1	PHILADELPHIA COUNTY COURT OF COMMON PLEAS
2	TRIAL DIVISION
3	
4	
5	X
6	IN RE: RISPERDAL LITIGATION :
7	:
8	THIS APPLIES TO ALL CASES : March Term 2010
9	: Case No. 296
10	X
11	
12	Toronto, Ontario, Canada
13	Friday, December 14, 2012
14	
15	
16	Videotaped Deposition of:
17	DR. DENIS DANEMAN
18	the witness, called for examination by counsel
19	for the Plaintiffs, pursuant to notice and
20	agreement, commencing at 9:20 a.m., at Toronto
21	Court Reporters, 65 Queen Street West, Suite 1410,
22	Toronto, before Virlana Kardash, RPR, CSR,
23	Commissioner of Oaths, when were present on behalf
24	of the respective parties:
25	

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1	APPEARANCES:	1	Exhibit No. 10 142
2		2	Exhibit No. 11 148
3	On behalf of the Plaintiffs:	3	Exhibit No. 12 153
4	CHRISTOPHER GOMEZ, Esquire	4	Exhibit No. 13 156
5	SHELLER P.C.	5	
6	1528 Walnut Street 3rd floor	6	
7	Philadelphia, Pennsylvania 19102	7	
8	215-790-7325	8	
9		9	
10	On behalf of Defendant Janssen Ortho:	10	
11	WILLIAM ESSIG, Esquire	11	
12	DINKER BIDDLE & REATH	12	
13	191 North Wacker Drive Suite 3700	13 14	
14 15	Chicago, Illinois 60606 312-569-1497	14	
16	512-509-1497	16	
17	On behalf of Defendants Excerpta Medica and	17	
18	Elsevier Inc.:	18	
19	M. TODD MOBLEY, Esquire	19	
20	PROSKAUER ROSE	20	
21	Eleven Times Square	21	
22	New York, New York 10036	22	
23	212-969-3212	23	
24		24	
25	Also present: Videographer P. Rodney Barnes	25	
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1	Page 3 C O N T E N T S	1	Page 5 P R O C E E D I N G S
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	Page 6		Page 8
1	defendants Excerpta Medica and Elsevier Inc.	1	pediatrics and then do a period of training in a
2	Whereupon,	2	subspecialty called Pediatric Endocrinology, which
3	DR. DENIS DANEMAN	3	basically deals with the hormone conditions of the
4	was called as a witness and, having first been duly	4	body.
5	sworn, was examined and testified as follows:	5	So there would be two or three major groups.
6	EXAMINATION	6	Diabetes in childhood would be one major group.
7	BY MR. GOMEZ:	7	Calcium and bone problems would be a second major
8	Q Good morning, Dr. Daneman.	8	group, and then general endocrine problems would be
9	A Good morning.	9	the third major group.
10	Q My name is Christopher Gomez. I represent	10	Q Okay. We're in Toronto, Canada?
11	a number of plaintiffs who have filed lawsuits in the	11	A Yes.
12	Philadelphia County Court of Common Pleas against the		Q How long have you worked in Toronto?
13	manufacturers of Risperdal and a medical writing	13	A In my present situation, since 1981.
14	company named Excerpta Medica and Elsevier.	14	Q And if you don't mind, give me your present
15	Are you familiar with that litigation in any	15	title and where you work.
16	way?	16	A I work at the Hospital for Sick Children
17	A I am.	17 18	and the University of Toronto in the Department of Pediatrics where I'm currently Professor and Chair of
18 19	Q Okay. We're going to talk about that a little bit later, but before we begin, if you need to	18 19	the department of Pediatrics at the University of
20	take a break at any time, please let me know, and	20	Toronto and Pediatrician in Chief at the Hospital for
20	we'll be sure to accommodate you. Have you ever been	20	Sick Children.
22	deposed before?	22	MR. ESSIG: Doctor, if I may, you may want
23	A I have.	23	to take your time. It's going to be hard for our
24	Q I won't spend too much time then, but I	24	court reporter.
25	just want to go over a few ground rules. I'll be	25	THE COURT REPORTER: Slow down. Thank you.
	Page 7		Page 9
1	asking the questions, and you'll be giving the	1	BY MR. GOMEZ:
2	asking the questions, and you'll be giving the answers. Do you understand that?	2	BY MR. GOMEZ: Q Dr. Daneman, you kindly provided me with
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	Dogo 10		Dage 12
1	Page 10 A Yes.	1	Page 12 $\Omega$ . Lust so the jury understand and this is
		1	Q Just so the jury understand and this is
2	Q I'm going to be showing you a number of	2	on videotape. So there's a high likelihood the jury
3	documents today and asking you questions about them,	3	will see this deposition can you tell them what
4	but the first thing I'm going to do and mark as an	4	prolactin is?
5	exhibit is a document that you brought today which is	5	A Prolactin is a hormone that is secreted by
6	a two-page document entitled "Denis Daneman Comments		the anterior part of the pituitary gland, and its main
7	on Prolactin."	7	function is to support lactation in the woman who has
8	Let me just mark that as Exhibit 1.	8	just given birth to a baby. That's the lactin part of
9	(Whereupon, Exhibit No. 1 was marked for	9	it. It stimulates the lactotrophs in the breast to
10	identification.)	10	produce milk. That's its major role.
11	MR. ESSIG: Chris, were you planning on	11	Q Okay. And the first No. 1 here is the
12	marking the curriculum vitae as well? I have a copy	12	segmentation of prolactin levels. What does that
13	if you want to mark that.	13	mean?
14	MR. GOMEZ: Yes. Remind me to do that as	14	A I tried at this time when I put this
15	well. I'll do it right after this. I'm not going to	15	together to determine from the literature if there was
16	ask him any questions about it, but we might as well	16	a level of prolactin that had clinical significance.
17	put it on the record.	17	And this is the best I could come up with. Levels
18	BY MR. GOMEZ:	18	above 200 usually are associated with a tumor in the
19	Q Doctor, I'm going to hand you what I've	19	pituitary gland in which the lactotrophs those are
20	marked as Exhibit 1. And if you wouldn't mind handing	20	the cells that produce prolactin form a tumor and
21	your copy there to Mr. Essig so I'll have one to ask	21	produce prolactin in an uncontrolled manner.
22	you questions about. Doctor, prior to this	22	And you usually have levels above 200. And that
23	deposition, did you receive a request in writing or	23	might be associated with a whole variety of side
24	any other way to produce certain documents in	24	effects, not at all common in the pediatric population
25	preparation for your deposition today?	25	under 18. Much more common in the adult population.
	Page 11		Page 13
1	A I did. I did.	1	My reading of the literature at the time was
2	Q Is this one of those documents?	2	that in the 100 to 200 range, it was usually
3	A I produced what I had, and then I found one	3	clinically important that below 100 it was difficult
4	more document, and this was it. So that's why I	4	to be sure of what the importance was. And below 30,
5	produced it today.	5	I couldn't find evidence that it was clinically
6	Q Okay. And this is entitled "Denis Daneman	6	important.
7	Comments on Prolactin." Do you see that at the top?	7	Then I made the comment that levels can be
8	A Yes.	8	influenced by stress, usually not above 50, although
9	Q When did you write this?	9	we have seen them occasionally above 50. And I
10	A I can't give you an exact date, but prior	10	wondered for the purposes of the Janssen Ortho
11	to the publication of that article, I put together	11	Risperdal studies whether we should segment into
12	some thoughts on how one would go about looking at the		tertiles according to available data or else below the
13	effect of prolactin on the body if you will.	13	upper limits of normal, 25 to 30, in the 30 to 50, and
14	Q The effects of the prolactin on the body,	14	above 50 range to see if the problem is that this
15	would that be specifically as to children and	15	is not a binary or ternary thing.
16	adolescents?	16	It's a constant. It doesn't go from 25 to 50
17	A Yes. I have no experience in adult.	17	and then to 150. So this was just my thinking aloud.
18	Q Did you do this on your own, or did someone	18	Q When you're talking about these levels, is
19	ask you to do this, to write this?	19	this a one-time level? Or is this did you take
20	A I did this as a way of thinking through how	20	into account prolonged use and prolonged prolactin
	we should analyze the data that came up in the Janssen	21	elevation at these different
21		22	A So
21	Ortho Risperdal studies.	LL	A 50
	Ortho Risperdal studies. Q After you wrote this up, did you send it to	22 23	Q I'm sorry. Let me finish my question.
22			
22 23	Q After you wrote this up, did you send it to	23	Q I'm sorry. Let me finish my question.

4 (Pages 10 to 13)

