.

104:14 Do you agree with me that when

104:15 preparing or developing manuscripts, you should

104:16 never misrepresent clinical research and/or

104:17 clinical trial results, including the fabrication

104:18 or misreporting of data?

104:21 - 105:3

**Binder, Carin 07-17-2013 (00:00:20)**

104:21 THE WITNESS: I agree.

104:22 BY MR. GOMEZ:

104:23 Q. Do you agree that if a

Page/Line

Source

ID

104:24 pharmaceutical company performs a clinical trial  
 104:25 and then publishes the results of that clinical  
 105:1 trial in a medical journal article, that it should  
 105:2 report the negative clinical trial results as well  
 105:3 as the positive? Is that fair?

105:6 - 105:20

**Binder, Carin 07-17-2013 (00:00:23)**

105:6 THE WITNESS: It should be a fair and  
 105:7 unbiased reporting of the data.

105:8 BY MR. GOMEZ:

105:9 Q. And a fair and unbiased reporting  
 105:10 of the data would include both negative and  
 105:11 positive results.

105:12 A. It would.

105:13 Q. All right. It should -- the  
 105:14 medical article should be accurate.

105:15 A. It should be.

105:16 Q. It should be complete. You would  
 105:17 agree?

105:18 A. I would agree.

105:19 Q. And the article should avoid  
 105:20 commercial promotion.

105:23 - 105:23

**Binder, Carin 07-17-2013 (00:00:00)**

105:23 Q. You would agree?

106:1 - 106:3

**Binder, Carin 07-17-2013 (00:00:04)**

106:1 THE WITNESS: It should be, once again,  
 106:2 as discussed, advancing scientific and medical  
 106:3 knowledge.

107:2 - 107:9

**Binder, Carin 07-17-2013 (00:00:19)**

107:2 Q. Okay. "Will there be a manuscript  
 107:3 generated from the weight gain ADHD correlational  
 107:4 analysis? Regards, Carin." Did I read that  
 107:5 correctly?

107:6 A. You did.

107:7 Q. Okay. What was Georges Gharabawi's  
 107:8 role in the Janssen/Johnson & Johnson family of  
 107:9 companies in December of 2001?

107:12 - 108:5

**Binder, Carin 07-17-2013 (00:00:50)**

107:12 THE WITNESS: I'm not entirely clear on  
 107:13 what his role was. However, he was working within  
 107:14 the psychiatry portfolio for the U.S. Janssen

Page/Line

Source

ID

107:15 company in medical affairs.

107:16 BY MR. GOMEZ:

107:17 Q. And he wrote back to you a little

107:18 later that day on December 5th, same people were

107:19 carboned, "Subject," "pediatric analysis."

107:20 "The brand team will need to meet

107:21 and agree on how to spin the message before we put

107:22 together any manuscripts." Did I read that

107:23 sentence right?

107:24 A. You did.

107:25 Q. He wrote, "Further, so far these

108:1 [analysis] were conducted on the US studies. I

108:2 think it will be stronger to replicate the same

108:3 [analysis] on CAN 19 and perhaps conduct a pooled

108:4 analysis. G." Did I read that right?

108:5 A. Yes.

108:8 - 108:18

**Binder, Carin 07-17-2013 (00:00:35)**

108:8 What is the "brand team"?

108:9 A. The "brand team" that Georges in

108:10 the U.S. would be referring to would be the team

108:11 that would work on the brand, and normally a brand

108:12 is a trademarked product name.

108:13 Q. Do you know what he meant when he

108:14 wrote, "The brand team will need to meet and agree

108:15 on how to spin the message before we put together

108:16 any manuscripts"?

108:17 A. I do not know what George meant

108:18 when he said that.

110:14 - 111:12

**Binder, Carin 07-17-2013 (00:00:47)**

110:14 Q. Ms. Binder, Exhibit 9 is an e-mail

110:15 from you on the "Subject" of the "Prolactin expert

110:16 meeting"?

110:17 Did you review this e-mail before

110:18 today?

110:19 A. Not that I recall.

110:20 Q. Okay. Do you remember this -- as

110:21 you sit here today and I just put it in front of

110:22 you, does it refresh your recollection about the

110:23 "Prolactin expert meeting" in January 2002?

110:24 A. Well, it establishes that there was

Page/Line

Source

ID

110:25 an expert meeting held in Toronto, yes.

111:1 Q. What do you generally remember

111:2 about that meeting, if anything?

111:3 A. Very little. Nothing.

111:4 Q. Was it an advise -- was it an

111:5 advisory board?

111:6 A. Can I read the e-mail --

111:7 Q. Please.

111:8 A. -- to answer?

111:9 Q. Yes, absolutely.

111:10 A. Okay.

111:11 Q. Why don't you take a second and

111:12 read it and then I'll ask you some questions.

111:13 - 112:22

**Binder, Carin 07-17-2013 (00:01:08)**

111:13 A. Okay. So then to your question was

111:14 this an advisory board meeting, the answer is no,

111:15 it was not an advisory board meeting.

111:16 Q. I'm sorry, it was what?

111:17 A. It was not an advisory board

111:18 meeting.

111:19 Q. Okay. A few general questions.

111:20 A. Hm-hmm.

111:21 Q. What's an action item?

111:22 A. An action item is something that is

111:23 on the to-do list to be implemented.

111:24 Q. So it'd be fair to say out of this

111:25 prolactin expert meeting --

112:1 A. Hm-hmm.

112:2 Q. -- one of the action items was to

112:3 write up an additional analysis plan and send it

112:4 to the participants of the meeting for review. Is

112:5 that fair?

112:6 A. That is what it states --

112:7 Q. Okay.

112:8 A. -- yes.

112:9 Q. And another action item that you're

112:10 reporting upon in this e-mail was that

112:11 "'Brainworks' has been hired to write the

112:12 manuscript on the results and write an abstract

112:13 and poster for AACAP in October." Did I read that

Page/Line

Source

ID

112:14 right?

112:15 A. Correct.

112:16 Q. Now, Brainworks is a medical

112:17 writing company?

112:18 A. If I remember correctly, they also

112:19 offer other services.

112:20 Q. But we can agree, based on this

112:21 e-mail, Brainworks is going to write the first

112:22 draft. Correct?

113:1 - 113:21

**Binder, Carin 07-17-2013 (00:00:54)**

113:1 THE WITNESS: Yes.

113:2 BY MR. GOMEZ:

113:3 Q. "Authors will include Moshang,

113:4 Daneman, Findling, Kusumakar." Did I read that

113:5 right?

113:6 A. Yes.

113:7 Q. "To discuss inclusion of Janssen

113:8 people as authors." Correct?

113:9 A. Correct.

113:10 Q. Besides -- if you go up to the top,

113:11 the attendees were Dr. Moshang and Dr. Daneman.

113:12 Correct?

113:13 A. Yes.

113:14 Q. And then "2 psychs," Bob -- "B.

113:15 Findling and V. [Kusumakar]." Correct?

113:16 A. Correct.

113:17 Q. Okay. Now that you've read this

113:18 e-mail, does this refresh your recollection as to

113:19 the initial planning for the Findling paper --

113:20 that would become the Findling paper in November

113:21 2003?

114:2 - 114:15

**Binder, Carin 07-17-2013 (00:00:39)**

114:2 A. This was part of the process of

114:3 looking at the data with a view to sharing it.

114:4 Q. Would it be fair to say that you

114:5 were instrumental in spearheading this effort to

114:6 develop a manuscript that looked at the pediatric

114:7 prolactin database?

114:8 A. I was instrumental in championing

114:9 that concept, yes.

Page/Line

Source

ID

114:10 Q. And you were also championing the  
114:11 concept of looking at the relationship between  
114:12 elevated prolactin levels and things like  
114:13 gynecomastia. Fair?

114:14 A. I was championing that based on  
114:15 physicians asking for that information, yes.

119:4 - 121:15

**Binder, Carin 07-17-2013 (00:02:38)**

119:4 MR. GOMEZ: Let me mark as Exhibit 11  
119:5 another e-mail and one-page attachment.

119:6 (Whereupon the above-mentioned  
119:7 document was marked for  
119:8 identification as Exhibit 11.)

119:9 BY MR. GOMEZ:

119:10 Q. And it's -- this is your e-mail  
119:11 again, Ms. Binder?

119:12 A. It says it's from Carin Binder.

119:13 Q. And it's dated Tuesday,  
119:14 February 12th, 2002? Agreed?

119:15 A. Correct.

119:16 Q. And you're sending it to the  
119:17 authors, the eventual authors of the Findling  
119:18 manuscript, among others.

119:19 A. Correct.

119:20 Q. Now, we see Dr. Findling there,  
119:21 Dr. Dunbar, who wrote another article. Correct?

119:22 A. She did.

119:23 Q. Okay. And the "Subject" is "AACAP  
119:24 prolactin abstract," and it's the attachment.

119:25 Correct?

120:1 A. Correct.

120:2 Q. Okay. If you turn the page to the  
120:3 attachment, okay, this -- at the top it says,  
120:4 "ABSTRACT SUBMISSION - PAGE TWO"? Agreed?

120:5 A. It does.

120:6 Q. And the abstract is entitled,  
120:7 "Prolactin levels in children after long term  
120:8 treatment with risperidone." Did I read that  
120:9 right?

120:10 A. Correct.

120:11 Q. In the "Results" section, it reads,

Page/Line

Source

ID

120:12 "Less than 6% of children had prolactin related  
120:13 side effects." Agreed?

120:14 A. It does.

120:15 MR. MURPHY: Sorry, where are you?

120:16 MR. GOMEZ: I'm sorry, in the "Results"  
120:17 section in the box? Do you see it?

120:18 MR. MURPHY: Okay.

120:19 BY MR. GOMEZ:

120:20 Q. And then it reads, "There appeared  
120:21 to be no correlation between prolactin levels and  
120:22 prolactin related side effects." Did I read that  
120:23 correctly?

120:24 A. Yes.

120:25 Q. What is an "ABSTRACT SUBMISSION"?

121:1 A. It's a submission that goes into  
121:2 the conference abstract scientific team for  
121:3 review, and they make a decision as to whether the  
121:4 abstract meets whatever criteria they have set to  
121:5 be accepted, and then to have a full poster or  
121:6 oral presentation presented.

121:7 Q. So in February of 2002, you've  
121:8 already met with the eventual authors of the  
121:9 Findling 2003 article, shown them an analysis plan  
121:10 and asked for comment, and then prepared an  
121:11 abstract with a deadline of February 15th to be  
121:12 shown at AACAP.

121:13 Is that a fair summation of what  
121:14 I've shown you in the last few minutes?

121:15 A. It is.

122:10 - 124:17

**Binder, Carin 07-17-2013 (00:02:30)**

122:10 (Whereupon the below-mentioned  
122:11 document was marked for  
122:12 identification as Exhibit 12.)

122:13 BY MR. GOMEZ:

122:14 Q. I've marked as Binder 12 another  
122:15 exhibit with an attachment. And Ms. Binder,  
122:16 that's your e-mail? Correct?

122:17 A. It has my name on it as a sender,  
122:18 yes.

122:19 Q. And it's dated Friday, March 1st,

Page/Line

Source

ID

122:20 2002? Correct?  
122:21 A. It is.  
122:22 Q. And you're sending to Gahan Pandina  
122:23 an attachment entitled, "Long-term Risperidone vs  
122:24 Prola." We assume that's prolactin. Correct? Do  
122:25 you see the little -- the --  
123:1 A. The little --  
123:2 Q. -- Microsoft Word icon?  
123:3 A. Yes.  
123:4 Q. Okay.  
123:5 A. Yes.  
123:6 Q. And the subject is "RIS-CAN-19/20,  
123:7 RIS-USA-93/97 and RIS-INT-41."  
123:8 A. Yes.  
123:9 Q. Okay. And those are the five DBD  
123:10 studies. Correct?  
123:11 A. Yes.  
123:12 Q. And the attachment you're sending  
123:13 to Gahan Pandina is originally something that was  
123:14 sent to you by Ann Leung at Scian. Correct?  
123:15 A. Yes.  
123:16 Q. And what was she sending to you on  
123:17 February 22nd, 2002?  
123:18 A. So according to the e-mail, it --  
123:19 the file contains tables and graphs for RIS CAN 19  
123:20 and 20, RIS USA 93/97 and RIS INT 41.  
123:21 Q. Let's -- I have a few questions  
123:22 about these documents. If you could go to the  
123:23 Bate stamp and it's JJRE number ending in 014.  
123:24 Are you there?  
123:25 A. Yeah, I am there.  
124:1 Q. And the heading at the top is  
124:2 "Long-Term Risperidone Tx," that's treatment, "vs.  
124:3 Prolactin"?  
124:4 A. Hm-hmm.  
124:5 Q. "Statistical Documentation for  
124:6 Manuscript Support - February 22[nd], 2002."  
124:7 Correct?  
124:8 A. Correct.  
124:9 Q. Okay. The "Objectives" is written



Page/Line

Source

ID

124:10 as "The purpose of this project is to investigate  
 124:11 the relationship between long-term Risperidone  
 124:12 treatment and prolactin levels, and the  
 124:13 association between prolactin-related side effects  
 124:14 and prolactin observations and other predictive  
 124:15 factors such as gender, age and Tanner stage."  
 124:16 Did I read that right?  
 124:17 A. Yes.

124:18 - 124:21

**Binder, Carin 07-17-2013 (00:00:08)**

124:18 Q. The issues -- the "predictive  
 124:19 factors" such as "gender, age and Tanner stage,"  
 124:20 is that something that Dr. Dunbar was writing  
 124:21 about in another manuscript?

125:2 - 125:3

**Binder, Carin 07-17-2013 (00:00:04)**

125:2 THE WITNESS: Yes, she did work on, from  
 125:3 what I recall, Tanner staging.

125:4 - 127:6

**Binder, Carin 07-17-2013 (00:02:25)**

125:4 BY MR. GOMEZ:

125:5 Q. If you could go to Bate stamp  
 125:6 ending in 16.

125:7 A. Yes.

125:8 Q. And the reason I point -- I want  
 125:9 to -- it reads on this page, "In Table 8, the  
 125:10 incidence of prolactin observations > ... 30 ng/mL  
 125:11 is summarized by time period across subsets" a)  
 125:12 and e)? Did I read that...

125:13 MR. MURPHY: "a) through e)."

125:14 MR. GOMEZ: I'm sorry, "a) through e),"

125:15 I'm sorry.