	Page 14		Page 16
1	did you take that into account or do a search on that	1	Q Let me back up and follow up on
2	issue?	2	gynecomastia. That is breast growth in males; is that
3	MR. ESSIG: Objection to the form.	3	right?
4	BY MR. GOMEZ:	4	A Yes.
5	Q You can answer.	5	Q That's how it's defined?
6	A So if you go down to No. 4, relationship of	6	A Yes.
7	level to side effects, my assessment from the	7	Q You say it's usually fatty. What do you
8 9	literature I read was that the higher the level, the	8 9	mean by that?
10	more likely my spelling there is incorrect I notice now.	10	A So in many males who are a little overweight, there can be fatty tissue in the breast
11	The higher the level of prolactin, the more	11	region, and we call that pseudogynecomastia. True
12	likely the side effects. But the duration was very	12	gynecomastia is when the duct tissue of the breast is
13	important as well. Although I cannot recall finding	13	actually enlarged.
14	anything to suggest what the duration exactly was that		You can have both together. You can have one or
15	required attention.	15	the other.
16	Q You say the higher the level equals more	16	Q When you say that one of the side effects
17	likely; that's what you wrote here?	17	of prolactin is gynecomastia correct is that
18	A More likely side effects. So above 200	18	what you wrote here?
19	more likely than below 100.	19	A I wrote that. It can be.
20 21	Q And when you say "side effects," what are we talking about?	20 21	Q Is one of the side effects of prolactin fatty gynecomastia?
21	A So what prolactin does besides in the woman	21	A So the more fatty tissue in the breast, the
23	who's just given birth to a baby and has an estrogen	23	more likely the testosterone to estrogen conversion
24	primed ductular system in the breast, it stimulates	24	that I believe is the spirit in which that's written.
25	production of milk in the breast. That's the effect	25	Although I can't go back 12 years or so and tell you
	Page 15		Page 17
1	of prolactin.	1	exactly why that's there.
2	In somebody who's not just had a baby, high	2	Q Would it be fair to say that true
3 4	prolactin levels can in females and this is under No. 2 delay puberty, cause menstrual disturbances,	3 4	gynecomastia is usually evidenced by some sort of breast tissue?
5	amenorrhea, or loss of menstrual cycles, decrease in	5	A Yes.
		•	
6	the number of mensulual cycles, menormagia, which is	6	
6 7	the number of menstrual cycles, menorrhagia, which is increased bleeding during menstrual cycles,	6 7	Q And that can be seen or palpated by a doctor?
7 8	increased bleeding during menstrual cycles, infertility and galactorrhea.	7 8	Q And that can be seen or palpated by a doctor? A Yes. Yes.
7 8 9	increased bleeding during menstrual cycles, infertility and galactorrhea. Galactorrhea is production of milk from the male	7 8 9	<ul><li>Q And that can be seen or palpated by a doctor?</li><li>A Yes. Yes.</li><li>Q Going back to the segmentation of prolactin</li></ul>
7 8 9 10	increased bleeding during menstrual cycles, infertility and galactorrhea. Galactorrhea is production of milk from the male or female breast at a time that they're not pregnant	7 8 9 10	<ul> <li>Q And that can be seen or palpated by a doctor?</li> <li>A Yes. Yes.</li> <li>Q Going back to the segmentation of prolactin levels, if you have a prolactin level between 18 and</li> </ul>
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7 8 9 10 11 12 13 14	increased bleeding during menstrual cycles, infertility and galactorrhea. Galactorrhea is production of milk from the male or female breast at a time that they're not pregnant or lactating. In the male, it can cause hypergonadism, which is underactivity of the testicles, gynecomastia, which is male breast development.	7 8 9 10 11 12 13 14	Q And that can be seen or palpated by a doctor? A Yes. Yes. Q Going back to the segmentation of prolactin levels, if you have a prolactin level between 18 and 30 and it's prolonged, is the likelihood of side effects more prevalent? A I have no evidence that it's prevalent at all. I have nothing in the literature that guides me
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7 8 9 10 11 12 13 14 15 16 17 18	<ul> <li>increased bleeding during menstrual cycles,</li> <li>infertility and galactorrhea.</li> <li>Galactorrhea is production of milk from the male</li> <li>or female breast at a time that they're not pregnant</li> <li>or lactating. In the male, it can cause</li> <li>hypergonadism, which is underactivity of the</li> <li>testicles, gynecomastia, which is male breast</li> <li>development.</li> <li>And in brackets I put there it's often fatty</li> <li>tissue rather than true gynecomastia. Galactorrhea is</li> <li>much less common in the male than the female. It can</li> <li>delay puberty. And there have been occasional case</li> </ul>	7 8 9 10 11 12 13 14 15 16 17 18	Q And that can be seen or palpated by a doctor? A Yes. Yes. Q Going back to the segmentation of prolactin levels, if you have a prolactin level between 18 and 30 and it's prolonged, is the likelihood of side effects more prevalent? A I have no evidence that it's prevalent at all. I have nothing in the literature that guides me on that nor clinical experience. Q Under No. 5 you have value of Tanner staging. What did you mean when you wrote that, that title "Value of Tanner Staging"?
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	<ul> <li>increased bleeding during menstrual cycles,</li> <li>infertility and galactorrhea.</li> <li>Galactorrhea is production of milk from the male</li> <li>or female breast at a time that they're not pregnant</li> <li>or lactating. In the male, it can cause</li> <li>hypergonadism, which is underactivity of the</li> <li>testicles, gynecomastia, which is male breast</li> <li>development.</li> <li>And in brackets I put there it's often fatty</li> <li>tissue rather than true gynecomastia. Galactorrhea is</li> <li>much less common in the male than the female. It can</li> <li>delay puberty. And there have been occasional case</li> <li>reports of high prolactin levels interfering with</li> <li>growth.</li> <li>But that's very, very unusual and I don't think</li> <li>holds up. There's also some question as to the effect</li> </ul>	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q And that can be seen or palpated by a doctor? A Yes. Yes. Q Going back to the segmentation of prolactin levels, if you have a prolactin level between 18 and 30 and it's prolonged, is the likelihood of side effects more prevalent? A I have no evidence that it's prevalent at all. I have nothing in the literature that guides me on that nor clinical experience. Q Under No. 5 you have value of Tanner staging. What did you mean when you wrote that, that title "Value of Tanner Staging"? A Tanner staging gives you an idea of where the child that you're examining is on the continuum of prepuberty, early, mid, late puberty, and full sexual maturation. And if you're going to look at side

5 (Pages 14 to 17)

	Page 18		Page 20
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>Q Can a young man in puberty, ages 12 to 14, develop gynecomastia from prolactin elevation?</li> <li>A It's a very good question, and the literature doesn't answer that with a definitive answer. The number of boys in the 12 to 14 year age group in puberty who have gynecomastia without elevation of prolactin is very high.</li> <li>At some point in time, if you examine boys throughout puberty as they go through Tanner stages two, three, and up to four, up to two thirds of them will have some degree of breast tissue that develops and then regresses over time.</li> <li>Q So if I understand you correctly, the fact that a boy is in puberty okay it's more likely that if he develops gynecomastia, it's from normal development through puberty?</li> <li>A Pubertal gynecomastia from prolactin elevation caused by antipsychotics?</li> <li>MR. ESSIG: Objection to the form. THE WITNESS: I don't have a definitive answer to that from the medical literature. BY MR. GOMEZ:</li> <li>Q Based on your research and what you did</li> </ul>	$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>A Yes.</li> <li>Q It's an atypical antipsychotic?</li> <li>A Absolutely.</li> <li>Q Is it your understanding that Risperdal raises prolactin? That's one of its side effects, so to speak?</li> <li>A Yes.</li> <li>Q And as a result of Risperdal raising prolactin, it can cause gynecomastia, generally? MR. ESSIG: Object to the form. THE WITNESS: It can. BY MR. GOMEZ:</li> <li>Q With what we just talked about right there and what you spoke earlier about puberty, if a boy between the ages of 12 and 14 develops gynecomastia, does the fact that he's in puberty eliminate all other causes of the gynecomastia? MR. ESSIG: Object to the form. THE WITNESS: So you'd have to have a significantly higher incidence of gynecomastia with the agent that you're talking about to be able to make a cause-and-effect relationship. BY MR. GOMEZ:</li> <li>Q If a doctor, an endocrinologist or any other doctor, is determining what caused a 12 to 14</li> </ul>
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>Page 19</li> <li>back before 2003, for example, in writing this up, can you categorically dismiss antipsychotic-induced prolactin elevation as a cause for gynecomastia in a boy in puberty? MR. ESSIG: Object to the form. THE WITNESS: How do I respond to the objection? BY MR. GOMEZ:</li> <li>Q You can answer. Did you understand my question?</li> <li>A I don't understand the word "categorical" in the medical sense of the term. It requires me to give you a black and white answer, and the answer from the medical literature doesn't allow the answer to say categorically prolactin can cause it.</li> <li>And one has to recognize that the medical literature stands at that point in time where the comments were made at that study, and it's free to be turned over by any subsequent studies. And I haven't seen anything in the literature since then that would categorically turn over the conclusions of that particular study.</li> <li>Q Okay. Let me back up and just ask a general question. Okay? Are you familiar with Risperdal and what type of drug it is?</li> </ul>	$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	Page 21 year old boy's gynecomastia, can he dismiss out of hand every other cause just because that boy is in puberty? A No. MR. ESSIG: Objection to the form. BY MR. GOMEZ: Q We were talking about pubertal development in gynecomastia. You mentioned that the percentage is very high. Do you remember talking about that? A Yes. Q Where did you get that from? A From the medical literature textbooks and over many years of experience of seeing hundreds of thousands of teenage boys. You know, you said earlier my major career is in pediatric diabetes. We see tons of teenage boys. We do the examination. We stage their puberty. And a significant number of them develop gynecomastia during the early to mid stages of puberty. Q Can you put a percentage on the percentage of boys in puberty between the ages of 12 and 14 who develop gynecomastia? MR. ESSIG: Object to the form. THE WITNESS: It's been said if you examine them carefully, up to two thirds would have some

	Page 22		Page 24
1	evidence of gynecomastia.	1	that, do you remember any specific posters from this
2	BY MR. GOMEZ:	2	article that were published earlier than 2003?
3	Q Are you referring to what they call the	3	A There was one poster which is referred to
4	"Boyscout Study" or the study by Neidich(ph.) from	4	in some of the information I gave you.
5	1961?	5	Q Okay. Now, who is Dr. Findling?
6	A I can't tell you who wrote the article.	6	A Dr. Findling is a child psychiatrist in
7	This came from Clinical Endocrinology and Metabolism	7	Cleveland who is a principal investigator of a number
8	some years ago. And I don't have the reference at my	8	of studies of different medications in children with
9	fingertips.	9	different types of psychiatric conditions.
10	Q You can put that aside. I might come back	10	Q When was the last time you spoke to Dr.
11	to that. I'll take Mr. Essig up on his offer for a	11	Findling, if you remember?
12	copy of your CV. I just want to put that on the	12	A I spoke to him probably in the last six
13	record. Do you have a copy we can mark and the doctor		months.
14	can look at?	14	Q Okay. Did you talk about this article at
15	(Whereupon, Exhibit No. 2 was marked for	15	all?
16	identification.)	16	A So Dr. Findling came as a potential
17	MR. ESSIG: Do you want me to give it to	17	candidate for a job interview at the University of
18	him?	18	Toronto and the Hospital for Sick Children. And I was
19	MR. GOMEZ: That's fine. Let me just put a	19	interviewing him, and I mentioned that we had
20	sticker on it.	20	coauthored an article together.
21	BY MR. GOMEZ:	21	And that's all we said.
22	Q Doctor, I've marked as Exhibit 2 your	22	Q Do you know where he currently works?
23	curriculum vitae. You list in your CV you list by	23	A At that time he was in Cleveland, and i
24 25	year the number of publications that you were an author on. Is that a fair assessment?	24 25	believe he's still there.
23	autior off. Is that a fair assessment?	23	Q Who is Dr. Or V. Kusumaker? Do you know
	Page 23		Page 25
1		1	who that is?
$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$		1 2	A I believe he's a Canadian psychiatrist
2 3	<ul><li>Q Did you list any posters?</li><li>A I haven't put any posters for a long time</li></ul>	$\frac{2}{3}$	who's been part of these studies as well.
4	because there are just too many. I've left posters	4	Q Do you know who Dr. Kusumaker worked for?
5	off for a long time because it got to be 200, 300	5	A No.
6	plus, and I just took them off my CV.	6	Q Do you know who Dr. Thomas Moshang is?
7	Q Fair enough. Let's go to page it	7	A Thomas Moshang was the Head of Pediatric
8	doesn't have a page number, but 2003. It's about	8	Endocrinology of Children's Hospital of Philadelphia
9	halfway through. Are you there?	9	at the University of Pennsylvania at the time. He's
10	A I opened it on that page.	10	since deceased.
11	Q Where the numbers under 2003 starts at 128?	11	Q Do you know Goedele DeSmedt?
12	A That's where I am.	12	A I do not.
13	Q Okay. On No. 131	13	Q Who is S. Binder?
14	A Yes.	14	A Carin Binder worked for Janssen Ortho at
15	Q It reads Findling R., Kusumaker V., Daneman	15	the time, and she was the one who coordinated the
16	D that's you; correct?	16	contributions that Tom Moshang and I made to this
17	A Correct.	17	article.
18	Q Moshang T.?	18	Q It's Carin Binder, not "S. Binder"; is that
19	A Yes.	19	fair?
20	Q DeSmedt G.?	20	A Yes. Correct.
20	Z Desineur G.:		
20	A Yes.	21	Q Is Carin Binder a doctor?
21 22	<ul><li>A Yes.</li><li>Q Binder S. And it's entitled "Prolactin</li></ul>	22	A No.
21 22 23	A Yes. Q Binder S. And it's entitled "Prolactin Levels During Long-term Risperidone Treatment in	22 23	A No. Q What does she do?
21 22 23 24	A Yes. Q Binder S. And it's entitled "Prolactin Levels During Long-term Risperidone Treatment in Children and Adolescents," The Journal of Clinical	22 23 24	<ul><li>A No.</li><li>Q What does she do?</li><li>A She worked in Janssen Ortho at the time, I</li></ul>
21 22 23	A Yes. Q Binder S. And it's entitled "Prolactin Levels During Long-term Risperidone Treatment in	22 23	A No. Q What does she do?

7 (Pages 22 to 25)

	Page 26		Dage 29
1		1	Page 28
1 2	<ul><li>Q And Janssen Ortho is a Canadian company?</li><li>A I don't know where it's headquartered.</li></ul>	1 2	Q Let me sticking with your CV, going to, I think, No. 143. Are you there?
3	Q When was the last time you spoke to Carin	3	A I'm there.
4	Binder?	4	Q And No. 143 is from the year 2004, and it's
5	A About this study, probably there 2003,	5	another journal article with the lead author of Dunbar
6	2004. And I saw her once again at a meeting somewhere	6	F. or Fiona Dunbar; is that correct?
7	in the interim. I cannot recall where. We just said	7	A Yes.
8	hello to each other, and that was it.	8	Q Did you meet before this article was
9	Q What was your understanding of the purpose	9	published, or did you meet her after?
10	of this medical article?	10	A Before this article was published.
11	A So Risperidone was a relatively new	11	Q And again, there's Dr. Kusumaker; do you
12	treatment for these indications. You need to watch	12	see him?
13	for two things. One is effectiveness or efficacy, and	13	A Yes.
14	the other is the potential for side effects. And this	14	Q And you're one of the listed authors there,
15	was putting together of a number of studies that had	15	D. Daneman; correct?
16 17	been done in different places to see whether let me take a step back.	16 17	A Yes. Q M. Schulz, who is that?
18	Q Sure.	18	A Miklos Schulz is a biostatistician who's
19	A So any time you do a study, you have a	19	company did the biostatistical analysis of these data.
20	primary outcome which is based on effectiveness, and	20	Q And Miklos Sculz is, as far as your
21	you have secondary outcomes, which can be secondary	21	understanding, a Janssen employee?
22	effectiveness or side effects. And you may have the	22	A No.
23	power to look at the primary outcome but not the power	23	Q No?
24	to look at the secondary outcome.	24	A Not from my understanding at all.
25	So putting together a number of studies and	25	Q Who does he work for?
	Page 27		Page 29
1	looking for the secondary outcomes and the side	1	A I thought he had his own private company
2	effects may give you much more information than just	2	that did biostatistical analysis.
2 3	effects may give you much more information than just looking at a single one.	2 3	that did biostatistical analysis. Q And the title of this article was "Growth
2 3 4	effects may give you much more information than just looking at a single one. Q And your role was to deal with the	2 3 4	that did biostatistical analysis. Q And the title of this article was "Growth and Sexual Maturation during Long-Term Treatment with
2 3 4 5	effects may give you much more information than just looking at a single one. Q And your role was to deal with the secondary outcomes that dealt with the safety issues?	2 3 4 5	that did biostatistical analysis. Q And the title of this article was "Growth and Sexual Maturation during Long-Term Treatment with Risperidone"?
2 3 4 5 6	effects may give you much more information than just looking at a single one. Q And your role was to deal with the secondary outcomes that dealt with the safety issues? A Specifically around prolactin.	2 3 4 5 6	that did biostatistical analysis. Q And the title of this article was "Growth and Sexual Maturation during Long-Term Treatment with Risperidone"? A Yes.
2 3 4 5 6 7	effects may give you much more information than just looking at a single one. Q And your role was to deal with the secondary outcomes that dealt with the safety issues? A Specifically around prolactin. Q Do you remember specifically when you were	2 3 4 5 6 7	<ul> <li>that did biostatistical analysis.</li> <li>Q And the title of this article was "Growth and Sexual Maturation during Long-Term Treatment with Risperidone"?</li> <li>A Yes.</li> <li>Q American Journal of Psychiatry. And it's</li> </ul>
2 3 4 5 6 7 8	effects may give you much more information than just looking at a single one. Q And your role was to deal with the secondary outcomes that dealt with the safety issues? A Specifically around prolactin. Q Do you remember specifically when you were first contacted by Carin Binder?	2 3 4 5 6 7 8	<ul> <li>that did biostatistical analysis.</li> <li>Q And the title of this article was "Growth and Sexual Maturation during Long-Term Treatment with Risperidone"?</li> <li>A Yes.</li> <li>Q American Journal of Psychiatry. And it's published in 2004; correct?</li> </ul>
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8 (Pages 26 to 29)

	Page 30		Page 32
1	A To the best of my knowledge, they were	1	A No.
2	randomized control trials.	2	(Whereupon, Exhibit No. 3 was marked for
3	Q Have you ever heard of a study R-I-S-I-N-T	3	identification.)
4	41?	4	BY MR. GOMEZ:
5	A I don't know any studies by those titles.	5	Q Could you take a moment and just briefly
6	Can you give me the name of the study?	6	look it over before I ask you some questions. Are you
7	Q Sure. Do you remember I'm just trying	7	finished?
8	to gather what you remember without looking at any	8	A I am.
9	documents. Do you remember an open label study?	9	Q I'm going to specifically focus on the
10	A There was an open label study among them,	10	front page of the email that was from Carin Binder
11	yes.	11	dated August 29, 2001. Do you see that there?
12	Q What information were you given from those	12	A I do.
13	five studies?	13	Q And it's to numerous individuals; some are
14	A To the best of my knowledge, we were I	14	carbon copied. And the subject is "Prolactin
15	was given and I suspect Tom Moshang was given the	15	Analysis." Did I read that right?
16	same thing a description of what the studies were	16	A Correct.
17	and what the outcomes of those studies were.	17	Q You're not listed as any of the
18	Q Did you look at any of what they call	18	recipients
19 20	clinical study reports? A Those individual patient study reports?	19 20	A Correct. Q on this email; correct?
20	Q Do you know what a clinical study report	20 21	Q on this email; correct? A Correct.
22	is?	22	Q Do you know Ivo Caers?
23	A So are we talking about the individual	23	A No.
24	patient, or are we talking about the group data?	24	Q Do you know who Rosanna Riccardelli is?
25	Q I'm talking about the individual studies.	25	A No.
		-	
	Page 31		Page 33
1	There was five of them. Correct?	1	Q Do you know Albert Derivan?
2	A Yes.	2	A No.
3	Q Did you review any of the	3	Q After reading this email, does it refresh
4	A I cannot recall that information.	4	your recollection regarding a meeting that took place
5	Q Did you look at any of the underlying individual subject data for side effects?	5	between Rosanna Riccardelli, Carin Binder, and yourself in 2001?
6 7	A No.	6 7	A I met with Carin Binder on more than one
8	Q What did you do to prepare for your	8	occasion, and sometimes there was somebody with her.
9	deposition today?	9	I cannot recall the name of the person. So that name
10	A I took out what I had, and I read the	10	doesn't ring a bell. But what's discussed here is
11	articles that we'd written.	11	very similar to what's discussed in that document you
12	Q And the documents that you reviewed are the	12	labeled 1.
13	four documents that were attached to an email that you	13	Q Okay. Okay. The document that you brought
14	sent to Mr. Essig?	14	with you this morning?
15	A I didn't go through those in any detail	15	A Yes.
16	because those were the earlier drafts of the final	16	Q Let me do you know what is referred to
17	component.	17	or what is meant by prolactin analysis?
18	Q So in preparation for your deposition	18	A I presume the prolactin data in these
19	today, you didn't review any of the drafts?	19	studies.
20	A No.	20	Q Let me read the first paragraph of the
21	Q Of the 2003 article?	21	email, and then I have a few questions for you. It
22	A No.	22	says, "Dear All, a quick update regarding the
23	Q I'm going to mark as an exhibit, as	23	prolactin analysis. Rosanna and I met with Dr. Denis
24 25	Exhibit 3, an email. Doctor, did you review this document in preparation for your deposition today?	24 25	Daneman, who is a peer of Dr. Tom Moshang and a pediatric endocrinologist."
23	document in preparation for your deposition today?	23	