125:16 BY MR. GOMEZ:

125:17 Q. Did I read that right?

125:18 A. Yes.

125:19 Q. And then at -- under the heading  
 125:20 "Documentation of Prolactin-related Side Effects,"  
 125:21 it reads, just down the page a little bit,  
 125:22 "Incidence of prolactin observations [greater or  
 125:23 equal to] 30 ng/mL is summarized in Table 14."

125:24 Correct? Did I read that right?

125:25 A. Yes, you did.

126:1 Q. Okay. Let's go to Table 14, if you

Page/Line

Source

ID

126:2 would, and I believe it's on Bate stamp ending in  
126:3 48? Are you there?

126:4 A. Yes.

126:5 Q. The title of Table 14 is "Incidence  
126:6 of Prolactin Observations [greater or equal to] 30  
126:7 ng/mL [-- rng/mL] in Each Period by  
126:8 Prolactin-related Side Effects."

126:9 And then "PAP - As Observed," and  
126:10 then the "Number" is the percentage of patients.  
126:11 Did I read that right?

126:12 A. You did.

126:13 Q. Okay. And it has two columns here  
126:14 or two... Two columns -- and two titled columns:  
126:15 One entitled "Patients with Side Effects (at any  
126:16 time)"? Correct?

126:17 A. Yes.

126:18 Q. And then one with "Patients without  
126:19 Side Effects." Correct?

126:20 A. Correct.

126:21 Q. And then it looks at different time  
126:22 periods. Right?

126:23 A. Correct.

126:24 Q. "Pre-dose," "Weeks 4 to 7," "Weeks  
126:25 8 to 12," so on down the line to the end at "Weeks  
127:1 52 to 55." Did I read that right?

127:2 A. Yes.

127:3 Q. And it's comparing those who  
127:4 suffered side effects with an elevated prolactin  
127:5 versus those that did not suffer a side effect and  
127:6 looks at elevated prolactin. Correct?

127:9 - 128:2 **Binder, Carin 07-17-2013 (00:01:00)**

127:9 THE WITNESS: Well, it looks at those  
127:10 with or without elevated prolactin levels and the  
127:11 side effects in each category.

127:12 BY MR. GOMEZ:

127:13 Q. And can you tell from just looking  
127:14 at this table whether there was a correlation?

127:15 A. I can't, no.

127:16 Q. If you could turn the page to Table  
127:17 15? And what -- Table 15 is also entitled,

Page/Line

Source

ID

127:18 "Prolactin-related Side Effects," and it's just

127:19 "Patient Data Listing"? Correct?

127:20 A. Correct.

127:21 Q. And it looks at -- would you agree

127:22 with me that this is looking at each individual

127:23 who suffered gynecomastia, among other things; and

127:24 one thing that's being shown is whether or not the

127:25 person recovered from a side effect? Is that

128:1 fair? Do you see that?

128:2 A. That is correct.

128:8 - 128:13

**Binder, Carin 07-17-2013 (00:00:18)**

128:8 BY MR. GOMEZ:

128:9 Q. This is Exhibit 13. Take a second

128:10 and look at that?

128:11 A. Okay.

128:12 Q. Just let me know when you're done

128:13 reviewing it?

128:14 - 130:8

**Binder, Carin 07-17-2013 (00:02:15)**

128:14 A. Okay.

128:15 Q. Sorry, the number on the exhibit is

128:16 13?

128:17 A. It is.

128:18 Q. Okay. Exhibit 13 is another e-mail

128:19 of yours, Ms. Binder? Correct?

128:20 A. Correct.

128:21 Q. And you wrote it on Thursday,

128:22 May 2nd, 2002?

128:23 A. Correct.

128:24 Q. And you were sending it to Vincent

128:25 Nys, Goedele De Smedt, Gahan Pandina, Albert

129:1 Derivan, and the authors of the Findling --

129:2 eventually became the Findling manuscript.

129:3 Correct?

129:4 A. Correct.

129:5 Q. And the "Subject" is "prolactin

129:6 poster-urgent."

129:7 A. Yes.

129:8 Q. Okay. Do you know what "poster"

129:9 you're referring to?

129:10 A. I didn't, and it says in the body,

Page/Line

Source

ID

129:11 "CINP."

129:12 Q. Okay. What's "CINP"?

129:13 A. I don't remember.

129:14 Q. Can you read the first paragraph of  
129:15 your e-mail?

129:16 A. Yes. "As you know in our meeting  
129:17 of Jan[uary] 22[nd], 2002, it was requested that  
129:18 we analyze prolactin data using cutoffs such as <  
129:19 31, >30 [to] 49, 50 [to] 100 etc. This analysis  
129:20 was conducted however the central laboratory used  
129:21 in the trials used a prolactin normal range of 2  
129:22 [to] 18 [nanograms per] ml in boys. In view of  
129:23 the lab normal range - the statistics have been  
129:24 rerun with the new normal ranges. This doesn't  
129:25 change any of the correlations i.e. still no  
130:1 correlation with prolactin levels and EPS, no  
130:2 correlation with prolactin levels and efficacy or  
130:3 side effects attributed to prolactin. What this  
130:4 new analysis does affect is the number of children  
130:5 at weeks 40 [to] 48 whose prolactin is >30 [in]  
130:6 (girls) or 18 [in] (boys). We have 110 children  
130:7 above normal prolactin levels at weeks 40 [to]  
130:8 48."

130:17 - 131:25

**Binder, Carin 07-17-2013 (00:01:29)**

130:17 Q. Ms. Binder, Exhibit 14 is your  
130:18 e-mail?

130:19 A. It is.

130:20 Q. And it's dated Wednesday, May 15th,  
130:21 2002?

130:22 A. It is.

130:23 Q. Who are you sending it to?

130:24 A. Gahan Pandina.

130:25 Q. And who else?

131:1 A. Copy to Megali Reyes-Harde.

131:2 Q. And you had an attachment entitled,  
131:3 "Long-term Risperidone vs Prola[ctin]"? Do you  
131:4 see the icon there?

131:5 A. Yes.

131:6 Q. And can you read what you wrote to  
131:7 Gahan Pandina.

Page/Line

Source

ID

131:8 A. "Hi Gahan, Here are choice selected  
131:9 tables you might like to have slides made for your  
131:10 June 14th meeting. The growth/maturation stuff is  
131:11 still rough and I have a hard copy. Please send  
131:12 me your fax number and I'll fax the 2 main tables  
131:13 to you. Regards, Carin."

131:14 Q. Have you seen this before today?

131:15 A. Not that I recall.

131:16 Q. Okay. But we can tell from this

131:17 e-mail that you would have seen it back in 2002.

131:18 There's no reason to doubt that. Right?

131:19 A. Correct.

131:20 Q. And you would have sent it to Gahan

131:21 Pandina. That's what this e-mail is showing.

131:22 Correct?

131:23 A. That is what it states, yes.

131:24 Q. I want to take your -- point your

131:25 attention to Bate stamp ending in 765 or Table 21.

132:1 - 133:1

**Binder, Carin 07-17-2013 (00:01:16)**

132:1 A. Okay.

132:2 Q. Table 21 is entitled,

132:3 "Prolactin-related Side Effects by Prolactin

132:4 Levels ... at or above Upper Limit of Normal."

132:5 Correct?

132:6 A. Yes.

132:7 Q. And again, this is "Long-Term

132:8 Risperidone [Treatment] vs Prolactin - Statistical

132:9 Documentation for Manuscript Support," and it's

132:10 dated May 15th, 2002. Correct?

132:11 A. Correct.

132:12 Q. What are we looking at here in

132:13 Table 21? Can you tell just by looking at it?

132:14 A. We are looking at, by "Time

132:15 Period," yes/no "Prolactin-related Side Effects"

132:16 potentially, sample size, and if the prolactin is

132:17 considered above the upper limit of normal or

132:18 normal, and statistical testing.

132:19 Q. Okay. And if you go to the bottom,

132:20 it says -- there's an asterisk and it says, "ULN"?

132:21 Do you see that?

Page/Line

Source

ID

132:22 A. Yes.

132:23 Q. It says, "The upper limit of normal  
132:24 for prolactin levels is 18 for males and 30 for  
132:25 females." Correct?

133:1 A. Correct.

133:11 - 133:22 **Binder, Carin 07-17-2013 (00:00:24)**

133:11 Q. Can you go back to 13 --

133:12 A. Okay.

133:13 Q. -- dated Thursday, May 2nd?

133:14 A. Hm-hmm.

133:15 Q. This -- these tables that we're

133:16 looking at in 14 --

133:17 A. Hm-hmm.

133:18 Q. -- okay, is this what you're

133:19 reporting to the authors on May 2nd, that the new

133:20 normal has been changed for boys from 30 to 18 and

133:21 that you've rerun the statistical analysis? Is

133:22 that what you're talking about?

133:25 - 134:1 **Binder, Carin 07-17-2013 (00:00:03)**

133:25 THE WITNESS: Yeah, I mean I don't know.

134:1 It could be.

134:14 - 135:23 **Binder, Carin 07-17-2013 (00:01:21)**

134:14 Q. Your

134:15 e-mail on May 2nd says, "the statistics have been

134:16 rerun with the new normal ranges." Correct?

134:17 A. Correct.

134:18 Q. And the new normal range is 18 for

134:19 boys. Correct?

134:20 A. Yes.

134:21 Q. And you report to them, meaning the

134:22 recipients of this e-mail, some of which are the

134:23 authors of the Findling 2003 manuscript --

134:24 A. Yes.

134:25 Q. -- that the values haven't changed

135:1 and that there is no correlation between elevated

135:2 prolactin and side effects. That's what you're

135:3 telling them. Correct?

135:4 A. Yes.

135:5 Q. Okay. Let's look at the

135:6 statistical table in Exhibit 14, Table 21,

Page/Line

Source

ID

135:7 specifically at "Weeks 8 to 12." Do you see that?

135:8 A. I do.

135:9 Q. And it's saying it looks at

135:10 prolactin and it says, "Above [Upper Limits of

135:11 Normal]," and then it says, "Normal." Do you see

135:12 that, going to the right?

135:13 A. I do.

135:14 Q. And it says 7.8 percent of upper

135:15 limits of normal developed a side effect versus 7

135:16 or 2.9 percent of patients with normal prolactin.

135:17 Agreed?

135:18 A. Yes.

135:19 Q. And the "Chi-Square Test p-Value"

135:20 is .0158. Do you see that?

135:21 A. I do.

135:22 Q. Is that statistically significant?

135:23 A. It is.

136:1 - 136:4

**Binder, Carin 07-17-2013 (00:00:12)**

136:1 No later than May 15th, 2002, you

136:2 would agree that you are aware of a statistically

136:3 significant association between elevated prolactin

136:4 and things like gynecomastia.

136:7 - 136:16

**Binder, Carin 07-17-2013 (00:00:28)**

136:7 THE WITNESS: It would be true for a time

136:8 period, yes.

136:9 BY MR. GOMEZ:

136:10 Q. And that you forwarded that

136:11 information, that there was a statistically

136:12 significant correlation at weeks 8 to 12, that is

136:13 exhibited on Table 21 in this exhibit, to Gahan

136:14 Pandina on May 15th, 2000.

136:15 A. So I forwarded all of the tables to

136:16 Gahan, yes.

136:17 - 137:9

**Binder, Carin 07-17-2013 (00:00:41)**

136:17 Q. And one more question about these

136:18 statistical tables. Looking where it talks about,

136:19 on Bate stamp ending in 765, there's nothing down

136:20 there when it's discussing prolactin related side

136:21 effects and their classifications about not

136:22 counting kids over the age of 10. You would

Page/Line	Source	ID
	136:23 agree?	
	136:24 A. That is correct --	
	136:25 Q. So this is --	
	137:1 A. -- I agree.	
	137:2 Q. I'm sorry, I didn't mean to	
	137:3 interrupt you.	
	137:4 A. No, I'm just -- just reading there,	
	137:5 it doesn't say anything about greater than the age	
	137:6 of 10, no.	
	137:7 Q. So this is an all-inclusive	
	137:8 analysis of everybody in the study, regardless of	
	137:9 age. Correct?	
137:12 - 137:12	<b>Binder, Carin 07-17-2013 (00:00:01)</b>	BINDER_07172013_PA_02
	137:12 THE WITNESS: It would appear to be.	
138:15 - 138:20	<b>Binder, Carin 07-17-2013 (00:00:16)</b>	BINDER_07172013_PA_02
	138:15 BY MR. GOMEZ:	
	138:16 Q. So we're up to May of 2002. Do you	
	138:17 remember, as you sit here today, when the first	
	138:18 draft of this article, this manuscript that	
	138:19 eventually would become the Findling paper, was	
	138:20 drafted?	
138:23 - 139:4	<b>Binder, Carin 07-17-2013 (00:00:20)</b>	BINDER_07172013_PA_02
	138:23 THE WITNESS: I do not.	
	138:24 BY MR. GOMEZ:	
	138:25 Q. You would expect to see in the	
	139:1 first draft of an article that is based on	
	139:2 statistical documentation as support a discussion	
	139:3 of the statistically significant correlation at	
	139:4 weeks 8 to 12. Agreed?	
139:7 - 139:21	<b>Binder, Carin 07-17-2013 (00:00:34)</b>	BINDER_07172013_PA_02
	139:7 THE WITNESS: I would expect to see in	
	139:8 the article what the primary end point is that was	
	139:9 selected for the analysis.	
	139:10 BY MR. GOMEZ:	
	139:11 Q. Okay. What does that mean?	
	139:12 A. So that is is the analysis run over	
	139:13 one week as an end point, is it run over six weeks	
	139:14 as an end point, is it run over a year as an end	
	139:15 point.	
	139:16 Q. If the purpose of the paper is to	



Page/Line

Source

ID

139:17 look for any relationship between elevated  
 139:18 prolactin and things like gynecomastia or SHAP,  
 139:19 okay, we would expect to see this statistically  
 139:20 significant relationship discussed somewhere in  
 139:21 the manuscript. Is that fair?

139:24 - 140:14

**Binder, Carin 07-17-2013 (00:00:40)**

139:24 THE WITNESS: Okay. I would have to go  
 139:25 back to the exhibit that has the analysis plan in  
 140:1 it to see what the primary analysis is.  
 140:2 And if I understand -- if I  
 140:3 remember correctly, the primary analysis was over  
 140:4 a one-year time frame; i.e., 48 weeks.  
 140:5 BY MR. GOMEZ:  
 140:6 Q. Okay. If the primary analysis --  
 140:7 A. Hm-hmm.  
 140:8 Q. -- time frame is over 48 weeks --  
 140:9 A. Yes.

140:10 Q. -- and the purpose of the paper is  
 140:11 to explore any relationship between elevated  
 140:12 prolactin and side effects like gynecomastia, you  
 140:13 would expect to see all relationships discussed  
 140:14 somewhere in the manuscript. Would you agree?

140:17 - 140:19

**Binder, Carin 07-17-2013 (00:00:07)**

140:17 THE WITNESS: I would expect to see  
 140:18 discussed the clinical interpretation of the data  
 140:19 over the time frame that was studied.

141:10 - 141:17

**Binder, Carin 07-17-2013 (00:00:23)**

141:10 Q. Ms. Binder, just to back up a  
 141:11 moment, in February of 2002, I showed you some  
 141:12 statistical tables from that time frame. Do you  
 141:13 remember seeing those just a moment ago?  
 141:14 A. I do.  
 141:15 Q. And a abstract was written in mid  
 141:16 February 2002 based on those tables. Would you  
 141:17 agree?

141:20 - 141:23

**Binder, Carin 07-17-2013 (00:00:03)**

141:20 THE WITNESS: For the CINP poster.  
 141:21 BY MR. GOMEZ:  
 141:22 Q. And --  
 141:23 A. Okay.

Page/Line

Source

ID

142:1 - 143:23

**Binder, Carin 07-17-2013 (00:01:50)**

142:1 The short abstract I showed you in  
142:2 February of 2002, one of the conclusions was that  
142:3 there was no correlation between elevated  
142:4 prolactin and side effects. Correct?  
142:5 MR. MURPHY: Which exhibit are you  
142:6 referring to, counsel?  
142:7 BY MR. GOMEZ:  
142:8 Q. Can you read the exhibit,  
142:9 Ms. Binder? It's right there.  
142:10 A. Exhibit 11.  
142:11 Q. Sorry.  
142:12 A. All right. So this is the AACAP  
142:13 abstract...  
142:14 Q. Hm-hmm?  
142:15 A. -- that potentially was submitted.  
142:16 Q. Okay. The AACAP abstract in  
142:17 Exhibit 11 that potentially was submitted --  
142:18 A. Right.  
142:19 Q. -- one of the conclusions was that  
142:20 there was no correlation between prolactin levels  
142:21 and side effects. Would you agree?  
142:22 A. Yes, "There appeared to be no  
142:23 correlation between prolactin levels and prolactin  
142:24 related side effects."  
142:25 Q. And then I showed you some  
143:1 exhibit -- an e-mail and then some statistical  
143:2 tables from May of 2002 that showed that the  
143:3 cutoffs were changed in boys from 30 to 18. I  
143:4 showed those to you just a moment ago. Correct?  
143:5 A. Correct.  
143:6 Q. Did that change in the cutoff  
143:7 values from 30 to 18 change your findings on the  
143:8 issue of whether there was a correlation between  
143:9 elevated prolactin levels and gynecomastia?  
143:10 A. I would have to go and look back at  
143:11 the data. Because in the article, it stated it  
143:12 did not.  
143:13 Q. Okay. We're going to get to the  
143:14 article again later on down the road, but in those

Page/Line

Source

ID

143:15 statistical tables for May that I just showed you,  
 143:16 it showed a statistically significant relationship  
 143:17 at weeks 8 to 12 between elevated prolactin and  
 143:18 side effects in Table 21. Agreed?

143:19 A. It did, for that time period.

143:20 Q. So changing the values from 30 to

143:21 18 changed your findings on the issue of no

143:22 correlation. Agreed?

143:23 A. I don't know that.

144:1 - 144:16

**Binder, Carin 07-17-2013 (00:00:29)**

144:1 Q. We can agree that based on the

144:2 e-mail that you sent to the authors, that's what

144:3 you were telling them, that the findings had not

144:4 changed based on the change from 30 to 18. Would

144:5 you agree?

144:6 A. Yes.

144:7 Q. I'm going to mark as Exhibit 15 an

144:8 e-mail from Dr. Moshang in response to your

144:9 e-mail.

144:10 (Whereupon the above-mentioned

144:11 document was marked for

144:12 identification as Exhibit 15.)

144:13 BY MR. GOMEZ:

144:14 Q. Want to take a second and look at

144:15 this?

144:16 A. Yes.

144:17 - 144:24

**Binder, Carin 07-17-2013 (00:00:20)**

144:17 Q. Have you had a chance to review

144:18 what you wrote in response to your e-mail?

144:19 A. Yup.

144:20 Q. Okay. And one of the things he

144:21 said in the e-mail that -- in response to your

144:22 e-mail was he thought that "just using the 18 as

144:23 the cut-off since it doesn't affect our findings

144:24 would be easiest." Did I read that right?

145:5 - 145:16

**Binder, Carin 07-17-2013 (00:00:27)**

145:5 BY MR. GOMEZ:

145:6 Q. Do you see that?

145:7 A. I do.

145:8 Q. Do you remember any discussions

Page/Line

Source

ID

145:9 with Dr. Moshang or any of the other authors on  
145:10 the issue of whether the findings were affected by  
145:11 the change from 30 to 18?

145:12 A. I do not recall.

145:13 Q. And we can agree that what

145:14 Dr. Moshang is telling you in this e-mail is 'Go  
145:15 ahead and use 18 as the cutoff since it doesn't  
145:16 affect our findings.'

145:19 - 145:24

**Binder, Carin 07-17-2013 (00:00:40)**

145:19 THE WITNESS: He says that, yes.

145:20 BY MR. GOMEZ:

145:21 Q. A moment ago you mentioned the CINP

145:22 poster. Remember that just a moment ago? I think  
145:23 this might shed some light on that.

145:24 A. Okay.

146:9 - 148:11

**Binder, Carin 07-17-2013 (00:02:48)**

146:9 BY MR. GOMEZ:

146:10 Q. Ms. Binder, this is your e-mail.

146:11 Right?

146:12 A. It is from me, yes.

146:13 Q. And it's dated Tuesday, May 7th,  
146:14 2002?

146:15 A. It is.

146:16 Q. The "Subject" is the "post hoc  
146:17 prolactin poster"? Correct?

146:18 A. Yes.

146:19 Q. Is this the -- was this prolactin  
146:20 poster sent to, based on this e-mail, any of the  
146:21 non-Janssen authors of the Findling article?

146:22 A. Well, according to this e-mail, it  
146:23 appears to be sent -- not sent to non-Janssen  
146:24 authors.

146:25 Q. So essentially Dr. Findling  
147:1 didn't -- he might have got another e-mail, but  
147:2 looking --

147:3 A. He is --

147:4 Q. -- at this e-mail, he's not on this  
147:5 one.

147:6 A. Correct.

147:7 Q. And either is Drs. Daneman or

Page/Line

Source

ID

147:8 Moshang. Correct?

147:9 A. Correct.

147:10 Q. And there's an attachment to this,

147:11 and it's a draft, a May 7th, 2002 draft, entitled,

147:12 "Normalization of Prolactin Levels in Children

147:13 after Long-term Treatment with Risperidone." Did

147:14 I read that right?

147:15 A. Yes.

147:16 Q. Okay. If you go to the first page

147:17 of the attachment, under the "INTRODUCTION"

147:18 section.

147:19 It reads at the bottom, "Thought

147:20 [among] pediatric endocrinologists concerning PRL

147:21 levels above 18 ng/ml but below 30 ng/ml and

147:22 without any clinical problems will not require

147:23 extensive investigation." Did I read that

147:24 correctly?

147:25 A. You did.

148:1 Q. Could you go to Bate stamp ending

148:2 in 69. The first bullet point reads, "Chi-square

148:3 tests were used to examine the relationship

148:4 between PRL," or prolactin, "and

148:5 [prolactin]-related side effects at or above the

148:6 upper limit of normal ... based on the central

148:7 laboratory normal ranges. ([Upper limits of

148:8 normal is] 18 for boys, 30 for girls)." Correct?

148:9 A. That's what it states, correct.

148:10 Q. Could you go to Bate stamp ending

148:11 in 74. Can you read the first bullet point.

148:12 - 150:21

**Binder, Carin 07-17-2013 (00:02:21)**

148:12 A. "there was no direct correlation

148:13 with prolactin elevation (>30 [nanograms per]

148:14 ml -girls; >18 [nanograms per] ml- boys) and

148:15 SHAP."

148:16 Q. That's an inaccurate statement.

148:17 Would you agree?

148:18 A. No.

148:19 Q. Why not?

148:20 A. Because the time point of the

148:21 analysis needs to be specified; and hence, the

Page/Line

Source

ID

148:22 objective was to look at this over a year in terms  
148:23 of what happens at the end of 48 weeks.  
148:24 Q. Okay. If you go to the  
148:25 "CONCLUSION" section.  
149:1 A. Hm-hmm.  
149:2 Q. There was -- if you read the second  
149:3 paragraph, second sentence. Can you read that?  
149:4 A. "There was no association between  
149:5 [prolactin] levels and side effects hypothetically  
149:6 attributable to prolactin," in parentheses,  
149:7 "(SHAP)."  
149:8 Q. That's an inaccurate statement.  
149:9 Would you agree?  
149:10 A. No, I would not.  
149:11 Q. Why not?  
149:12 A. 'Cause the sentence in front of it  
149:13 puts it in context: "Prolactin levels began to  
149:14 decrease after 8 weeks, despite an early increase,  
149:15 and were within normal limits although above  
149:16 baseline values."  
149:17 Q. When it says, "and were within  
149:18 normal limits although above baseline values,"  
149:19 that's referring to by the end of the study.  
149:20 Correct?  
149:21 A. Correct.  
149:22 Q. Which would have been between weeks  
149:23 48 and 54?  
149:24 A. I think it stopped at 48. So yeah,  
149:25 40 to 48.  
150:1 Q. So if prolactin levels begin to  
150:2 decrease after 8 weeks, okay, you would --  
150:3 A. Hm-hmm.  
150:4 Q. -- agree that the peak is shortly  
150:5 before 8 weeks?  
150:6 A. According to the tables that we  
150:7 just looked at --  
150:8 Q. And do you --  
150:9 A. -- looks like it --  
150:10 Q. Okay.  
150:11 A. -- yeah.

Page/Line

Source

ID

150:12 Q. And that the week -- time period  
 150:13 weeks 8 to 12 would be just below peak.  
 150:14 A. Hm-hmm.  
 150:15 Q. Agreed? Yes?  
 150:16 A. Yes.  
 150:17 Q. And based on Table 21 and the May  
 150:18 tables that we just looked at, there was a  
 150:19 statistically significant association using a  
 150:20 chi-squared test between elevated prolactin and  
 150:21 side effects. Agreed?

150:24 - 151:15

**Binder, Carin 07-17-2013 (00:00:52)**

150:24 THE WITNESS: Only at that time period of  
 150:25 8 to 12 weeks. But we're looking at a  
 151:1 longitudinal course. The objective was to say  
 151:2 what is the long-term impact of risperidone in  
 151:3 terms of these children.

151:4 BY MR. GOMEZ:

151:5 Q. You would agree that the  
 151:6 relationship we saw in Table 21 at weeks 8 to 12,  
 151:7 which is among other time periods that were looked  
 151:8 at and reported as non-statistically significant,  
 151:9 that 8 to 12 week time period is not being  
 151:10 mentioned here in this conclusion.

151:11 A. That is correct, in this draft  
 151:12 manuscript.

151:13 Q. Do you remember why you were  
 151:14 ignoring the weeks -- the information at weeks 8  
 151:15 to 12 in this poster?

151:18 - 152:9

**Binder, Carin 07-17-2013 (00:00:42)**

151:18 THE WITNESS: I don't know if I was  
 151:19 ignoring that or whether it was after a discussion  
 151:20 regarding clinical relevance with our authors.

151:21 BY MR. GOMEZ:

151:22 Q. Do you remember any discussion  
 151:23 regarding clinical relevance in the week 8 to 12  
 151:24 time period in all kids, including those with  
 151:25 puberty?

152:1 A. I do not.

152:2 Q. Were you aware that the poster that  
 152:3 we just looked at was presented in Montreal in

Page/Line

Source

ID

152:4 June of 2002?

152:5 A. I don't recall.

152:6 Q. Were you aware that physicians at  
152:7 that conference in Montreal in June of 2002 were  
152:8 being told that there was no association between  
152:9 elevated prolactin levels and side effects?

152:12 - 153:3

**Binder, Carin 07-17-2013 (00:00:39)**

152:12 THE WITNESS: I -- my perception is not  
152:13 that they weren't told, but when they read the  
152:14 poster, what was in the conclusions is that  
152:15 prolactin levels decrease over time, and that at  
152:16 this point in time, there is no association  
152:17 determined...

152:18 BY MR. GOMEZ:

152:19 Q. But there was --

152:20 A. -- by --

152:21 Q. -- an association at weeks 8 to 12,  
152:22 according to Table 21?

152:23 A. Correct.

152:24 Q. And that's not being reported in  
152:25 this CINP poster. Agreed?

153:1 A. Nor is the non-statistically  
153:2 significant findings reported on all the other  
153:3 weeks reported in this poster.

156:19 - 157:21

**Binder, Carin 07-17-2013 (00:01:16)**

156:19 Q. I've marked as Exhibit 17 an e-mail  
156:20 and an attachment. Did you review this in  
156:21 preparation for your deposition today?

156:22 A. No.

156:23 Q. Did you ask to review any of the  
156:24 drafts of the 2003 Findling article before your  
156:25 deposition today?

157:1 A. No.

157:2 Q. Why not?

157:3 A. They were drafts, it happened 12  
157:4 years ago, it's...

157:5 Q. Oh, sorry.

157:6 A. And the final output is what's in  
157:7 the public domain.

157:8 Q. The final output is what's in the



Page/Line

Source

ID

157:9 public domain, which has been roughly over a  
157:10 decade.

157:11 A. Correct.

157:12 Q. Does -- why does that time period,  
157:13 that duration, have any significance to what -- to  
157:14 this article that we're discussing today?

157:15 A. The duration and significance on  
157:16 arti -- the article and its significance is not  
157:17 the question here, Mr. Gomez.

157:18 It's that this is a long time ago,  
157:19 I worked on many, many projects and several other  
157:20 articles, and I do not have the recall that I used  
157:21 to have back when we were working on this project.