	Page 34		Page 36
1		1	-
1 2	"Our reasons for meeting with Dr. Daneman were	$\frac{1}{2}$	confidentiality agreement so that I don't have the
$\frac{2}{3}$	to review the analysis plan and obtain additional validation that the areas Dr. Moshang wished to focus	$\frac{2}{3}$	right to go off and publish it somewhere else.
	6		Q Okay. She goes on to write, "Firstly, Dr. D. felt that the prolactin elevation seen in the
4 5	on had a broad appeal, not just to ped endos but to	4 5	*
	answer questions from pediatricians, GPs, et cetera."	-	trials were not grossly abnormal." Do you remember
6	Did I read that correctly?	6	what you reviewed to make that determination?
7	A Correct.	7	A I don't remember what the first data that
8	Q Do you know what she meant when she wrote that she wanted additional validation that the areas	8	we reviewed were.
9		9	Q Were you ever shown tables of statistics or
10	Dr. Moshang wished to focus on. Do you know what she		tables of data combining all five studies?
11	meant by that?	11	A Yes.
12	A I'd be presuming. I'd be speculating. My	12	Q Did you search for that prior to this
13	speculation was that she wanted to make sure that Tom	13	deposition?
14	Moshang was not missing anything and that it was as	14	A I did.
15	broad as you'd need to have recommendations for	15	Q You did not have it anymore?
16	pediatricians and general practitioners who would be	16	A Didn't have it.
17	using this medication so they'd have as much	17	Q She goes on to write, "He stated that there
18	information at their disposal as possible.	18	was nothing in the literature or in guidelines to lead
19	Q Do you remember in 2001 or at any time	19	endos to create cutoff points except as follows: Less
20	prior to your meetings with Ms. Binder and at those	20	than 30, NG is okay. 30 to 100 is the gray zone. And
21	meetings a discussion on the issue of general	21	greater than 100 is abnormal."
22	practitioners or pediatricians having concern about	22	"And greater than 200, grossly abnormal." Did I
23	Risperdal raising prolactin and causing side effects	23	read that correctly?
24	like gynecomastia?	24	A Correct.
25	A There was previously evidence that	25	Q That's consistent with what we saw in
	Page 35		Page 37
1	prolactin that it was increased with Risperdal.	1	Exhibit 1?
2	And that's why this analysis was being formed. So	2	A Yes.
3	that any side effects could be detected.	3	Q "The important thing to consider is the
4	Q Do you remember any discussions that	4	height of prolactin elevation and the duration or
5	doctors treating children endocrinologists, general		
		5	elevation. The higher and longer the prolactin stays
6		5 6	elevation. The higher and longer the prolactin stays up, the more risk of sequelae." Did I read that
6 7	practitioners, pediatricians children on Risperdal were showing concern about prolactin-related side		elevation. The higher and longer the prolactin stays up, the more risk of sequelae." Did I read that correctly?
	practitioners, pediatricians children on Risperdal were showing concern about prolactin-related side	6	up, the more risk of sequelae." Did I read that
7	practitioners, pediatricians children on Risperdal	6 7	up, the more risk of sequelae." Did I read that correctly?
7 8	practitioners, pediatricians children on Risperdal were showing concern about prolactin-related side effects and were contacting the company to ask questions about that? MR. ESSIG: Objection to the form and	6 7 8	up, the more risk of sequelae." Did I read that correctly? A Correct. Q Is that at this point if you remember, was that your opinion, or did you learn that from the
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>practitioners, pediatricians children on Risperdal were showing concern about prolactin-related side effects and were contacting the company to ask questions about that?</li> <li>MR. ESSIG: Objection to the form and foundation.</li> <li>BY MR. GOMEZ:</li> <li>Q Do you recall anything like that?</li> <li>A No.</li> <li>Q She goes on to write, "Here is a synopsis of the conversation. And in parenthesis note Dr.</li> <li>Daneman signed a confidentiality agreement, was not involved in the P trials, nor does he know anyone that was involved."</li> <li>Did I read that correctly?</li> <li>A Correct.</li> <li>Q Why were you asked to sign a confidentiality agreement?</li> </ul>	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>up, the more risk of sequelae." Did I read that correctly? <ul> <li>A Correct.</li> <li>Q Is that at this point if you remember,</li> <li>was that your opinion, or did you learn that from the literature?</li> <li>A That would have been my opinion, confirmed by the literature.</li> <li>Q She goes on to write, "Dr. D. looked at the adverse events attributed to elevated prolactin, i.e. the 16 cases with gynecomastia, et cetera, and felt that these events might also be explained by reasons other than risperidone."</li> <li>"For example, any boy going through puberty has a decrease in testosterone and an increase in estrogen. So it's not unusual to see some evidence of gynecomastia in boys aged 12 to 14 years." Did I read that correctly?</li> </ul> </li> </ul>

Page 38 1 increase in testosterone, which is then converted to 2 estrogen. So it's not a decrease in testosterone. 3 It's an increase in testosterone and increase in 4 estrogen. 5 Q Olympian Comparison of the c	pubertal
2estrogen. So it's not a decrease in testosterone.2gynecomastia as part of the normal p3It's an increase in testosterone and increase in3development. That was the major of4estrogen.4QDid anybody ever come to y	pubertal
3It's an increase in testosterone and increase in estrogen.3development. That was the major of 43development. That was the major of 4QDid anybody ever come to y	-
4 estrogen. 4 Q Did anybody ever come to y	ma that management
5 Q Okay. 5 Daneman, here's some data. We hav	
6 A So that statement 6 studies where we've seen these adve	
7 Q So it should read, "Any boy going through 7 attributed to elevated prolactin, 16 c	eases of
8 puberty has an increase in testosterone and an 8 gynecomastia, et cetera"?	
9 increase in estrogen" is what it should say? 9 "Is there any other explanation f	for this besides
10 A Yes. 10 Risperdal treatment?"	
11 Q Okay. Okay. Do you remember what you 11 MR. ESSIG: Objection to the	
12 looked at specifically as to the adverse events 12 THE WITNESS: I do recall	talking to Tom
13 attributed to elevated prolactin, the 16 cases with 13 Moshang at a meeting and discussin	ig how best to look
14 gynecomastia, et cetera? 14 at a situation where you had a high f	frequency of
15 A I can't remember the exact documentation. 15 gynecomastia in a group, and you have	ad an intervention
16 Q Do you remember looking at any Janssen 16 which potentially could cause gynec	
17 documents that they gave to you which listed the 17 how I believe that SHAP A and SHAP	
18 adverse events in these studies along with the 18 BY MR. GOMEZ:	Ũ
19 clinical investigators' determination of drug 19 Q Now, we talked about that the	here were five
20 relationship? 20 studies; correct?	
21 MR. ESSIG: Objection to form. 21 A Yes.	
THE WITNESS: I remember being exposed to a 22 Q Were you aware that these 1	6 cases of
23 number of different documents, but it's too long ago 23 gynecomastia, et cetera, came from	
24 to remember the exact nature of those documents. 24 A No.	one study.
25 $25$ $25$ $25$ $25$ $25$ $25$ $25$	heard that?
Page 39	Page 41
1 BY MR. GOMEZ: 1 A I have no recollection of that	it whatsoever.
2 Q Do you remember talking to any of the 2 Q If you could go to the secon	d page of this
3 clinical investigators in these studies? 3 email, Ms. Binder writes, "Dr. D sta	ited it is not
4 A I didn't talk to any. 4 common to see galactorrhea due to l	
5 Q You did not talk to any clinical 5 unless estrogen is present. Dr. D als	
6 investigators? 6 brain-damaged children have early p	
7 A Dr. Findling and Kusumaker were part of a 7 hyperprolactinemia may delay pube	
8 discussion right towards the end of the analysis. 8 gain to the point of obesity may indu	
9 Q But you never spoke to any of the clinical 9 Did I read that correctly?	
10 investigators that were at the different sites that 10 A Yes.	
11 the studies took place? 11 Q What did you mean I'm so	orry. Strike
12 A No. No. 12 that. What is Ms. Binder talking ab	5
13 Q Did you ever look at any of the specific 13 you stated that brain-damaged child	
14 adverse event reports for each of these 16 cases? 14 puberty? And specifically, what do	
15 A As I said before, I was exposed to some 15 "brain-damaged children"?	jea mean og
16 information on each of these cases. I cannot remember 16 A I'm not sure that that's my di	irect quote
17 the exact nature of the documents that I saw. 17 But children who have sustained a s	-
18 Q It says here that you felt that these 18 or insult to the brain can have a disr	
19 events may also be explained by reasons other than 19 hypothalamic pituitary gonadal axis	
20 Risperdal; do you see that? 20 throughout prepuberty it's chronical	
1 6	
<ul><li>these 16 cases of gynecomastia, et cetera, other than</li><li>risperidone?</li><li>off earlier. So children who had sig</li><li>example, hypoxic ischemic damage</li></ul>	
25 risperidone?25 example, hypoxic ischemic damage	m the new born period

11 (Pages 38 to 41)