159:10 - 159:22

**Binder, Carin 07-17-2013 (00:00:30)**

159:10 Q. I've marked as Exhibit 17 an e-mail  
159:11 and an attachment. And this is your e-mail that  
159:12 I've shown you?

159:13 A. Yes.

159:14 Q. And it's dated July 16th, 2002?

159:15 A. Yes.

159:16 Q. What's the "Subject"?

159:17 A. "draft prolactin manuscript."

159:18 Q. Can -- any reason why it's being  
159:19 sent to Gahan Pandina and Vincent Nys?

159:20 A. As a final review. It says, "if  
159:21 there are [any] glaring omissions please let me  
159:22 know."

160:11 - 162:11

**Binder, Carin 07-17-2013 (00:02:52)**

160:11 Q. Can you read your e-mail to Gahan  
160:12 Pandina?

160:13 A. Yes. "Hi Gahan, As promised, if  
160:14 there are glaring omissions please let me know."

160:15 Q. Go to the first page of the  
160:16 attachment? Based on looking at this first page,  
160:17 we can agree this is a July 16th, 2002 revision or  
160:18 draft of the article that would eventually become  
160:19 the Findling manuscript that was published in  
160:20 November 2003?

160:21 A. It does say it's a draft, yes.

160:22 Q. I'm going to focus your attention

Page/Line

Source

ID

160:23 to Bate stamp ending in 40, 740.

160:24 A. Yes.

160:25 Q. The paragraph beginning, "The  
161:1 percentage of children," can you read that  
161:2 paragraph?

161:3 A. "The percentage of children with  
161:4 SHAP was assessed for patients with prolactin  
161:5 levels above the [upper limit of normal] versus  
161:6 patients with prolactin levels within the normal  
161:7 range at the various analysis time periods. The  
161:8 proportions were all comparable except for the  
161:9 Weeks 8 to 12 time period, in which 7.8% of  
161:10 patients who had prolactin above the [upper limit  
161:11 of normal] had SHAP at some point during the  
161:12 trial, while 2.9% of patients with prolactin  
161:13 levels within the normal range at Weeks 8 to 12  
161:14 experienced SHAP at some time during the study  
161:15 (P<0.02). There was no statistical difference in  
161:16 the percentage of patients who reported SHAP for  
161:17 any other analysis time period, whether or not  
161:18 prolactin levels were normal or above the [upper  
161:19 limit of normal] (range 3.7% to 6.9% with SHAP)."  
161:20 And then would you like me to  
161:21 continue reading?

161:22 Q. No, can you just stop there for one  
161:23 second and...

161:24 A. Okay.

161:25 Q. What you just read is a discussion  
162:1 of Table 21 and the May statistical tables that I  
162:2 showed you earlier. Correct?

162:3 A. Or a discussion of statistical  
162:4 tables, yes.

162:5 Q. And it's looking at statistically  
162:6 significant associations, that one's found at  
162:7 weeks 8 to 12, and it's also discussing all the  
162:8 other analysis time periods where there was not a  
162:9 statistically significant correlation. Agreed?

162:10 A. Not a correlation, but a  
162:11 statistical difference, you are correct.

162:16 - 162:19

**Binder, Carin 07-17-2013 (00:00:10)**

Page/Line

Source

ID

162:16 Q. Okay. Can you read... Can you  
162:17 take a moment and read the bracketed language and  
162:18 if you can, after you read it, tell me whether or  
162:19 not that's your comment.

162:20 - 163:24

**Binder, Carin 07-17-2013 (00:01:22)**

162:20 A. I don't know whose comment that  
162:21 was.

162:22 Q. Can you read into the record the  
162:23 bracketed language.

162:24 A. "How do you want to handle the one  
162:25 significant value? The poster states that there  
163:1 was no direct correlation with prolactin elevation  
163:2 and SHAP-what analysis was used for this? Can we  
163:3 get correlation coefficients for prolactin levels  
163:4 versus SHAP, as was done for prolactin levels  
163:5 versus age, and if no correlation just stick with  
163:6 that?"

163:7 Q. So what we see here in this comment  
163:8 is somebody is having questions about the  
163:9 significant value at weeks 8 to 12. Agreed?

163:10 A. Agreed.

163:11 Q. And one of the first questions they  
163:12 ask is "How do you want to handle the one  
163:13 significant value?" Agreed?

163:14 A. Correct.

163:15 Q. And "The poster states that there  
163:16 was no direct correlation with prolactin elevation  
163:17 and SHAP," would you agree that that's referring  
163:18 to either the abstract from February 2002 or the  
163:19 CINP poster from May of 2002?

163:20 A. It could be either one of those. I  
163:21 don't know.

163:22 Q. And it says, "what analysis was  
163:23 used for this?" Do you see that?

163:24 A. I do.

164:2 - 164:9

**Binder, Carin 07-17-2013 (00:00:21)**

164:2 If we're talking about the CINP  
164:3 poster where the cutoff value was 18 in boys,  
164:4 Table 21 and the May stats, we're talking about a  
164:5 chi-squared analysis. Agreed?

Page/Line	Source	ID
164:6	A. I don't know. Q. I represent to you that in the Table 21, it says, 'Chi-Squared Analysis' on the far right column. We can go back and look.	BINDER_07172013_PA_0111
164:16 - 164:20	<b>Binder, Carin 07-17-2013 (00:00:10)</b> Q. Okay. What analysis was used in May?	BINDER_07172013_PA_0111
164:18 A. I don't know. Depending -- 164:19 Q. You can go back and look, and read 164:20 it into the record, please.	164:21 - 165:16	BINDER_07172013_PA_0111
164:21 A. It is "Chi-Square Test." 164:22 Q. The next part of this comment reads, "Can we get correlation coefficients for prolactin levels versus SHAP, as was done for prolactin levels versus age, and if no correlation just stick with that?" Did I read that right? 165:1 A. Can you just tell me what page you're on again? 165:2 Q. I'm sorry, I'm on page 741 in the current draft. 165:3 MR. MURPHY: 741. 165:4 THE WITNESS: Okay. 741. "Can we get correlation coefficients for prolactin levels versus SHAP," yes. 165:5 BY MR. GOMEZ: 165:6 Q. Your answer is yes? 165:7 A. No, my answer is yes, I've read this. 165:8 Q. Okay. Is -- what's the answer to whether "we can get correlation coefficients for prolactin levels versus SHAP"?	165:19 - 165:25	BINDER_07172013_PA_0111
<b>Binder, Carin 07-17-2013 (00:00:11)</b> 165:19 THE WITNESS: I don't know if we can get 165:20 it or not. 165:21 BY MR. GOMEZ: 165:22 Q. Would it be fair to say that's not 165:23 possible because you need two continuous variables 165:24 to do a correlation coefficient? Would you agree? 165:25 A. I have no idea.	165:19 - 165:25	BINDER_07172013_PA_0111

Page/Line

Source

ID

169:9 - 169:18

**Binder, Carin 07-17-2013 (00:00:33)**

169:9 Q. Ms. Binder, I was going to ask you  
 169:10 about another draft that was dated July 30th,  
 169:11 2002. We'll come back to that in a moment.  
 169:12 The reason I was going to show that  
 169:13 to you was it had some comments from Dr. Pandina  
 169:14 about the stuff we've discussed in the first  
 169:15 draft, but let's move on in the interest of time.  
 169:16 Why was the decision made to change  
 169:17 the statistical analysis in September of 2002 for  
 169:18 the manuscript support for the Findling article?

169:21 - 171:11

**Binder, Carin 07-17-2013 (00:01:15)**

169:21 THE WITNESS: I don't know that the  
 169:22 statistical analysis was changed in September of  
 169:23 2002.  
 169:24 BY MR. GOMEZ:  
 169:25 Q. You have no memory as you sit here  
 170:1 today.  
 170:2 A. No.  
 170:3 Q. Okay. Let me show you this, then.  
 170:4 MR. GOMEZ: I'm going to skip an exhibit  
 170:5 and go to 19; and then, for the record's sake,  
 170:6 when they come with my copies, I'll go back to 18.  
 170:7 (Whereupon the above-mentioned  
 170:8 document was marked for  
 170:9 identification as Exhibit 19.)  
 170:10 THE WITNESS: Thank you.  
 170:11 BY MR. GOMEZ:  
 170:12 Q. I've marked as an exhibit 19,  
 170:13 Ms. Binder, a document entitled, "STATISTICAL  
 170:14 DOCUMENTATION, Long-Term Risperidone Treatment vs  
 170:15 Prolactin Pooled Analysis." Did I read that  
 170:16 right?  
 170:17 A. You did.  
 170:18 Q. And it's the "Protocols" for the  
 170:19 five DBD studies? Agreed?  
 170:20 A. Yes.  
 170:21 Q. And it's dated September 27th,  
 170:22 2002. Correct?  
 170:23 A. Correct.

Page/Line

Source

ID

170:24 Q. And if you could turn the page.

170:25 This is an "ANALYSIS PLAN"? Would you agree?

171:1 A. Yes.

171:2 Q. Okay. And the "objectives" are

171:3 listed there and there's five of them. Do you see

171:4 that?

171:5 A. Yes.

171:6 Q. And what does number 3 say?

171:7 A. "To explore the relationship

171:8 between prolactin levels and prolactin-related

171:9 side effects (SHAP)."

171:10 Q. And "SHAP" is gynecomastia.

171:11 Agreed?

171:15 - 173:19

**Binder, Carin 07-17-2013 (00:02:39)**

171:15 Q. Do you agree?

171:16 A. Gynecomastia is a side effect,

171:17 which may or may not be attributed to prolactin.

171:18 Q. So gynecomastia is one of a number

171:19 of side effects that are under the umbrella of

171:20 SHAP. Would you agree?

171:21 A. It was listed as one of them, yes.

171:22 Q. If you could go to the next page,

171:23 under the heading, "Key Variables Analyzed."

171:24 A. Yes.

171:25 Q. Do you see the second bullet point,

172:1 and then it says, "Prolactin-related side effects

172:2 (SHAP)"?

172:3 A. Hm-hmm.

172:4 Q. Okay. If you go down to the last

172:5 sentence, it reads, "To be classified as SHAP, the

172:6 duration of Amenorrhoea had to be at least one

172:7 week. Females with Gynaecomastia were included if

172:8 it had occurred for at least successive 31 days,

172:9 and males were included if they were less than 10

172:10 years of age." Did I read that correctly?

172:11 A. You did.

172:12 Q. So we are now seeing in September

172:13 of 2002, boys over the age of 10 are excluded from

172:14 the analysis. Would you agree?

172:15 A. From the analysis to be classified

Page/Line

Source

ID

172:16 as SHAP.

172:17 Q. Do you -- now that I've shown that

172:18 to you, do you remember that being discussed or...

172:19 I'll ask you one question.

172:20 A. I remember it being discussed.

172:21 Q. What do you remember?

172:22 A. I remember that puberty played a

172:23 role, and there was discussion amongst the

172:24 clinical experts as to at what point in time would

172:25 breasts appear on girls or would boys technically

173:1 be in puberty.

173:2 Q. And you're referring to

173:3 Drs. Moshang and Daneman, the pediatric

173:4 endocrinologist authors.

173:5 A. And potentially Findling and

173:6 Kusumakar.

173:7 Q. You can put that aside.

173:8 (Whereupon the below-mentioned

173:9 document was marked for

173:10 identification as Exhibit 20.)

173:11 BY MR. GOMEZ:

173:12 Q. Let me mark as Binder Exhibit 20

173:13 another draft of the Findling manuscript. This

173:14 one is dated October 4th, 2002. Do you see that

173:15 at the bottom left?

173:16 A. I do.

173:17 Q. And the title's changed, has it

173:18 not, from the first drafts that we saw? Let's go

173:19 back and look.

174:25 - 175:3

**Binder, Carin 07-17-2013 (00:00:09)**

174:25 Q. And we can agree that this is

175:1 another draft of the Findling manuscript based on

175:2 the authors that we see here on the front page.

175:3 A. Yes.

175:4 - 176:25

**Binder, Carin 07-17-2013 (00:02:35)**

175:4 Q. If you could go to the Bate stamp

175:5 ending in 82? It's the second page of the

175:6 attachment or the...

175:7 A. Yes.

175:8 Q. It lists in the "Results" section

Page/Line

Source

ID

175:9 that "SHAP were reported by 4.7% of the children;  
175:10 the most common was gynecomastia."  
175:11 And again it reads, "There was no  
175:12 direct correlation between prolactin elevation and  
175:13 SHAP." Did I read that correctly?  
175:14 A. Yes.  
175:15 Q. I just want to point out a few  
175:16 things from this article and then -- first draft  
175:17 and then we'll move on. If you could go to Bate  
175:18 stamp ending in 91. Are you there?  
175:19 A. Yes.  
175:20 Q. If you go to the second full  
175:21 paragraph, second-to-last sentence, beginning with  
175:22 "Patients"?  
175:23 A. Yes.  
175:24 Q. Take a second and look at that  
175:25 sentence. It's reflecting what we saw in the  
176:1 analysis plan; that kids over the age of 10 are  
176:2 not included in terms of looking at gynecomastia.  
176:3 Would you agree with that?  
176:4 A. That's what it states.  
176:5 Q. Go to the section beginning on page  
176:6 000?  
176:7 A. Yes.  
176:8 Q. The last paragraph of that page, if  
176:9 you could take a second and look at that  
176:10 paragraph, and then I'll have a question.  
176:11 MR. MURPHY: Are you on page 8000?  
176:12 MR. GOMEZ: I am. And it goes over to  
176:13 8001.  
176:14 THE WITNESS: Right.  
176:15 BY MR. GOMEZ:  
176:16 Q. It's discussing the different  
176:17 analysis time periods and the relationship between  
176:18 elevated prolactin and side effects. Would you  
176:19 agree?  
176:20 A. Yes.  
176:21 Q. It's the discussion that we saw in  
176:22 the first draft from July 16th; however, there's  
176:23 no discussion in this draft of the statistically



Page/Line

Source

ID

177:3 - 178:18

176:24 significant correlation we saw in Table 21 and the  
176:25 May tables. Would you agree?

**Binder, Carin 07-17-2013 (00:01:38)**

177:3 THE WITNESS: Based on this paragraph,  
177:4 there is no discussion of analysis by time points,  
177:5 correct.

177:6 BY MR. GOMEZ:

177:7 Q. And the reason there's no  
177:8 discussion about that statistically significant  
177:9 relationship at weeks 8 to 12 is because we're not  
177:10 counting kids with puberty. Agreed?

177:11 A. I don't know.

177:12 Q. If you could go to Bate stamp  
177:13 ending in 003.

177:14 A. Yes.

177:15 Q. There's a discussion in the second  
177:16 paragraph beginning, "Only 13 [of] 592"? Do you  
177:17 see that?

177:18 A. Yes.

177:19 Q. Okay. It reads, "No --" in the  
177:20 second sentence, it reads, "No correlation was  
177:21 found between SHAP and prolactin levels." Did I  
177:22 read that correctly?

177:23 A. Yes.

177:24 Q. And then this is some new language  
177:25 that we didn't see in the previous draft. It  
178:1 reads, "This is in keeping with other studies, in  
178:2 adults, also showing no correlation between  
178:3 prolactin levels and SHAP." Did I read that  
178:4 correctly?

178:5 A. You did.

178:6 Q. Do you know what study they're  
178:7 talking about there?

178:8 A. I don't know.

178:9 Q. Have you ever heard of the  
178:10 Kleinberg study?

178:11 A. Not that I recall.

178:12 Q. Do you remember any discussions  
178:13 with the authors or any of the people at Janssen  
178:14 that they wanted a publication to mirror the

Page/Line	Source	ID
178:20 - 178:21	<p>178:15 results of Kleinberg that there was no direct  178:16 correlation between prolactin levels and things  178:17 like gynecomastia in the adult population and they  178:18 wanted the same thing in the pediatric --</p> <p><b>Binder, Carin 07-17-2013 (00:00:00)</b></p> <p>178:20 BY MR. GOMEZ:  178:21 Q. -- population?</p>	BINDER_07172013_PA_02.000
178:24 - 178:24	<p><b>Binder, Carin 07-17-2013 (00:00:01)</b></p> <p>178:24 THE WITNESS: No.</p>	BINDER_07172013_PA_02.001
179:12 - 180:6	<p><b>Binder, Carin 07-17-2013 (00:00:53)</b></p> <p>179:12 Q. Ms. Binder, Exhibit 18 is another  179:13 e-mail and attachment. I want to focus on the  179:14 e-mail from Gahan Pandina sent Wednesday,  179:15 August 21st, 2002. Do you see that?  179:16 A. I do.  179:17 Q. And you were one of the recipients  179:18 of this e-mail?  179:19 A. I was.  179:20 Q. And you wrote, on the "Subject" of  179:21 the "pooled prolactin manuscript," "Dear Team,  179:22 Attached please find my comments. I think the  179:23 paper is overall constructed well and  179:24 well-written. I think we need to include the lack  179:25 of association between Tanner/height delay and  180:1 [prolactin] level or SHAP, as our advisors tell us  180:2 that this is one serious concern about prolactin."  180:3 Let me stop there and ask a  180:4 question. Do you remember any of your advisors  180:5 telling you that one of the serious concerns about  180:6 prolactin was SHAP?</p>	BINDER_07172013_PA_02.000
180:9 - 180:16	<p><b>Binder, Carin 07-17-2013 (00:00:12)</b></p> <p>180:9 THE WITNESS: What they told me is that  180:10 they were really interested in knowing what  180:11 happens in terms of prolactin elevation in  180:12 children.  180:13 BY MR. GOMEZ:  180:14 Q. Do you agree with me that  180:15 gynecomastia is a highly distressing adverse  180:16 event?</p>	BINDER_07172013_PA_02.000
180:20 - 180:24	<p><b>Binder, Carin 07-17-2013 (00:00:06)</b></p>	BINDER_07172013_PA_02.000

Page/Line

Source

ID

180:20 Q. Do you agree with that?

180:21 A. I'm sure it can be very

180:22 distressing.

180:23 Q. Do you believe it's a serious

180:24 adverse event?

181:3 - 181:13

**Binder, Carin 07-17-2013 (00:00:27)**

181:3 Q. Can you answer my question?

181:4 A. So the definition of serious is

181:5 really based on more of a physician judgment based

181:6 on how the person feels about it --

181:7 Q. And from --

181:8 A. -- and whether it's life

181:9 endangering.

181:10 Q. As you sit here today, do you

181:11 think, from a layperson's perspective, a

181:12 nonmedical opinion, do you think gynecomastia is a

181:13 big deal?

181:16 - 183:10

**Binder, Carin 07-17-2013 (00:02:05)**

181:16 THE WITNESS: I would have to look at it

181:17 in terms of risk benefit. So what am I treating

181:18 and what am I willing to put up with in order to

181:19 have that treatment.

181:20 And so if I'm treating a cut with a

181:21 band-aid and it causes me to have a bleed, that's

181:22 to me serious and the benefit of using a band-aid

181:23 is not worth it.

181:24 So it's about risk benefit.

181:25 BY MR. GOMEZ:

182:1 Q. Okay. Reading on, he writes, "If

182:2 we can demonstrate that the transient rise in PRL

182:3 [or prolactin] does not result in abnormal

182:4 maturation or SHAP, this would be most reassuring

182:5 to clinicians." Did I read that correctly?

182:6 A. You did.

182:7 Q. Do you remember any discussions

182:8 with Dr. Pandina where he said to you or you ever

182:9 heard him say to anybody, "If we can't demonstrate

182:10 lack of association between elevation -- elevated

182:11 prolactin levels and SHAP, clinicians are not

182:12 going to be reassured about Risperdal"?

Page/Line

Source

ID

182:13 A. I do not remember him saying that.

182:14 Q. He writes, "I realize that these

182:15 manuscripts are being developed in parallel, but

182:16 the relationship here is important." And he's

182:17 referring to the Findling article and the Dunbar

182:18 article. Would you agree?

182:19 A. According to this, yes.

182:20 Q. He writes, "[We also --] We have

182:21 also had many concerns about patients who are

182:22 maintained on stimulants, as this might affect

182:23 [prolactin] level, and no [subanalysis] were

182:24 included. Perhaps we can discuss prior to the

182:25 next revision. [Congratulation on the --]

183:1 Congratulations on the Tanner data being accepted.

183:2 Great news. Maybe this will make it easier for us

183:3 to include this as a subanalysis in [the] paper.

183:4 Gahan." Did I read that right?

183:5 A. You did.

183:6 Q. Okay. Let's go down to the e-mail

183:7 on August 15th. Okay? Do you see that?

183:8 A. I do.

183:9 Q. And that's your e-mail?

183:10 A. It is.

183:13 - 184:13

**Binder, Carin 07-17-2013 (00:01:06)**

183:13 Dr. Findling, Dr. Moshang and

183:14 Dr. Daneman are not on this e-mail. Would you

183:15 agree?

183:16 A. That is correct.

183:17 Q. And the "Subject" is the "pooled

183:18 prolactin manuscript"?

183:19 A. Yes.

183:20 Q. And you are sending it to the

183:21 "Pediatric Publication Team." Agreed?

183:22 A. So it states.

183:23 Q. And asking them to "review the

183:24 attached draft manuscript." Correct?

183:25 A. Yes.

184:1 Q. The second paragraph of your

184:2 e-mail, can you read that?

184:3 A. The second paragraph. "Key

Page/Line

Source

ID

184:4 message- prolactin rise is transient and not  
 184:5 related to side effects hypothetically attributed  
 184:6 to prolactin, EPS or efficacy response."  
 184:7 Q. And we're going to look at the  
 184:8 section on SHAP in a moment, but based on the  
 184:9 first draft that we looked at, the relationship  
 184:10 found at weeks 8 to 12 showing that there was a  
 184:11 relationship with side effects hypothetically  
 184:12 attributed to prolactin flies in the face of that  
 184:13 key message, would you agree?

184:16 - 184:23

**Binder, Carin 07-17-2013 (00:00:23)**

184:16 THE WITNESS: So the stats just reported  
 184:17 on whether it was statistically significant or  
 184:18 not.  
 184:19 The prolactin rise, as we saw,  
 184:20 peaked at week 8 and started to go down. The time  
 184:21 period you are referring to is weeks 8 to 12,  
 184:22 which showed a difference that was statistically  
 184:23 significant, yes.

186:24 - 187:9

**Binder, Carin 07-17-2013 (00:00:22)**

186:24 Q. We saw in the  
 186:25 initial draft from July 16th a discussion of the  
 187:1 relationship between elevated prolactin levels and  
 187:2 SHAP at various analysis time periods.

187:3 A. Hm-hmm.

187:4 Q. Yes?

187:5 A. We did.

187:6 Q. Okay. And they found a  
 187:7 statistically significant relationship at weeks 8  
 187:8 to 12.

187:9 A. They did.

188:3 - 189:1

**Binder, Carin 07-17-2013 (00:01:02)**

188:3 Q. Let me ask it this way, in a  
 188:4 different roundabout way: What -- the fact that  
 188:5 you had a key message that you talked about in  
 188:6 your e-mail of "prolactin rise [being] transient  
 188:7 and not related to side effects hypothetically  
 188:8 attributed to prolactin," did you decide at any  
 188:9 point to take out the discussion of the  
 188:10 statistically significant relationship at weeks 8

Page/Line

Source

ID

188:11 to 12 so you could meet your key message?  
 188:12 A. It wasn't -- number one, I don't  
 188:13 recall. And number two, it wasn't my decision to  
 188:14 make; it was a group decision, including the  
 188:15 authors.  
 188:16 Q. Did anybody tell Dr. Findling to  
 188:17 take it out?  
 188:18 MR. MURPHY: To take out reference to the  
 188:19 8 to 12 week --  
 188:20 MR. GOMEZ: Yes, I'm sorry.  
 188:21 BY MR. GOMEZ:  
 188:22 Q. "it," meaning the weeks 8 to 12  
 188:23 relationship, did anybody tell Dr. Findling to  
 188:24 take that discussion out?  
 188:25 A. I don't know. You would need to  
 189:1 ask Dr. Findling.

190:7 - 191:20

**Binder, Carin 07-17-2013 (00:01:29)**

190:7 Q. The sentence beginning, "The  
 190:8 percentage of children with SHAP," and ending  
 190:9 with, "P=0.02," is the identical language we saw  
 190:10 in the July 16th draft. And it's discussing all  
 190:11 the various analysis time periods, including the  
 190:12 statistically significant one at weeks 8 to 12.  
 190:13 Would you agree?  
 190:14 A. It would appear so, yes.  
 190:15 Q. And then there's a comment in  
 190:16 parentheses after the "P=0.02." Do you see that?  
 190:17 A. Yes.  
 190:18 Q. Okay. I'll read that. "(this may  
 190:19 be notable as this could be seen to suggest that  
 190:20 patients who show an initial rise during the  
 190:21 'peak' period above [upper limits of normal] do  
 190:22 have a higher propensity for SHAP. I think we  
 190:23 need to discuss this somewhere in the manuscript.  
 190:24 Gahan)." Did I read that correctly?  
 190:25 A. You did.  
 191:1 Q. Do you remember discussing that  
 191:2 comment with Dr. Pandina at any time?  
 191:3 A. I do not.  
 191:4 Q. And what he's saying here is that

Page/Line

Source

ID

191:5 those kids at weeks 8 to 12 who had an elevated  
 191:6 prolactin level were at an increased risk for  
 191:7 gynecomastia. Would you agree?  
 191:8 MR. MURPHY: Would you agree that that's  
 191:9 what he's saying?  
 191:10 THE WITNESS: Would I agree that that's  
 191:11 what he said. That's what he's written.  
 191:12 BY MR. GOMEZ:  
 191:13 Q. Do you agree with that?  
 191:14 A. Not necessarily.  
 191:15 Q. And what's your basis for not  
 191:16 agreeing with that?  
 191:17 A. Again, it goes back to I'm not a  
 191:18 scientific expert in this, and the clinical  
 191:19 relevance of the rise in prolactin also needs to  
 191:20 be assessed.

193:13 - 193:19

**Binder, Carin 07-17-2013 (00:00:23)**

193:13 Q. As an author of  
 193:14 this article, okay, the discussion that we're  
 193:15 looking at here about the various analysis time  
 193:16 periods and the comparison of elevated prolactin  
 193:17 levels and side effects, do you find it proper  
 193:18 or -- or do you find it proper that all  
 193:19 relationships are being discussed?

193:22 - 194:20

**Binder, Carin 07-17-2013 (00:00:46)**

193:22 THE WITNESS: It's not a question,  
 193:23 Mr. Gomez, of proper or not proper. It's a  
 193:24 question of the clinicians having expertise,  
 193:25 reading this, and being -- and having their sort  
 194:1 of clinical expertise weighing in.  
 194:2 BY MR. GOMEZ:  
 194:3 Q. Right. And the clinicians who  
 194:4 are --  
 194:5 A. So...  
 194:6 Q. -- reading this are discussing all  
 194:7 relationships in this paragraph. That's what's in  
 194:8 the paper at this point, through July 30th, 2002.  
 194:9 Agreed?  
 194:10 A. Ye -- well, in this paragraph, it's  
 194:11 looking by time period, yes.

Page/Line

Source

ID

194:12 Q. And I can show you the final paper,  
194:13 but there's also a paragraph looking at time  
194:14 periods.

194:15 A. Okay.

194:16 Q. Do you remember looking at that?

194:17 A. No.

194:18 Q. Okay. I'll show that to you in a

194:19 little while.

194:20 A. Okay.

194:21 - 194:25

**Binder, Carin 07-17-2013 (00:00:14)**

194:21 Q. Before we move on, this draft dated  
194:22 July 30th is discussing all children regardless of  
194:23 age. Would you agree?

194:24 A. I don't know. I would have to go  
194:25 back and read this.

195:15 - 195:19

**Binder, Carin 07-17-2013 (00:00:07)**

195:15 BY MR. GOMEZ:

195:16 Q. Just so the jury understands, take  
195:17 your time and look through that and tell me if it  
195:18 discusses all children, and there's no cutoff for  
195:19 age.

195:20 - 196:11

**Binder, Carin 07-17-2013 (00:00:33)**

195:20 A. Okay. It appears to include all  
195:21 children up to the age of 15.

195:22 Q. But there's no cutoff for  
195:23 gynecomastia in terms of being over the age of 10.

195:24 A. I did not look --

195:25 Q. Or no --

196:1 A. -- for that.

196:2 Q. -- exclusion for gynecomastia.

196:3 Agreed?

196:4 A. Is the question did they use a  
196:5 cutoff of 10?