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1	may be more likely to have early puberty than if they	1	United States?
2	didn't have that.	2	A I'm going to presume I was but probably
3	Q Going down into the email, it says, "In	3	more likely a Canadian indication than the U.S.
4	general, he agreed with the analysis outline." Do you	4	indication.
5	remember ever being provided an analysis outline?	5	Q Was there has Risperdal ever been
6	A I can't recall whether it was, but there	6	indicated to treat children in Canada?
7	was a discussion of how the data were going to be	7	A I don't know the answer to that question,
8	analyzed.	8	but there are many, many children who receive
9	Q She goes on to write, "If we don't have a	9	Risperdal on a regular basis.
10	great deal of Tanner data, he recommended that we use	10	Q Are you familiar with the term "off label
11	age as a correlation, parenthesis, surrogate marker."	11	prescription"?
12	A Yes.	12	A Yes.
13	Q What does that mean?	13	Q What is that?
14	A So ideally, you'd like to have you'd	14	A So once a product, medication is approved
15	like to know when people are pubertal, which is called	15	for use for a specific indication, physicians can
16	Tanner stage one. And then as they go into early	16	prescribe it for other indications very judiciously
17	puberty, Tanner stage two, three. And then advanced	17	and carefully. And that's called off label.
18	puberty, four, five, which is sexual maturation.	18	Q When you say, "very judiciously and
19	And there was someone who did measurement in the		carefully," does that mean that physicians will look
20 21	U.K. and classified puberty along these lines. The	20	to sources of information for information to share
21	problem with using age as a surrogate marker is you don't start everybody doesn't start puberty at age	21 22	with their patients regarding efficacy and safety, for example?
22	10 and reach level three at age 12.	22	A Ideally, they should, yes.
23	There's a spectrum. So boys start between say	23	Q One of the sources that physicians who
25	10 and 14 years of age. And you'd expect a spectrum.	24	prescribe drugs like Risperdal to an off-label
23	To and 14 years of age. And you'd expect a speed and	23	presente drugs like Risperdal to all off-laber
	Page 43		Page 45
1	But if you don't have the Tanner staging, the next	1	population like children and adolescents would be the
2	best thing is to look at age as the surrogate marker.	2	medical literature; correct?
3	Q Okay. You can put that aside. This might	3	A Yes.
4	be a good opportunity just to take a short break.	4	Q It would also be posters and abstracts that
5	A Sure.	5	are shown at conventions; correct?
6	VIDEOGRAPHER: Going off the record at	6	A Posters and abstracts at conventions would
7	10:12 a.m.	7	be sort of the lowest level of communication. It's
8	(Recess from 10:12 a.m. to 10:20 a.m.)	8	really a communication to that band of people that is
9 10	VIDEOGRAPHER: Going back on the record at 10:20 a.m.	9 10	going to be at that meeting, which is often highly specialized small groups of people.
11	BY MR. GOMEZ:	10	Q For example, there might be conferences of
12	Q Dr. Daneman, before I mark our next	12	psychiatrists, for example?
13	exhibit, I wanted to follow up on one thing you said	12	A Yes.
14	earlier. Correct me if I am wrong. Was it your	14	Q You mentioned the lowest level of
15	understanding that this article was being written to	15	communication. Is there a secondary level or a top
16	seek some sort of pediatric indication?	16	level?
17	MR. ESSIG: Objection to form and	17	A The top level is systematic reviews or meta
18	foundation.	18	analysis of many different studies, systematic reviews
19	THE WITNESS: My understanding was that my	19	of the entire literature. Meta analysis means you
20	role was to comment on the prolactin levels and how	20	take a whole lot of studies, and you review them
21	they related to potential side effects. I wasn't	21	together.
22	informed as seeking of an indication.	22	And then practice guidelines would come out from
23	BY MR. GOMEZ:	23	august bodies, national, international, sometimes
24	Q Were you aware that in 2001 time frame that	24	local, but usually national, international, giving the
25	Risperdal was not indicated to treat children in the	25	guidelines for the treatment of certain conditions.

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$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	So that there would be if let's go back to diabetes. The American Diabetes Association has clinical practice guidelines. The Canadian Diabetes Association has clinical practice guidelines. Most of these are based, to some extent, on evidence-based medicine, which means the highest level of evidence. The problem in the pediatric population is that there's only a certain amount of evidence to support what we do. And a lot of assumptions are made from the adult literature. So whenever we can get pediatric data, it's very important. Q So it would be fair to say that a doctor who is deciding to prescribe Risperdal might look to the medical literature, specifically to the adult literature if no pediatric literature is present, for information on efficacy and safety; is that fair? A Yes. Q How would you characterize the article from 2003 that you were a coauthor on? Is that a meta analysis or top level of medical literature? A No, it's an analysis of the available data. The ideal would be to have a single study in which enough patients were randomized to receive the drug versus not and treated for a long-enough period of time so that the primary outcome and the secondary	$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>Q And it should also be balanced?</li> <li>A Well, there's a peer-review process that goes on in order to provide the checks and balances to those sorts of things. There are always individual interpretations for everything. There's some things are that black and white which don't require any interpretation, but there are other things that are much more nuanced or shaded that are interpreted one way by the authors, and often the journals provide editorials, commentaries, and other things to provide counterbalance and so on.</li> <li>Q According to your CV, you're a reviewer as well? You review journal articles; correct?</li> <li>A Yes. Yes.</li> <li>Q When you review journal articles, do you expect them to be balanced in terms of how they report the data, specifically safety data?</li> <li>A Yes.</li> <li>Q I've marked as Exhibit 4 a printout of an email from Mr. Essig to me regarding the documents that I asked you to, through my deposition notice, to go back and look for.</li> <li>A Yes.</li> <li>(Whereupon, Exhibit No. 4 was marked for identification.)</li> </ul>
	Page 47		Page 49
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\end{array} $	outcomes were reached. That would be the strongest. This is a quite a lot down the line. And this is not a, you know, the American Academy of Pediatric Neurology or Pediatric Endocrinology that's giving an outcome. It's a group of people analyzing these studies. So it's part of the process. Q And as part of the strike that. And one of the reasons to draft articles like this and have them published is so prescribing physicians can be informed about any issues of efficacy and safety; is that fair? A That's fair, yes. Q And you would agree with me that medical literature like the article that we see that we're going to talk about more in detail and what we've seen so far should be done in an accurate manner; is that fair? MR. ESSIG: Objection to the form. But go ahead. THE WITNESS: Yes. BY MR. GOMEZ:	$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\end{array} $	BY MR. GOMEZ: Q And according to this and I have them all on this exhibit you provided four documents; is that fair? A Yes. Q The first two are February 19, 2003, revision. And I'm specifically referring to the attachments on the first page of the email. The first two are dealing with the 2004 article? A Yes. Q By Dunbar; is that correct? A Yes. Q And then we have the PRL. That's prolactin; correct? A Yes. Q That's revised July '03, final doc, and that's the 2003 article? A Yes. Q With Findling as the lead author; correct? A Yes. Q And then a prolactin ACAP abstract dated 2/13/02. And that is the abstract that was presented
22 23 24 25	Q And it should be in an objective manner as well; is that a fair statement? A Yes.	22 23 24 25	at ACAP on the 2003 Findling article; is that correct? A Yes. Q Now, before we go look at the article

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	Page 50		Page 52
1		1	-
$\frac{1}{2}$	itself and, specifically, the 2003 revised version that's attached to this email, did you specifically	2	part of this exhibit that you wanted to get in touch with Carin Binder; do you see that down there?
3	do you specifically remember what whether or not	$\frac{2}{3}$	A I did.
4	you wrote anything?	4	Q Did you get in touch with Carin Binder?
5	A I didn't write parts of the article. I	5	A No. No.
6	commented on them. I can't give you exact detail as	6	Q Okay. If you could go to the back and go
7	to which parts I commented on and suggested changes	7	forward until we find the last attachments which the
8	to, but I would have been I would have been an	8	2003, July '03 draft. And let me know when you're
9	internal reviewer and commenting on the way in which	9	there.
10	it was written.	10	A I'm there.
11	Q So it's fair to say somebody else wrote it?	11	MR. ESSIG: Chris, just so I'm clear, did I
12	A Yes.	12	miss something or what shows that it's the July, 2003,
13	Q And sent it to you for your comments?	13	draft?
14	A Yes.	14	MR. GOMEZ: Well, it was the attachment.
15	Q And then incorporated your comments, and	15	If you look in the attachment email go to the
16	that was eventually the final product?	16	front.
17	A Yes.	17	THE WITNESS: The attachment.
18	Q The published version?	18	MR. GOMEZ: It says, "Attachment revised
19	A Yes.	19	July 3, dot final doc."
20	Q Do you remember how many drafts you	20	MR. ESSIG: I see. Thank you.
21 22	received? A No.	21 22	BY MR. GOMEZ:
22	Q Do you think the one attached to this email	22	Q Doctor, where I have you looking at now, is that the July '03 attachment that we were talking
23 24	that you produced today was the only one you reviewed?	23 24	about earlier?
25	A I don't think it was the only one, but I	24	A This is what that attachment is, yes.
23		23	Tr This is what that attachment is, yes.
	Page 51		Page 53
1	Page 51 don't know the answer to that question. There would	1	Page 53 Q Okay.
1 2	-	1 2	-
2 3	don't know the answer to that question. There would be a suggestion, to answer that question, on the articles which would tell you when they were reviewed,		Q Okay. MR. ESSIG: Just so that we're clear, you're saying this document here is the document that
2 3 4	don't know the answer to that question. There would be a suggestion, to answer that question, on the articles which would tell you when they were reviewed, when they were received, when they were accepted.	2 3 4	Q Okay. MR. ESSIG: Just so that we're clear, you're saying this document here is the document that was attached as labeled above here on the email as
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>don't know the answer to that question. There would be a suggestion, to answer that question, on the articles which would tell you when they were reviewed, when they were received, when they were accepted.</li> <li>Q Are you talking about the final article?</li> <li>A Yes.</li> <li>Q We'll take a look at that in a second. Do you remember who sent you these strike that. Do you remember who sent you the July 3 prolactin revision?</li> <li>A My communication was with Carin Binder. So I would presume it was her. I can't recall receiving anything from anybody else.</li> <li>Q We talked about the process, that somebody else wrote it, you reviewed it, added comments. Yet you still were listed as an author. That's something that's just normal and customary in the medical publishing world?</li> <li>A So you would have you can see from my CV that there are sometimes many, many authors on an article. Somebody is the primary author, who writes the article, and the other people add their comments and criticisms and iterates until everybody is</li> </ul>	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>Q Okay. MR. ESSIG: Just so that we're clear, you're saying this document here is the document that was attached as labeled above here on the email as revised July '03? MR. GOMEZ: That's correct. MR. ESSIG: Okay. We're not saying that it's necessarily from July '03. We're just saying that's the name of the document? MR. GOMEZ: That's the name of the document. That's fair. MR. ESSIG: Okay. BY MR. GOMEZ: Q And Doctor, the title is "Prolactin Levels during Long-term Risperidone Treatment in Children and Adolescents"? A Correct. Q And the byline lists numerous authors, of which you're listed there, Denis Daneman, M.D., the Hospital for Sick Children, University of Toronto. Did I read that correctly? A Correct: Q And along with Dr. Moshang, he's another</li> </ul>