196:6 Q. Sure, that's the question. Did  
196:7 they use a cutoff of 10 in that draft?

196:8 MR. MURPHY: Specific to gynecomastia,  
196:9 counsel?

196:10 MR. GOMEZ: Specific to gynecomastia.

196:11 MR. MURPHY: Okay.

196:12 - 196:13

**Binder, Carin 07-17-2013 (00:00:05)**



Page/Line	Source	ID
196:14 - 196:18	<p>196:12 THE WITNESS: So it would appear that 196:13 they used the entire set of males and females.</p> <p><b>Binder, Carin 07-17-2013 (00:00:14)</b></p>	BINDER_07172013_PA_02110
196:21 - 197:25	<p>196:14 BY MR. GOMEZ: 196:15 Q. Why did you and the people working 196:16 on this article at Janssen decide to exclude 196:17 children over the age of 10 and then present that 196:18 paper at an advisory board in November 2002?</p> <p><b>Binder, Carin 07-17-2013 (00:01:21)</b></p> <p>196:21 THE WITNESS: So firstly, it wasn't the 196:22 people at Janssen and myself that excluded those 196:23 patients. It was based on an e-mail which you 196:24 showed to me whereby there was a discussion with 196:25 Dr. Daneman about the variables that could 197:1 influence gynecomastia, as well as amenorrhea and 197:2 dysmenorrhea. 197:3 So based on -- and then you showed 197:4 me another e-mail from Thomas Moshang where he 197:5 talked about the blurring of lines between age and 197:6 prolactin. 197:7 Hence, it wasn't my decision or 197:8 Janssen's decision; it was an author consensus 197:9 decision as to what analysis to go forward with 197:10 for the final manuscript. 197:11 BY MR. GOMEZ: 197:12 Q. What was your input on that author 197:13 consensus decision? 197:14 MR. MURPHY: On this issue of age? 197:15 MR. GOMEZ: Yeah, it's a follow-up 197:16 question to her question. 197:17 THE WITNESS: I defer to the pediatric 197:18 endocrinologists. 197:19 BY MR. GOMEZ: 197:20 Q. Before we move into the fall of 197:21 2002, just so the jury understands, you didn't 197:22 change the analysis - "you" meaning Janssen or the 197:23 authors - to meet the key message that there was 197:24 no relationship between elevated prolactin and 197:25 side effects.</p> <p><b>Binder, Carin 07-17-2013 (00:00:39)</b></p>	BINDER_07172013_PA_02110
198:3 - 198:15		BINDER_07172013_PA_02110

Page/Line

Source

ID

198:3 THE WITNESS: The intent had nothing to  
198:4 do with the key message. The intent was to answer  
198:5 a scientific question.

198:6 BY MR. GOMEZ:

198:7 Q. Do you remember presenting the --

198:8 what was essentially the October 4th draft I

198:9 showed you in Exhibit 20 to an advisory board in

198:10 November 2002?

198:11 A. No.

198:12 Q. Do you remember at that advisory

198:13 board, your experts that Janssen brings to look at

198:14 data telling Janssen to redo the paper and include

198:15 all kids with gynecomastia?

198:18 - 198:25

**Binder, Carin 07-17-2013 (00:00:20)**

198:18 Q. Is your answer no?

198:19 A. I don't recall that.

198:20 Q. Okay. Do you remember them -- the

198:21 advisors telling Janssen at this advisory board

198:22 that to present the paper as written in October of

198:23 2002 excluding kids over the age of 10 was, quote,

198:24 "hiding data"? Do you remember that?

198:25 A. I do not remember that.

199:6 - 200:22

**Binder, Carin 07-17-2013 (00:01:51)**

199:6 BY MR. GOMEZ:

199:7 Q. I've marked as Exhibit 21 another

199:8 e-mail and attachment.

199:9 A. Thank you.

199:10 Q. Ms. Binder, is that your e-mail

199:11 that I put in front of you?

199:12 A. It is.

199:13 Q. And it's a -- dated October 11th,

199:14 2002?

199:15 A. Yes.

199:16 Q. And it has an attachment entitled,

199:17 "Table 16.doc"? Do you see that?

199:18 A. Yes.

199:19 Q. And you're writing to a Susan

199:20 Conti? Yes?

199:21 A. Yes.

199:22 Q. Can you read what you wrote?

Page/Line

Source

ID

199:23 A. "SUsan, we just redid the prolactin  
199:24 analysis with new definition of SHAP. I can't  
199:25 open the poster but can you ensure that the  
200:1 appropriate info on SHAP (table 16 attached) is  
200:2 updated and just to cover ourselves - can you  
200:3 state somewhere in the poster that this is an  
200:4 interim analysis. This just covers us in case  
200:5 [of] our manuscript differs from the poster due to  
200:6 final quality checks of the data."

200:7 Q. If you turn to page -- a couple of  
200:8 pages, you're going to see Table 16?

200:9 A. Yes.

200:10 Q. And it's entitled, "Incidents of  
200:11 Prolactin-related Side Effects (SHAP)," at the  
200:12 top?

200:13 A. Yes.

200:14 Q. And it excludes, based on the notes  
200:15 at the bottom, kids over the age of 10 with  
200:16 gynecomastia. Correct?

200:17 A. "females ... > ... 31 days of  
200:18 Gynaecomastia and males < 10 ... are included."

200:19 Q. Okay. That's just the opposite of  
200:20 what I said. Right?

200:21 A. Yes.

200:22 Q. All right. You can put that aside.

200:23 - 201:1 **Binder, Carin 07-17-2013 (00:00:14)**

200:23 Do you remember presenting the data  
200:24 excluding kids over the age of 10 at AACAP in  
200:25 October 2002?

201:1 A. I don't recall.

201:20 - 203:13 **Binder, Carin 07-17-2013 (00:01:57)**

201:20 Q. Exhibit 22 is another one of your  
201:21 e-mails, Ms. Binder. Correct?

201:22 A. Yes.

201:23 Q. And it looks like on November 12th,  
201:24 2002, you're forwarding "Prolactin Slides"?

201:25 A. So it states.

202:1 Q. And there's an attachment. As you  
202:2 can see, it is a PowerPoint presentation on page 3  
202:3 of the exhibit?

Page/Line

Source

ID

202:4 A. Okay.

202:5 Q. Do you remember preparing or

202:6 helping prepare for the November 15th advisory

202:7 board -- child and adolescent advisory board in

202:8 New York City?

202:9 A. I do not.

202:10 Q. Do you remember giving a

202:11 presentation at that advisory board?

202:12 A. I do not.

202:13 Q. Okay. Let me show you this and see

202:14 if it refreshes your recollection. You could go

202:15 to the third page, which is Bate stamp ending in

202:16 417?

202:17 A. Hm-hmm.

202:18 Q. It reads, "Long-term Risperidone

202:19 Treatment: Prolactin Sub-analysis," and

202:20 "Presented by: Carin Binder." Correct?

202:21 A. Yes.

202:22 Q. And it's referring to "Authors: R.

202:23 Findling, V. Kusumakar, D. Daneman, T. Moshang, G.

202:24 De Smedt, C. Binder."

202:25 You're referring -- or this

203:1 document is referring to the Findling authors of

203:2 the 2003 article. Agreed?

203:3 A. Well, that article wasn't published

203:4 in November of 2002.

203:5 Q. Let me rephrase the question. The

203:6 authors that are mentioned there are the authors

203:7 on the Findling 2003 article. Would you agree?

203:8 A. Yes.

203:9 Q. Okay. If you could turn the page,

203:10 there are the five DBD studies? Agreed? On the

203:11 table?

203:12 A. Yes.

203:13 Q. If you could go to Bate stamp

203:14 - 204:11

**Binder, Carin 07-17-2013 (00:01:06)**

203:14 ending in 464. And just let me know when you're

203:15 there?

203:16 A. Yes.

203:17 Q. Okay. The source of this slide,

Page/Line

Source

ID

203:18 which is a bar graph? Agreed?

203:19 A. Yes.

203:20 Q. Is the "Statistical Documentation

203:21 for Manuscript Support - 27[th of] Sept[ember]02:

203:22 Table 20." Did I read that correctly?

203:23 A. You did.

203:24 Q. Okay. And the title of this is

203:25 "Percent of Patients with SHAP: Normal Versus..."

204:1 "Normal Versus [greater or equal to upper limits

204:2 of normal]"?

204:3 A. Yes.

204:4 Q. And it's looking at various

204:5 analysis time periods? Correct?

204:6 A. Yes.

204:7 Q. And it's comparing those with

204:8 elevated prolactin versus those with normal

204:9 prolactin and the percentage of each that went on

204:10 to develop a side effect like gynecomastia.

204:11 Agreed?

204:14 - 204:18

**Binder, Carin 07-17-2013 (00:00:11)**

204:14 THE WITNESS: Yes.

204:15 BY MR. GOMEZ:

204:16 Q. And all of these time periods that

204:17 are being shown in this slide are not

204:18 statistically significant. Would you agree?

204:21 - 205:4

**Binder, Carin 07-17-2013 (00:00:23)**

204:21 THE WITNESS: According to the P values,

204:22 that is correct.

204:23 BY MR. GOMEZ:

204:24 Q. Now that I've shown that to you, do

204:25 you remember presenting the -- what was

205:1 essentially the October 4th, 2002 draft to the

205:2 pediatric advisory board in November 2002?

205:3 A. I do not.

205:4 Q. You can put that aside.

205:15 - 206:12

**Binder, Carin 07-17-2013 (00:00:46)**

205:15 BY MR. GOMEZ:

205:16 Q. Ms. Binder, I've marked as

205:17 Exhibit 23 a document entitled, "RISPERDAL CHILD

205:18 AND ADOLESCENT PSYCHIATRY NATIONAL ADVISORY  
BOARD

Page/Line

Source

ID

205:19 MEETING." And it's a meeting report? Would you  
205:20 agree?

205:21 A. Yes.

205:22 Q. And the "Meeting Date" was

205:23 November 15th, 2002. "Location: The Palace  
205:24 Hotel, New York City." Did I read that right?

205:25 A. Yes.

206:1 Q. Now that you've seen this, do you  
206:2 remember going to New York City in November 2002  
206:3 to attend this meeting?

206:4 A. I do not.

206:5 Q. If you could just go to the back of  
206:6 the document, the last page. Are you there?

206:7 A. Yes.

206:8 Q. Under "JANSSEN ATTENDEES," is that  
206:9 your name --

206:10 A. It is.

206:11 Q. -- first in line?

206:12 A. Yes.

206:13 - 208:2

**Binder, Carin 07-17-2013 (00:01:47)**

206:13 Q. Remember earlier today we talked  
206:14 about action items?

206:15 A. Yes.

206:16 Q. If you could go to Bates -- page 14  
206:17 of the document, Bate stamp 111?

206:18 A. Yes.

206:19 Q. It says, "ACTION ITEMS BASED ON THE  
206:20 OUTCOME OF THIS MEETING"? Is that what I -- did I  
206:21 read that right? Yes?

206:22 MR. MURPHY: At the top.

206:23 THE WITNESS: Oh. Yes.

206:24 BY MR. GOMEZ:

206:25 Q. If you could turn the page, the  
207:1 discussion continues of action items and the top  
207:2 of page 15 is "Prolactin levels"?

207:3 A. Yes.

207:4 Q. And then "Side-effects,  
207:5 hypothetically attributable to prolactin (SHAP)."  
207:6 Did I read that right?

207:7 A. Yes.

Page/Line

Source

ID

207:8 Q. Number 1 action item under this  
 207:9 heading was "Reanalyze the data on SHAP to include  
 207:10 all boys with gynecomastia, not just those under  
 207:11 the age of 10." Did I read that correctly?  
 207:12 A. Yes.  
 207:13 Q. Okay. Do you remember anybody at  
 207:14 the conference telling the advisors that you're --  
 207:15 that Janssen or -- had already done the analysis?  
 207:16 A. I do not remember.  
 207:17 Q. Is it fair to say that Janssen  
 207:18 didn't share the analysis of all children that  
 207:19 they had previously done in May of 2002 where they  
 207:20 found a statistically significant relationship  
 207:21 with the advisors at this November conference?  
 207:22 A. I don't know.  
 207:23 Q. Number 3, it says, "The definition  
 207:24 of SHAP should be ... inclusive as possible." Did  
 207:25 I read that correctly?  
 208:1 A. Point 3?  
 208:2 Q. Yes.

208:16 - 209:14

**Binder, Carin 07-17-2013 (00:00:59)**

208:16 Q. "The definition of SHAP should be  
 208:17 ... inclusive as possible." What do you take that  
 208:18 to mean?  
 208:19 A. I don't.  
 208:20 Q. You don't what?  
 208:21 A. I don't take it to mean anything.  
 208:22 It's a statement that someone noted in the minutes  
 208:23 or a report.  
 208:24 Q. It goes on in point 3, "then  
 208:25 compared with the incidence of SHAP with the more  
 209:1 inclusive definition to that with the more narrow  
 209:2 definition." Did I read that correctly?  
 209:3 A. You did.  
 209:4 Q. What does that mean?  
 209:5 A. We would have to go back to see  
 209:6 what data was being presented to them and what the  
 209:7 attributes were.  
 209:8 Q. You don't agree with me that the  
 209:9 data that was presented to them was the analysis

Page/Line

Source

ID

209:17 - 211:4

209:10 that excluded kids over the age of 10?

209:11 A. Well --

209:12 MR. MURPHY: At this meeting?

209:13 BY MR. GOMEZ:

209:14 Q. At this meeting in November 2002?

**Binder, Carin 07-17-2013 (00:01:45)**

209:17 THE WITNESS: Yeah, I would have to go

209:18 through this dec, if this is the dec that was

209:19 presented, to see what exactly was presented.

209:20 BY MR. GOMEZ:

209:21 Q. Remember I -- when I took you

209:22 through that exhibit, I showed you... Why don't

209:23 you go ahead and look through it.

209:24 A. What would you like me to look for?

209:25 Q. I want -- does that presentation

210:1 that you hold in your hand there exclude kids over

210:2 the age of 10?

210:3 A. Okay. Is this the presentation

210:4 that was presented November 12th?

210:5 Q. It's a presentation with your name

210:6 on it.

210:7 A. Yes, but you're asking me...

210:8 Q. Well --

210:9 A. -- to infer that this was presented

210:10 November 15th.

210:11 Q. Can you infer or not?