14 (Pages 50 to 53)

1       A. Since diseased, yes.       Q. So if a prescribing physician who's about         2       Q. And Dr. Findling is a psychiatrist;       C. Deprescribe Risperdal to a child, an adolescent, and is concrented about side cifects associated with the adolescent, and is concrented about side cifects associated with the prescription to the form. Calls for speculation, is one of the first places he's going to go is the abstract?         6       Q. And Myek Kusumaker M.D., she's or he's melocy by J and J Pharmaceutical R&D, Titusville, and Yoart Mc and Goodele DeSmedt is also employed by J and Goodele DeSmedt is also employed by J and Goodele DeSmedt is also employed by J and J Pharmaceutical R&D out of Belgium?       New Jersey; correct?         1       A. Yes.       Brannaceutical R&D out of Belgium?       BY MR. GOMEZ:         13       and J Pharmaceutical R&D out of Belgium?       J       BY MR. GOMEZ:         14       A. Yes.       Q. That's published, I assume page, page 2, special thanks       BY MR. GOMEZ:         14       A. Yes.       Yes.       Q. Do that same page, page 2, special thanks       Don't know.         20       D on that same page, page 2, special thanks       Page St       Q. That's published; I assume, in Canada every sery and the parkacguines, the adset act?         21       you that earlier.       Q. In a you know Al Derivan? I think I asked       Q. That's published; I assume, in Canada every sery and the parkacguines, in adset act?         2       Q. Noyou know AD erivan? I think I asked?		Page 54		Page 56
2       Q. And Dr. Findling is a psychiatrist;       2       to prescribe Risperdal to a child, an adolescent, and         4       A. Yes.       is concentrated about side effects associated with         5       Q. And he's with the Case Western Reserve       is to mend about side effects associated with         6       University in Cleveland, Ohio?       is the abstract?         7       A. Correct.       6         9       Iterature is not necessarily the first place they       would go. The Compendium of Pharmaceutical         11       A. Yes.       9         12       Q. And Goodele DeSmedt is also employed by J       and J Pharmaceutical R&D out of Belgium?         13       and J Pharmaceutical R&D out of Belgium?       1         14       A. Yes.       10         15       Q. And if you turn the page, Carin Binder,       15         16       sie discover:       10         17       G. Mat Schuk, We talked about him He's the       10         16       orther sprescription drug label?       20         17       you that earlier.       12         18       A. Yes.       2         2       A. Yes.       2         2       A. Yes.       2         2       A. No.       2	1		1	Page 56 $\Omega$ So if a prescribing physician who's about
3         correct?         3         is concerned about side effects associated with           4         A Yes.         4         prolation, is one of the first places he's going to go           5         Q And he's with the Case Western Reserve         6         University in Cleveland, Ohio?         7           7         A Correct.         8         Q And Vivek Kusumaker M.D., she's or he's         6         MR. ESSIG: Objection to the form. Calls           7         A Correct.         9         Interture is not necessarily the first places he's going to go           10         New Jersey; correct?         10         New Jersey; correct?         11           13         and J Pharmaceutical R&D out of Belgium?         14         A Yes.         13           13         and J Pharmaceutical R&D out of Belgium?         13         BY MR. GOMEZ:           14         A Yes.         13         BY MR. GOMEZ:           15         A Correct?         18         A Correct?           16         Information about the drugs themschese without looking for the bustatistician?           17         you that carlier.         20         A Weis dan Leung? L-E-U-N-G.           24         A Don't know.         20         Who's Am Leung? L-E-U-N-G.           24         A Don't know.         20			1	
4       A Yes.       4       prolactin, is one of the first places he's going to go         5       Q. And he's with the Case Western Reserve       5       is the abstract?         6       University in Cleveland, Ohio?       MR.ESSIG: Objection to the form. Calls         7       A Correct.       MR.ESSIG: Objection to the form. Calls         9       employed by 1 and J Pharmaceutical R&D, Titusville,       9         10       New Feys:       File WITNESS: 1 suspect the medical         11       A Yes.       BY MR. GOMEZ:         12       Q. And if you turn the page, Carin Binder,       Substances, the CPS, in the U. S. And in Canada it         13       and J Pharmaceutical R&D out of Belgium?       14         14       A Yes.       BY MR. GOMEZ:         15       A Andi fyou turn the page, Carin Binder,       15         16       the's amployed by Jansen Ortho here in Toronto,       16         17       Canada, correct?       Q. Mon that same page, page 2, special thanks       10         19       Q. On that same page, page 2, special thanks       20         10       to Miklos Schulz. We talked about him. He's the         21       biostatistician?       21         22       A. Yes.       21         23       Q. Who's Ann Leung?				
5       Q       And he's with the Case Western Reserve       5       is the abstract?         6       University in Cleveland, Ohio?       7         7       A       Correct.       6         8       employed by J and J Pharmaceutical R&D, Titusville,       11       8         10       New Jersey; correct?       11       14       Yes.         12       Q       And dir you turn the page, Carin Binder,       15       6       Merey out an look at a whole lot of         15       accorrect?       16       and J Pharmaceutical R&D out of Belgium?       14       A       Yes.         16       she's employed by Jansen Ortho here in Toronto,       17       Canada; correct?       18       A Correct.       18       Q       Out hat same page, page 2, special thanks       10       10       Wiher you can look at a whole lot of       10       10       10       11       Merey ou can look at a whole lot of       10       10       11       14       Webrey ou an updated book every year         17       at the primary studies.       18       Q       14       14       14       14       14       14       14       14       14       16       16       16       16       16       16       16       16				
6       University in Cleveland, Ohio?       A       MR. ESSIG: Objection to the form. Calls         7       A       Correct.       For speculation.         9       employed by J and J Pharmaceutical R&D. Titusville,       Iterature is not necessarily the first place they         11       A       Yes.       Iterature is not necessarily the first place they         13       and J Pharmaceutical R&D out of Belgium?       BY MR. GOMEZ:         14       A       Yes.       BY MR. GOMEZ:         15       A       A forgo the the package insert       Information about the drugs themselves without looking at a whole lot of         16       she's employed by Jansen Ortho here in Toronto,       Information about the drugs themselves without looking at at the indications, the side         20       A Correct.       O       You'r celerring to like the package insert         10       ort hory or glabel?       A       With all the pharmaceutical agenise.         21       biostatistician?       With all the pharmaceutical agenise.       A         22       A       Yes.       Page 55       Q         23       Q       And you know Al Derivan? I think I asked       So       O That's published.       So         30       A norects.       Q       A Yes.       Q       That's published.<			4	
7       A Correct.       7       for speculation.         8       Q And Vivek Kusumaker M.D., she's or he's       9       THE WITNESS: 1 suspect the medical         10       New Jersey: correct?       10       Would go. The Compondium of Pharmaceutical         11       A Yes.       11       Substances, the CPS, in the U.S. And in Canada it         12       Q And Goedele DeSmedt is also employed by J       11       Substances, the CPS, in the U.S. And in Canada it         12       and J Pharmaceutical R&D out of Belgium?       14       BY MR. GOMEZ:         14       A Yes.       Correct.       15       A Where you can look at a whole lot of         16       information about the drugs themselves without looking       16       information about adado the oversy year         15       A Correct.       18       Q You're refering to like the package insert         19       O nut kat same page, page 2, special thanks       19       or the prescription drug label?         20       A Yes.       20       A Wel alk the pharmaceutical agents. And you can go         21       with at same page. Name? I think I asked       20       You'n's called the CPS in Canada.         2       A No.       2       Q That's published. I assume, in Canada.         3       Q And you know Dr. Fiona Dunbar; correct?			5	
8       C And Vivek Kusumaker M.D., she's or he's       9       THE WITNESS: I suspect the medical         9       employed by J and J Pharmaceutical R&D. Titusville,       9       literature is not necessarily the first place they         10       New Jersey; correct?       10       would a.       11       Substances, the CPS, in the U.S. And in Canada it         11       A Yes.       11       12       would         13       and J Pharmaceutical R&D out of Belgium?       14       Q I'm sorry. I didn't mean to interrupt you.         14       A Yes.       13       BY MR. GOMEZ:         15       A Correct.       16       information about the drugs themselves without looking         16       she's employed by Jansen Ortho here in Toronto,       16       information about the drugs themselves without looking         17       at Mois Schulz. We talked about him. He's the       16       information about sate whole lot of         10       Q Who's Ann Leung? L-E-U-N-G.       24       A Wel, we get an updated book every year         24       A Don't Know.       22       the pharmaceutical agents. And you cango         25       you whow Al Derivan? I think I asked       23       effects, the dosing, situations that you need to -         24       A No.       Yes.       2       Q That's one source wher			07	
9         employed by J and J Pharmaceutical R&D, Titusville, 10         9         literature is not necessarily the first place they 10         9           11         A Yes.         10         would go. The Compendium of Pharmaceutical 11         11         Substances, the CPS, in the U.S. And in Canada it 12         would -           12         and J Pharmaceutical R&D out of Belgium?         13         BY MR. GOMEZ:         13           14         A Yes.         14         Q Tansory. I diaft mean to interrupt you.           15         G And if you turn the page, Carin Binder, 16         16         information about the drugs themselves without looking 17           16         scorrect?         18         A Correct.         18         Q You're referring to like the package insert 19         of the prescription drug label?           20         to Miklos Schulz. We talked about him. He's the 21         10         A Wels, we tan updated book every year 21           21         with all the pharmaceutical agents. And you can go 22         21         with all the pharmaceutical agents. And you can go 23           22         A Yes.         23         Plage 55         24         A No.           23         Q Who's Ann Leung? 1-F-U-N-G.         24         Q That's published?         24           3         Q Mod you know Dr. Fiona Dunbar; correct?         3			0	