210:12 A. I don't infer.

210:13 Q. If one of the action items is

210:14 asking Janssen to compare the incidence of SHAP

210:15 with the -- compare "the incidence of SHAP [among]

210:16 the more inclusive definition," meaning everybody,

210:17 versus the exclusive definition, those kids over

210:18 the age of 10, do you remember anybody from

210:19 Janssen telling the advisors, "We already did

210:20 that"?

210:21 A. I don't recall.

210:22 Q. Number 4, "When publishing the

210:23 prolactin results, data on all children with

210:24 gynecomastia should be included." Was that read

210:25 correctly?



Page/Line

Source

ID

211:1 A. Yes.

211:2 Q. What does that mean to you?

211:3 A. It is a recommendation by a group

211:4 of people that stated exactly what you said.

212:3 - 212:7

**Binder, Carin 07-17-2013 (00:00:11)**

212:3 Q. The item, "When publishing the

212:4 prolactin results, data on all children with

212:5 gynecomastia should be included," was referring to

212:6 the Findling article that was presented at this

212:7 conference. Would you agree?

212:10 - 212:21

**Binder, Carin 07-17-2013 (00:00:29)**

212:10 THE WITNESS: Okay. There was no

212:11 Findling article in 2002. I don't know which

212:12 slides were presented at this meeting.

212:13 BY MR. GOMEZ:

212:14 Q. There was no Findling article in

212:15 2002, but there were Findling drafts of a

212:16 manuscript that was eventually published in

212:17 November 2003. Agreed?

212:18 A. Yes.

212:19 Q. And yet the draft from October 4th,

212:20 2002 was presented at this conference. Would you

212:21 agree?

212:24 - 213:14

**Binder, Carin 07-17-2013 (00:00:39)**

212:24 THE WITNESS: I have... I have no -- no

212:25 hard evidence that the 2002 October draft was

213:1 presented at this meeting. And I do not recall

213:2 this meeting or what was presented at this

213:3 meeting.

213:4 BY MR. GOMEZ:

213:5 Q. Number 5, "The incidence of SHAP in

213:6 patients with normal versus ... ULN [or upper

213:7 limits of normal] prolactin levels should be

213:8 compared using nonparametric statistics." Did I

213:9 read that correctly?

213:10 A. You did.

213:11 Q. When that action item was

213:12 discussed, did anybody from Janssen stand up and

213:13 say, "Hey, we already did that"?

213:14 A. I don't know.



Page/Line

Source

ID

215:22 levels for prolactin predose risperidone and 6  
 215:23 months after the most recent risperidone dose  
 215:24 change.' This is a conservative view - the US  
 215:25 advisors recommended that we should not recommend  
 216:1 monitoring of prolactin levels."

216:2 "My feelings are mixed only because  
 216:3 if the patient does have a prolactinoma (rare) it  
 216:4 should be diagnosed as soon as possible."

216:5 Point 2, "Secondly, the US group  
 216:6 recommended that the manuscript list all cases of  
 216:7 gynecomastia in males and state whether prolactin  
 216:8 levels were normal or elevated as well as state  
 216:9 the new rates of gynecomastia as identified by the  
 216:10 endos. They felt that applying the endos position  
 216:11 of gynecomastia in boys in puberty not being SHAP  
 216:12 without listing all gynecomastia was 'hiding  
 216:13 data'."

216:14 "My thoughts - I have no problem  
 216:15 adding in gynecomastia in boys > 10 and keeping the  
 216:16 ped endo analysis in the manuscript. I believe  
 216:17 most of the decrease in SHAP via ped endos was due  
 216:18 to dropping out dysmenorrhea, penis disorder etc."  
 216:19 "Regards, Carin."

216:22 - 217:11

**Binder, Carin 07-17-2013 (00:00:35)**

216:22 Number 1, "The authors have just  
 216:23 finished reviewing the manuscript." Do you see  
 216:24 that?

216:25 A. I do.

217:1 Q. Okay. Would there be e-mails? How  
 217:2 would the manuscript have been sent to the authors  
 217:3 to review?

217:4 A. I can only make assumptions that it  
 217:5 would be e-mails.

217:6 Q. Can we make the assumption that you  
 217:7 are the one that would have e-mailed the authors?

217:8 A. Potentially myself or the medical  
 217:9 writer.

217:10 Q. The medical writer was who?

217:11 A. I don't remember.

217:12 - 220:5

**Binder, Carin 07-17-2013 (00:03:16)**

Page/Line

Source

ID

217:12 Q. And you agreed with putting back  
217:13 in, according to your e-mail...  
217:14 Or I'm sorry, you agreed with  
217:15 "adding in gynecomastia in boys > 10," based on  
217:16 your e-mail.  
217:17 A. What it states is, "I have no  
217:18 problem adding in gynecomastia in boys > 10."  
217:19 Q. And what did you mean when you  
217:20 said, "keeping the ped endo analysis in the  
217:21 manuscript"?  
217:22 A. Keeping the analysis that the  
217:23 pediatric endos had recommended and were  
217:24 reviewing.  
217:25 Q. Do you remember around this time  
218:1 frame, November 18th, 2002, any discussions to put  
218:2 into or implement the action points recommended by  
218:3 the advisors at the November 15th conference?  
218:4 A. I do not remember.  
218:5 MR. GOMEZ: Let me mark as Exhibit 25  
218:6 another e-mail and attachment.  
218:7 (Whereupon the above-mentioned  
218:8 document was marked for  
218:9 identification as Exhibit 25.)  
218:10 BY MR. GOMEZ:  
218:11 Q. Exhibit 25 is your e-mail,  
218:12 Ms. Binder?  
218:13 A. It is.  
218:14 Q. What's the date?  
218:15 A. November 21st, 2002.  
218:16 Q. And you're sending the e-mail to  
218:17 Gahan Pandina, Goedele De Smedt, Vincent Nys,  
218:18 Vivek Kusumakar. Agreed?  
218:19 A. Yes.  
218:20 Q. "Subject: latest Prolactin  
218:21 manuscript"? Yes?  
218:22 A. Yes.  
218:23 Q. Drs. Daneman, Moshang and Findling  
218:24 are not on this e-mail. Agreed?  
218:25 A. Correct.  
219:1 Q. Can you read your e-mail?

Page/Line

Source

ID

219:2 A. "Dear All,"  
 219:3 "Attached please find the revised  
 219:4 Nov[ember] 19th prolactin manuscript. The  
 219:5 revisions now include a nauseating amount of info  
 219:6 on SHAP, specifically gynecomastia throughout all  
 219:7 ages and a ris total dose vs. prolactin analysis.  
 219:8 There's nothing to find people. I have  
 219:9 highlighted the conservative approach to measuring  
 219:10 prolactin in the discussion and would like your  
 219:11 view as to whether we should delete prolactin  
 219:12 monitoring."  
 219:13 "Please let me know your thoughts  
 219:14 since I wasn't going to recirculate this document  
 219:15 to the whole pub team until I have your thoughts."  
 219:16 "Note this revision includes [the  
 219:17 majority of author comments (some minor  
 219:18 text,grammar not included) note, references need  
 219:19 to be renumbered."  
 219:20 "Regards, Carin."  
 219:21 Q. Ms. Binder, you've been asked about  
 219:22 this e-mail in previous depositions. What did you  
 219:23 mean when you wrote, "The revisions now include a  
 219:24 nauseating amount of info on SHAP, specifically  
 219:25 gynecomastia"?  
 220:1 A. What I meant by that was an  
 220:2 excessive extraordinary amount of data.  
 220:3 Q. And why is an extraordinary amount  
 220:4 of data on a side effect of -- like gynecomastia  
 220:5 nauseating to you?  
 220:8 - 221:3 **Binder, Carin 07-17-2013 (00:01:08)**  
 220:8 THE WITNESS: It's not nauseating to me.  
 220:9 It was a colloquial way to say that the data's  
 220:10 been looked at every which way.  
 220:11 BY MR. GOMEZ:  
 220:12 Q. Okay. "the data's been looked at  
 220:13 every which way," and then you emphasize and  
 220:14 exclaim, "There's nothing to find people." What  
 220:15 does that mean?  
 220:16 A. What that means is it would appear  
 220:17 that there is no clinical significance to

Page/Line

Source

ID

220:18 prolactin and SHAP.

220:19 Q. In whose assessment is that, that

220:20 there's no clinical significance?

220:21 A. Based on the experts.

220:22 Q. And who are the experts?

220:23 A. Tom Moshang, Denis Daneman, Robert

220:24 Findling, Vivek Kusumakar.

220:25 Q. When you wrote, "There's nothing to

221:1 find people," okay, are you ignoring the

221:2 statistically significant correlation at weeks 8

221:3 to 12 or discounting it?

221:6 - 221:14 **Binder, Carin 07-17-2013 (00:00:21)**

221:6 THE WITNESS: Neither.

221:7 BY MR. GOMEZ:

221:8 Q. Do you think the statistically

221:9 significant correlation would be of interest to

221:10 some clinicians who were prescribing Risperdal to

221:11 children and adolescents?

221:12 A. That's not my judgment to make.

221:13 Q. If it's not your judgment to make,

221:14 why is it not in the final paper?

221:18 - 222:5 **Binder, Carin 07-17-2013 (00:00:37)**

221:18 THE WITNESS: The intent again was to

221:19 show -- or explore long-term effects of prolactin

221:20 and SHAP.

221:21 BY MR. GOMEZ:

221:22 Q. Are you testifying here today that

221:23 the relationship at weeks 8 to 12 does not exhibit

221:24 long-term effects?

221:25 A. I'm not inferring anything. You

222:1 would need to ask your experts.

222:2 Q. Why would you submit this draft

222:3 internally to get everybody's position on

222:4 monitoring before you would send it to the outside

222:5 authors?

222:12 - 223:8 **Binder, Carin 07-17-2013 (00:01:07)**

222:12 THE WITNESS: From a company perspective,

222:13 people like Goedele De Smedt and Vincent Nys are

222:14 operating -- or were operating at a level beyond

222:15 just my little Canadian boundaries; hence, they

Page/Line	Source	ID
	222:16 would be involved in regulatory discussions around 222:17 the world, to which I'm not privy and would not 222:18 have been privy. 222:19 And hence, if there were regulatory 222:20 discussions about monitoring that was going to 222:21 appear on a label, it may or may not have been 222:22 appropriate to incorporate that into a manuscript. 222:23 BY MR. GOMEZ: 222:24 Q. Did Georges Gharabawi have anything 222:25 to do with regulatory? 223:1 A. I don't know. 223:2 Q. What about Gahan Pandina? Weren't 223:3 they both in medical affairs? 223:4 A. They were in U.S. medical affairs. 223:5 Q. Do you know as you sit here today 223:6 whether or not in this time frame, U.S. medical 223:7 affairs had any say on issues of regulatory 223:8 compliance?	
223:11 - 223:11	<b>Binder, Carin 07-17-2013 (00:00:01)</b>	BINDER_07172013_PA_02_001
	223:11 THE WITNESS: I have no idea.	
224:9 - 224:17	<b>Binder, Carin 07-17-2013 (00:00:26)</b>	BINDER_07172013_PA_02_027
	224:9 Q. Let's turn the page to the 224:10 attachment. And at the bottom, it's revised 224:11 November 19th, 2002? Correct? 224:12 A. Correct. 224:13 Q. And this is another draft of what 224:14 would eventually become the Findling 2003 article. 224:15 Would you agree? 224:16 A. Yes. 224:17 Q. I point your attention to Bate	
224:18 - 224:24	<b>Binder, Carin 07-17-2013 (00:00:26)</b>	BINDER_07172013_PA_02_034
	224:18 stamp ending in 082. 224:19 A. Yes. 224:20 Q. Of all the drafts we've looked at 224:21 today, this is the first that talk about SHAP(A) 224:22 and SHAP(B) that we've talked about earlier today 224:23 that was seen in the final article. Would you 224:24 agree?	
225:2 - 225:2	<b>Binder, Carin 07-17-2013 (00:00:02)</b>	BINDER_07172013_PA_02_038
	225:2 THE WITNESS: Yes.	

Page/Line

Source

ID

225:20 - 227:8

**Binder, Carin 07-17-2013 (00:01:54)**

225:20 Q. See the paragraph under the table?

225:21 A. Yes.

225:22 Q. Okay? Is... I'll read it. "The

225:23 percentage of children with SHAP(A) was assessed

225:24 for patients with prolactin levels above the

225:25 [upper limits of normal] versus patients with

226:1 prolactin levels within the normal range at the

226:2 various [analysis] time periods."

226:3 And SHAP(A) is the inclusive

226:4 analysis; there's no exclusion of kids over the

226:5 age of 10. Correct?

226:6 A. I believe you are correct.

226:7 Q. The paragraph goes on. "The

226:8 proportions were all comparable except for Weeks 8

226:9 to 12 time period, in which 7.8% of [the] patients

226:10 who had prolactin above the ULN had SHAP at some

226:11 point during the trial, while 2.9% of [the]

226:12 patients with prolactin levels within the normal

226:13 range at Weeks 8 to 12 experienced SHAP at some

226:14 time during the study," and there's a "P=0.02."

226:15 Did I read that correctly?

226:16 A. You did.

226:17 Q. Then the next sentence talks about

226:18 the fact that there was, quote, "There was no

226:19 statistical difference in the percentage of

226:20 patients who reported SHAP for any other analysis

226:21 time period, whether or not prolactin levels were

226:22 normal or above the [upper limits of normal]."

226:23 So it was discussing all the other

226:24 analysis time periods besides weeks 8 to 12 in

226:25 SHAP(A). Right?

227:1 A. Yes.

227:2 Q. Okay. And then it reads, "This

227:3 holds true for the SHAP(B) analysis as well."

227:4 So in this paragraph, the

227:5 comparison of elevated prolactin levels and side

227:6 effects like gynecomastia, to explore that

227:7 relationship, is being discussed all inclusively;

227:8 it's including SHAP(A) and SHAP(B). Correct?