10       New Jersey: correct?       10       would g.o. The Compendium of Pharmaccutical         11       A Yes.       13       and J Pharmaccutical R&D out of Belgium?       14       New Jersey: Correct?       13         14       A Yes.       13       and J Pharmaccutical R&D out of Belgium?       14       Q Tm sorry. I didht mean to interrupt you.         15       Q And if you turn the page, Carin Binder,       16       information about the drugs themselves without looking at the primary studies.         16       she's employed by Janssen Ortho here in Toronto,       16       information about the drugs themselves without looking at the primary studies.         17       at Correct.       19       Q       On that same page, page 2, special thanks.         10       to Miklos Schulz. We talked about him. He's the       18       Q       You're referring to like the package insert         12       to Miklos Schulz. We talked about him. He's the       18       Q       Tharey sublished, i assume, in Canada every year         21       with all the phications, the side       22       through, and they list all the infications, the side         23       Q       Who's Ann Leung? L-E-U-N-G.       24       Q       That's published, I assume, in Canada every         25       Q       Do you know Al Derivan?       Think I asked       The wasting a be			_	1
11A Yes.11Substances, the CPS, in the U. S. And in Canada it12Q And Goedele DeSmedt is also employed by J13BY MR. GOMEZ:14A Yes.14Q Pm sorry. Ididn't mean to interrupt you.15Q And if you turn the page, Carin Binder,15Where you can look at a whole lot of16she's employed by Janssen Ortho here in Toronto,16Merey you can look at a whole lot of17Canada; correct?18A Correct.18A Correct.18Q You'r eferring to like the package insert19Q On that same page, page 2, special thanks10You'r eferring to like the package insert20to Miklos Schulz. We talked about him. He's the10You'r eferring to like the package insert21who's Am Leung? L-E-U-N-G.23Well, we get an updated book every year23Q Who's Am Leung? L-E-U-N-G.23effects, the dosing, situations that you need to -24A Don't know.23effects, the dosing, situations that you need to -25Q Do you know AI Derivan? I think I asked14A Yes.2A Noo.214A Yes.3Q And you know Dr. Fiona Dunbar; correct?3PDR? Does that ring a bell?4A Yes.4Yes. H's called the Physician's Desk Reference?3Q If we could turn the page to page 3. It6Tof rinformation about safety and efficacy?7A So that's no first source because it's98A If's a one-page summary of everything that14 <td< td=""><td></td><td></td><td></td><td></td></td<>				
12       Q       And Gioedele DeSmedt is also employed by J       12       would         13       and J Pharmaceutical R&D out of Belgium?       13       BY MR. GOMEZ:         14       A Yes.       15       Q       And if you turn the page, Carin Binder,         15       Q       And if you turn the page, Carin Binder,       15       A       Where you can look at a whole lot of         16       she's employed by Janssen Ortho here in Toronto,       16       information about the drugs themselves without looking at the primary studies.         18       A       Correct.       18       Q       You're referring to like the package insert         19       O       On that same page, page 2, special thanks       18       Q       You're referring to like the package insert         20       M Kes.       You's Ann Leung? 1FU-N-G.       24       Q       That's all the indications, the side         23       Q       Who's Ann Leung? 1FU-N-G.       24       Q       That's published, Lassume, in Canada every         24       A       You that earlier.       21       you that earlier.       22       Q         3       Q       And you know Dr. Fiona Dunbar; correct?       3       P       A       Yes.         4       A Yes.       G				
13       and J Pharmaceutical R&D out of Belgium?       13       BY MR. GOMEZ:         14       A Yes.       Q Im sorry. 1 didn't mean to interrupt you.         15       Q And if you turn the page, Carin Binder,       14       Q Im sorry. 1 didn't mean to interrupt you.         16       she's employed by Janssen Ortho here in Toronto,       A Where you can look at a whole lot of         16       information about the drugs themselves without looking         17       canada; correct?       A Correct.         18       A Correct.       Q On that same page, page 2, special thanks         19       Q On that same page, page 2, special thanks       O who's Ann Leung? L-E-U-N-G.         21       Who's Ann Leung? L-E-U-N-G.       Cather the dosing, situations that you need to         23       Q Who's Ann Leung? L-E-U-N-G.       Cather the dosing, situations that you need to         24       A Don't know.       Page 55       Page 55         2       Q That's published, I assume, in Canada every       Yes.         2       A Yes.       1       A Yes.         2       A Yes.       2       If s called the Physician's Desk Reference?         3       Q And you know Dr. Fiona Dunbar; correct?       4       A Yes.       Yes. It's called the CPS in Canada.         5       O If we could				
14       A Yes.         15       Q And if you turn the page, Carin Binder,         16       she's employed by Janssen Ortho here in Toronto,         17       Canada; correct?         18       A Correct.         19       Q On that same page, page 2, special thanks         20       to Miklos Schulz. We talked about him. He's the         21       biostatistician?         22       A Yes.         23       Q Who's Ann Leung? L-E-U-N-G.         24       A Don't know.         25       Q Do you know Al Derivan? I think I asked         7       you that eartlier.         2       A No.         2       A No.         3       Q If's called the Physician's Desk Reference?         3       Q Ha's an abstract?         4       Yes.         1       A Yes.         5       Q If we could turn the page to page 3. It         6       reads under background - and this is the abstract.         7       A Wey is there an abstract?         8       A It's a one-page summary of everything that         16       a It's allow the whole article wise and the interature?         11       have the article by itself when it's published?         16       O				
15       Q       And if you turn the page, Carin Binder,         16       she's employed by Janssen Ortho here in Toronto,       16         17       Canada; correct?       16         18       A       Correct.       17         19       Q       On that same page, page 2, special thanks       18       Q       You're referring to like the package insert         19       Q       On that same page, page 2, special thanks       18       Q       You're referring to like the package insert         10       O thiklos Schulz. We talked about him. He's the       information about the drugs themselves without looking         21       A       Yes.       21       A       Well, we get an updated book every year         23       Q       Who's Ann Leung? L-E-U-N-G.       23       effects, the dosing, situations that you cang to through and they list all the indications, the side         25       Q       Do you know Al Derivan? I think I asked       23       year like it is in the United States?         2       A       No.       2       Q       Tfa's aoilysican's Desk Reference?         3       Q       And you know Dr. Fiona Dunbar, correct?       1       A       Yes.         3       A       It's a one-page summary of everything that an abstract?       PIPR? Does that ring a bel				
16       she's cmployed by Janssen Ortho here in Toronto,       16       information about the drugs themselves without looking         17       Canada, correct?       8       A Correct.       9       Q       On that same page, page 2, special thanks         20       to Miklos Schulz. We talked about him. He's the       biostatistician?       19       or the prescription drug label?         21       A Yes.       20       Mo's Ann Leung? L-E-U-N-G.       24       A Don't know.         23       Q Who's Ann Leung? L-E-U-N-G.       24       A Don't know.       22         25       Q Do you know Al Derivan? I think I asked       23       cffects, the dosing, situations that you ned to         24       A No.       20       That's published, I assume, in Canada every       25         2       A No.       2       Q If's called the Physician's Desk Reference?       3         3       Q And you know Dr. Fiona Dunbar, correct?       1       A Yes.       2       Q If's called the Physician's Desk Reference?         3       Q If we could turn the page to page 3. It       6       G origon what you just is the abstract.       7       A So that's my first source be medical       10         10       Q Why is there an abstract?       Whon's the ear and betract?       7       A So that's my first source be medical				
17       Canada; correct?         18       A Correct.         19       Q on that same page, page 2, special thanks         20       to Miklos Schulz. We talked about him. He's the         21       biostatistician?         22       A Yes.         23       Q Who's Ann Leung? L-E-U-N-G.         24       A Don't know.         25       Q Do you know Al Derivan? I think I asked         26       A Yes.         27       You that earlier.         2       A No.         3       Q And you know Dr. Fiona Dunbar; correct?         4       A Yes.         2       Q Ha's called the Physician's Desk Reference?         3       Q If we could turn the page to page 3. It         6       reads under background and this is the abstract.         7       What's an abstract?         8       A It's a one-page summary of everything that         1       follows, a preeis.         10       Q Why is there an abstract? Why not just         11       have the article by itself when it's published?         13       on editings. It allows it to be published?         14       format without the whole article being there. And it         15       one of the first places doctors go when				
18       A       Correct.       18       Q       You're referring to like the package insert         19       Q       On that same page, page 2, special thanks       18       Q       You're referring to like the package insert         19       Q       On that same page, page 2, special thanks       19       or the prescription drug label?         21       biostatistician?       21       with all the pharmaceutical agents. And you can go         22       A       Yes.       21       with all the pharmaceutical agents. And you can go         23       Q       Who's Ann Leung? L-E-U-N-G.       24       A       Don't know.       22         23       Q       Who's Ann Leung? L-E-U-N-G.       24       Q       That's published. I assume, in Canada every         25       Q       Do you know Al Derivan? I think I asked       25       year like it is in the United States?         1       A       Yes.       Q       That's published. I assume, in Canada.       2         3       Q       And you know Dr. Fiona Dunbar; correct?       4       A       Yes.       21       A Yes.         3       Q       If we could turn the page to page 3. It       5       Q       That's one-page summary of everything that       5       3       A It's a one-page summary				