Page/Line	Source	ID
227:12 - 228:3	<p><b>Binder, Carin 07-17-2013 (00:00:54)</b>  227:12 THE WITNESS: Correct.  227:13 BY MR. GOMEZ:  227:14 Q. And the SHAP(A) population includes  227:15 those kids with puberty -- in puberty. Would you  227:16 agree?  227:17 A. Let me check the analysis plan.  227:18 Right. So it included age group  227:19 levels. So there was analysis of prolactin levels  227:20 by age.  227:21 Q. Okay. If you could turn the page?  227:22 A. To 85?  227:23 Q. 85.  227:24 A. Yeah.  227:25 Q. There's the second paragraph? And  228:1 that's the paragraph doing the same comparison,  228:2 but it's only looking at the SHAP(B) patients.  228:3 Would you agree?</p>	MARK_07172013_PA_02111
228:6 - 228:23	<p><b>Binder, Carin 07-17-2013 (00:00:17)</b>  228:6 THE WITNESS: Okay. So you want me to  228:7 read -- so it's the second paragraph of that page?  228:8 BY MR. GOMEZ:  228:9 Q. Sure. I'll pull your attention to  228:10 the first sentence of --  228:11 A. The first --  228:12 Q. -- the page.  228:13 A. -- sen -- okay.  228:14 Q. "All further comments will describe  228:15 the --"  228:16 A. "SHAP(B)."  228:17 Q. "-- SHAP(B) population."  228:18 A. Yes.  228:19 Q. Okay?  228:20 A. Yes.  228:21 Q. After you've read that, the next  228:22 paragraph is excluding kids over the age of 10.  228:23 Would you agree?</p>	MARK_07172013_PA_02112
228:24 - 228:24	<p><b>Binder, Carin 07-17-2013 (00:00:03)</b>  228:24 A. Yes, for SHAP(B).</p>	MARK_07172013_PA_02113
230:13 - 230:24	<p><b>Binder, Carin 07-17-2013 (00:00:25)</b></p>	MARK_07172013_PA_02114

Page/Line

Source

ID

230:13 Q. This

230:14 paragraph is talking about SHAP(A) kids. Correct?

230:15 A. It is.

230:16 Q. SHAP(A) kids are those kids even

230:17 with puberty. Correct?

230:18 A. Correct.

230:19 Q. Now go to -- based on what I've

230:20 just showed you, the sentence reading, "No

230:21 correlation was found between SHAP and prolactin

230:22 levels, even when male gynecomastia during puberty

230:23 was included," is inaccurate. Would you agree?

230:24 A. No.

231:1 - 231:3

**Binder, Carin 07-17-2013 (00:00:02)**

231:1 THE WITNESS: No, I wouldn't.

231:2 BY MR. GOMEZ:

231:3 Q. Why would you not agree with that?

231:6 - 231:9

**Binder, Carin 07-17-2013 (00:00:06)**

231:6 THE WITNESS: Because the article clearly

231:7 states, this draft, that the comments pertain to

231:8 the SHAP(B) population.

231:9 BY MR. GOMEZ:

231:12 - 232:24

**Binder, Carin 07-17-2013 (00:01:35)**

231:12 THE WITNESS: On your identifier 085, at

231:13 the top of the page, it states, "All further

231:14 comments will describe the SHAP(B) population."

231:15 And secondly, there is no time

231:16 frame denoted regarding the comment on page 88.

231:17 So over time, there is no statistically

231:18 significant difference from day zero to week 48 is

231:19 the interpretation of this.

231:20 BY MR. GOMEZ:

231:21 Q. Okay. You reference "All further

231:22 comments" at the top of that page. Right?

231:23 A. "will describe ... SHAP(B)

231:24 population."

231:25 Q. In the previous page, it was a

232:1 SHAP(A) discussion, where everybody's included.

232:2 We've agreed on that.

232:3 A. Right.

232:4 Q. Right?

Page/Line

Source

ID

232:5 A. Yes.

232:6 Q. Okay. Then going forward from  
232:7 that, all further comments are going to talk about  
232:8 the SHAP(B) population. And if I point your  
232:9 attention to the last page...

232:10 A. Hm-hmm.

232:11 Q. Or the page we were talking about.

232:12 MR. MURPHY: Namely.

232:13 MR. GOMEZ: Bate stamped 088.

232:14 THE WITNESS: Hm-hmm?

232:15 BY MR. GOMEZ:

232:16 Q. "No correlation was found between  
232:17 SHAP and prolactin levels, even when male  
232:18 gynecomastia during puberty was included," is  
232:19 inaccurate, because it's including kids with  
232:20 puberty. SHAP(B) doesn't include kids in puberty.  
232:21 Would you agree?

232:22 A. That is correct.

232:23 Q. So based on what I've just shared  
232:24 with you, that sentence is inaccurate.

233:6 - 233:10

**Binder, Carin 07-17-2013 (00:00:09)**

233:6 A. It's the same answer, Mr. Gomez.  
233:7 It's over the entirety of the study. Why don't  
233:8 you ask me the question -- sorry.  
233:9 MR. MURPHY: You've answered the  
233:10 question.

233:20 - 234:17

**Binder, Carin 07-17-2013 (00:00:55)**

233:20 Q. We can agree that based on this  
233:21 draft in August of 2002, after the advisory board  
233:22 told Janssen to include all information on  
233:23 gynecomastia, the discussion of the statistically  
233:24 significant relationship at weeks 8 to 12 is back  
233:25 in the drafts for the manuscript. Correct?

234:1 A. I'm not sure about the dates. You  
234:2 just referenced August 2002.

234:3 Q. Yeah, if you look on that draft we  
234:4 were just looking at, it's dated --

234:5 A. It says --

234:6 Q. -- August 19th, 2002.

234:7 A. It says November 19th, 2002.

Page/Line

Source

ID

234:8 Q. And you are absolutely correct. I  
 234:9 stand corrected. It says November 19th, 2002.  
 234:10 Okay?  
 234:11 A. Okay.  
 234:12 Q. As of November 19th, 2002, the  
 234:13 discussion of the statistically significant  
 234:14 relationship at weeks 8 to 12 that came from the  
 234:15 five DBD studies is being discussed in the draft  
 234:16 that would eventually become the Findling article.  
 234:17 Do you agree?

234:20 - 235:2

**Binder, Carin 07-17-2013 (00:00:22)**

234:20 THE WITNESS: Yes.  
 234:21 BY MR. GOMEZ:  
 234:22 Q. Do you remember any discussions  
 234:23 with Dr. Findling about whether or not to include  
 234:24 that in the final paper going forward from  
 234:25 November 2002 to when it was submitted in  
 235:1 January 2003?  
 235:2 A. I do not.

235:5 - 236:24

**Binder, Carin 07-17-2013 (00:02:33)**

235:5 MR. GOMEZ: Let me just mark as an  
 235:6 exhibit... I'll mark as Exhibit 26 another e-mail  
 235:7 dated January 8th, 2003 or thereabouts. And --  
 235:8 well, January 2003 e-mail chain.  
 235:9 (Whereupon the above-mentioned  
 235:10 document was marked for  
 235:11 identification as Exhibit 26.)

235:12 BY MR. GOMEZ:

235:13 Q. And I'll represent to you this  
 235:14 e-mail's talking about Mental -- World Mental  
 235:15 Health Day in 2003 that was going to take place in  
 235:16 October, and finding a physician to talk about  
 235:17 disruptive behavioral disorders.  
 235:18 You responded to Pamela Rasmussen  
 235:19 and Vincent Nys on this subject on January 3rd,  
 235:20 2003. Can you read what you wrote?  
 235:21 A. At 9:34 a.m.?  
 235:22 Q. That's correct.  
 235:23 A. "Pam - Peter has been involved in  
 235:24 quite a few US med[ical] affairs ad boards over

Page/Line

Source

ID

235 5 the past year and he was in Hamburg Germany for  
 236 the RIS - DBD sessions. He is known for ADHD but  
 236 apparently once he saw our data he became an  
 236 advocate for risperidone and has stated that he  
 236 would be willing to go to the FDA with Janssen to  
 236 discuss getting the indication."  
 236 "Findling is OK but I find he  
 236 doesn't stand up firmly for his convictions and  
 236 tends to be swayed. On the other hand - he'll  
 236 do/say whatever you want him to... Your choice  
 236 0 Pam."  
 236 1 Q. Do you remember -- after reading  
 236 2 this e-mail, do you remember anybody at Janssen  
 236 3 ever telling Dr. Findling what to say?  
 236 4 A. I do not.  
 236 5 Q. At any time, not just in regards to  
 236 6 this article.  
 236 7 A. I do not.  
 236 8 Q. Dr. Findling wrote other articles  
 236 9 about risperidone in Janssen clinical trials.  
 236 0 Agreed?  
 236 1 A. I'm sure he did.  
 236 2 Q. And he wrote an article about RIS  
 236 3 I -- RIS USA 97. Do you remember?  
 236 4 A. I know that article exists, yes.

243:20 - 244:12

**Binder, Court 07-17-2013 (00-00-10)**

243:20 Q. You worked for Janssen-Ortho Inc.  
 243:21 between May -- in the year 2002. Agreed?  
 243:22 A. Yes.  
 243:23 Q. And you conducted a prolactin  
 243:24 reanalysis involving pooling five studies. We've  
 243:25 talked about that. Right?  
 244:1 A. Yes.  
 244:2 Q. Okay. And as part of that analysis  
 244:3 plan, a chi-square analysis was done comparing  
 244:4 elevated prolactin levels with those with normal  
 244:5 prolactin levels at various analysis time periods.  
 244:6 Correct?  
 244:7 A. Yes.  
 244:8 Q. All right. And in May of 2002,

Page/Line

Source

ID

244:9 Table 21, using a chi-squared analysis, showed a  
 244:10 statistically significant relationship between  
 244:11 elevated prolactin levels and things like  
 244:12 gynecomastia or SHAP. Agreed?

244:15 - 244:16

**Binder, Carin 07-17-2013 (00:00:04)**

244:15 THE WITNESS: It showed a statistically  
 244:16 significant difference for weeks 8 to 12.

250:7 - 251:15

**Binder, Carin 07-17-2013 (00:01:30)**

250:7 Q. The purpose of this paper, ma'am,  
 250:8 was to educate physicians regarding Risperdal's  
 250:9 elevated prolactin and gynecomastia and any  
 250:10 relationship. Agreed? You can look in the  
 250:11 abstract if you need to.  
 250:12 A. The objective of this analysis was  
 250:13 to investigate serum prolactin levels in children  
 250:14 and adolescents who received long-term risperidone  
 250:15 treatment and to explore any possible correlation  
 250:16 with side effects hypothetically attributable to  
 250:17 elevated prolactin levels, because -- so that was  
 250:18 the objective.  
 250:19 Q. Was the analysis designed to  
 250:20 investigate prolactin levels in children and  
 250:21 adolescents and explore any relationship with  
 250:22 SHAP?  
 250:23 A. Correct, to explore any possible  
 250:24 correlation with side effects hypothetically  
 250:25 attributable to elevated serum prolactin. It  
 251:1 doesn't say serum.  
 251:2 Q. And after all the documents I've  
 251:3 shown you today, you agree that in May of 2002,  
 251:4 you were aware of a relationship between elevated  
 251:5 prolactin levels and SHAP.  
 251:6 A. You've pointed out to me that there  
 251:7 was a statistically significant difference in one  
 251:8 time point.  
 251:9 Q. And you were aware of that  
 251:10 statistically significant difference at one time  
 251:11 point in May of 2002. Do you agree?  
 251:12 A. I would have seen the tables, yes.  
 251:13 Q. And you would have forwarded those

Page/Line

Source

ID

251:14 tables to Gahan Pandina, so we can assume he was  
 251:15 aware of it as well. Would you agree?  
 251:18 - 252:14 **Binder, Carin 07-17-2013 (00:00:57)**  
 251:18 THE WITNESS: I don't know if I would  
 251:19 have forwarded those tables to Gahan Pandina.  
 251:20 BY MR. GOMEZ:  
 251:21 Q. We can go back and look at the  
 251:22 exhibit. I represent to you that you actually  
 251:23 forwarded the -- forwarded them to him.  
 251:24 A. Okay.  
 251:25 Q. Okay? And the reason -- would you  
 252:1 agree with me the reason you were forwarding them  
 252:2 to him, so he would read them and be aware of  
 252:3 what's in them? Would you agree?  
 252:4 A. As whatever is stated in the e-mail  
 252:5 to him, for his input, for his review, for his  
 252:6 knowledge.  
 252:7 Q. Based on all the documents we've  
 252:8 seen today, the first two drafts in July of 2002  
 252:9 discuss the statistically significant relationship  
 252:10 at weeks 8 to 12. Do you agree with that?  
 252:11 A. The... There was a paragraph in  
 252:12 those drafts that you showed me, yes.  
 252:13 Q. And we can agree that it was taken  
 252:14 out of the October 4th, 2002 draft.  
 252:19 - 253:5 **Binder, Carin 07-17-2013 (00:00:31)**  
 252:19 THE WITNESS: It seems so, yes.  
 252:20 BY MR. GOMEZ:  
 252:21 Q. And then after the November 15th  
 252:22 advisory board, another draft was circulated, and  
 252:23 the statistically significant relationship was  
 252:24 back in. Do you agree with that, after all I've  
 252:25 shown you today?  
 253:1 A. I saw that, yes.  
 253:2 Q. And we can agree, after everything  
 253:3 I've shown you today, that the statistically  
 253:4 significant relationship was not in the final  
 253:5 paper. Agreed?  
 253:8 - 253:9 **Binder, Carin 07-17-2013 (00:00:08)**  
 253:8 THE WITNESS: What is not in the final

Page/Line

Source

ID

253:9 paper is the 8 to 12 week analysis with SHAP(A).

Our Designations = 02:25:45

Their Counters = 00:02:38

**Total Time = 02:28:23**

**Documents Shown**

BINDER 2013-EXHIBIT11  
BINDER 2013-EXHIBIT12  
BINDER 2013-EXHIBIT13  
BINDER 2013-EXHIBIT14  
BINDER 2013-EXHIBIT15  
BINDER 2013-EXHIBIT16  
BINDER 2013-EXHIBIT17  
BINDER 2013-EXHIBIT18  
BINDER 2013-EXHIBIT19  
BINDER 2013-EXHIBIT2  
BINDER 2013-EXHIBIT20  
BINDER 2013-EXHIBIT21  
BINDER 2013-EXHIBIT22  
BINDER 2013-EXHIBIT23  
BINDER 2013-EXHIBIT24  
BINDER 2013-EXHIBIT25  
BINDER 2013-EXHIBIT26  
BINDER 2013-EXHIBIT3  
BINDER 2013-EXHIBIT6  
BINDER 2013-EXHIBIT7  
BINDER 2013-EXHIBIT8  
BINDER 2013-EXHIBIT9