19       Q       On that same page, page 2, special thanks       19       or the prescription drug label?         20       to Miklos Schulz. We talked about him. He's the       20       A Well, we get an updated book every year         21       A Yes.       20       Who's Ann Leung? L-E-U-N-G.       22       at Well, we get an updated book every year         22       A Yes.       23       Q Who's Ann Leung? L-E-U-N-G.       23       effects, the dosing, situations that you need to         24       A Don't know.       23       effects, the dosing, situations that you need to         25       Q Do you know Al Derivan? I think I asked       24       Page 55         1       you that earlier.       2       Q If's called the Physician's Desk Reference?         3       Q And you know Dr. Fiona Dunbar; correct?       3       PDR? Does that ring a bell?       4         4       A Yes.       2       Q That's one source where physicians can go       6         6       reads under background and this is the abstract.       7       A So that's my first source because it's         7       Mastract?       Why not just       14       A Yes.       9         10       Q Why is there an abstract?       9       Q Would the second source be medical         10       Iterature?				1
20       to Miklos Schulz. We talked about him. He's the         21       biostatistician?         22       A Yes.         23       Q Who's Ann Leung? L-E-U-N-G.         24       A Don't know.         25       Q Do you know Al Derivan? 1 think I asked         Page 55         Page 55         2       A No.         3       Q And you know Dr. Fiona Dunbar; correct?         4       A Yes.         2       A It's a one-page summary of everything that         6       reads under background and this is the abstract?         8       A It's a one-page summary of everything that         9       follows, a precis.         10       Q Why is there an abstract? Why not just         11       have the article by itself when it's published?         12       A Two things. It allows it to be published?         13       on Medline, PubMed, or one of these places in this is         14       format without the whole article being there. And it         15       also allows people to just skim the literature.         16       Going on what you just said there, this is         17       MR. ESSIG: Objection to the form.         19       MR. ESSIG: Objection to the form.         <				
<ul> <li>21 biostatistician?</li> <li>22 A Yes.</li> <li>23 Q Who's Ann Leung? L-E-U-N-G.</li> <li>24 A Don't know.</li> <li>25 Q Do you know Al Derivan? I think I asked</li> <li>26 Page 55</li> <li>1 you that earlier.</li> <li>2 A No.</li> <li>3 Q And you know Dr. Fiona Dunbar; correct?</li> <li>4 A Yes.</li> <li>2 A Yes.</li> <li>2 Q It's called the Physician's Desk Reference?</li> <li>3 PDR? Does that ring a bell?</li> <li>4 A Yes. It's called the CPS in Canada.</li> <li>5 Q If we could turn the page to page 3. It</li> <li>6 reads under background and this is the abstract.</li> <li>7 What's an abstract?</li> <li>8 A It's a one-page summary of everything that</li> <li>9 follows, a precis.</li> <li>10 Q Why is there an abstract? Why not just</li> <li>11 have the article by itself when it's published?</li> <li>12 A Two things. It allows it to be published?</li> <li>13 on Medline, PubMed, or one of these places in this</li> <li>14 format without the whole article being there. And it</li> <li>15 also allows people to just skim the literature.</li> <li>16 Q Going on what you just said there, this is</li> <li>17 one of the first places doctors go when reviewing a</li> <li>18 journal article?</li> <li>19 MR. ESSIG: Objection to the form.</li> <li>10 BY MR, GOMEZ:</li> <li>11 A Depends. If it's if you're looking for</li> <li>12 A Depends. If it's if you're looking for</li> <li>13 the mat of the article, you read the whole article.</li> <li>14 Hyou're looking for a quick fix, you look at the</li> </ul>				1 1 0
22       A       Yes.       22       through, and they list all the indications, the side effects, the dosing, situations that you need to         24       A       Don't know.       23       Q       That's published, I assume, in Canada every         25       Q       Do you know Al Derivan? I think I asked       Page 55         1       You that earlier.       2       A       No.         2       A       No.       2       Q       It's called the Physician's Desk Reference?         3       Q       And you know Dr. Fiona Dunbar; correct?       3       Q       It's called the Physician's Desk Reference?         3       Q       And you know Dr. Fiona Dunbar; correct?       4       A       Yes.       2       Q       Ta's one source where physicians can go       to for information about safety and efficacy?       7       A       So that's my first source because it's       8       sitting right there.       9       Q       Would the second source be medical       10       10       11       A       Yes.       1       A       Yes.       14       A Yes.       9       Q       Would the second source be medical       10       10       11       11       14       14       14       14       14       14       14       14       14 <td></td> <td></td> <td></td> <td></td>				
23       Q       Who's Ann Leung? L-E-U-N-G.       23       effects, the dosing, situations that you need to         24       A       Don't know.       24       Q       That's published, I assume, in Canada every         25       Q       Do you know Al Derivan? I think I asked       25       year like it is in the United States?         Page 57         1       you that earlier.       2       Q       It's called the Physician's Desk Reference?         3       Q       And you know Dr. Fiona Dunbar; correct?       4       A       Yes.         4       A       Yes.       2       Q       It's called the Physician's Desk Reference?         3       PARe 55       Q       That's one source where physicians can go       6         6       reads under background and this is the abstract.       7       M As o that's my first source because it's         8       A It's a on expage summary of everything that       9       Q       Would the second source be medical         10       Q       Why is there an abstract? Why not just       1       A Yes.       9       Q         11       have the article by itself when it's published?       13       Q       Okay. So if a doctor had specific         12       A       Two things. It allows th				
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	Page 58		Page 60
1		1	
1 2	with side effects hypothetically attributable to prolactin, SHAP."	2	analysis? A Potentially, yes.
$\frac{2}{3}$	Did I read that correctly?	3	Q If you go down on this page to the
4	A Yes.	4	conclusion, it reads, "With long-term risperidone
5	Q So the main purpose of this article was to	5	treatment in children, serum prolactin levels tended
6	look at any relationship with Risperdal and things	6	to rise and peak within the first one to two months
7	like gynecomastia; is that a fair assessment?	7	and then steadily declined to values within or very
8	A Yes.	8	close to the normal range by three to five months."
9	Q When it's written "any relationship," what	9	Did I read that correctly?
10	does that mean?	10	A Correct.
11	A A cause-and-effect relationship.	11	Q Then it reads, "There was no relationship
12	Q Okay. When you're talking about	12	between the occurrence of SHAP extrapyramidal symptoms
13	relationship, are we talking about associations? Or	13	or improvement on the conduct problem subscale of the
14	are we talking about correlations?	14	N-CBRF and prolactin elevation."
15	A So you're talking about both. A study like	15	A Yes.
16	this is not going to be definitive in its answer	16	Q To break that down, that last sentence,
17	because it's only a certain dosing of Risperdal. It's	17	would you agree with me that the reader can strike
18	only a certain duration. It's only a certain set of	18	that. What is meant there is that the conclusion of
19	indications where it is.	19	this article was there was no relationship between the
20	This is not the final answer.	20	occurrence of SHAP and prolactin elevation; is that
21	Q So is it true that certain tests or	21	correct?
22	statistical tests were done to determine whether or	22	A Correct.
23	not there was relationships, i.e. correlations or	23	Q Let's go to page 7. The second paragraph,
24	associations?	24	it reads, "There are no data in children as to the
25	A Yes.	25	degree of prolactin elevation that warrants concern in
	Page 59		Page 61
1	Q And if there was found to be an	1	relationship to potential inhibition of growth, sexual
2	association, would we expect to see that in the body	2	development, or potential side effects such as
3	of the article?	3	gynecomastia or galactorrhea."
4	A You'd expect to see it in the body of the	4	Did I read that correctly?
5	article.	5	A Yes.
6	Q You would?	6	Q Okay. And that was your understanding as
7	A If there was a relationship, yes.	7	well back in 2001. There was nothing in the
8	Q Okay. What tests, if you know, are done to	8	literature on this?
9	determine associations?	9	MR. ESSIG: Objection. Form and
10	A Each set of data are going to be looked at	10	foundation. You just said 2001. I think we were
11	in these cases by highly qualified biostatisticians	11	talking about 2003
12	who can give the best information in looking at these	12	BY MR. GOMEZ:
13	correlations with the correlation coefficients, the	13	Q Well, I'll rephrase the question. Back in
14	relationship between level and severity.	14	2001 when you were first contacted by Carin Binder,
15	So if you can define severity as one, two,	15	you were asked to look at
16	three, four, five and level as five, ten, 15, 20 and	16	A My clinical experience, my reading of the
17	there's a nice straight line that fits, that would be	17	literature didn't give me the answers to that
18	the best correlation.	18	question.
19	Q To test whether or not there was a correlation you need to do a correlation coefficient	19	Q Okay. And that's what that sentence is
20	correlation, you need to do a correlation coefficient test; is that correct?	20 21	telling us as well; correct?
21 22		21 22	A Yes, yes. O It goes on to read the article "It is the
22	A That's one of the ways of looking at it,	22	Q It goes on to read, the article, "It is the experience of the authors," and in parenthesis,
23 24	yes. Q And if you're going to determine if there's	23 24	"pediatric endocrinologists TM and DD" that's Tom
24	an association, you would do a test like a chi-square	24 25	Moshang and Denis Daneman; correct?
23	un association, you would do a test like a em-square	23	woshang and Doms Danoman, concet:

11QIs a prolactin level between 18 and 3012considered abnormal?13ASo the normal range in males under 18 and14normal females under 30 considered in the normal15range. But it's been changing over time. And in our16experience and it's still my experience to this17day that levels under 30, in fact, probably under1815 are rarely if ever associated with any significant19side effects.20Q21"Prolonged elevations between 18 and 30 can lead to22side effects." Is it more likely that they can lead23to side effects based on a longer duration?24A25Q26Q27Page 631objective of this post-hoc analysis was to investigate1objective of this post-hoc analysis was to investigate		Page 62		Page 64
Page 631objective of this post-hoc analysis was to investigate2serum prolactin levels in children and adolescents3with long-term risperidone treatment and to explore4any possible correlation with side effects5hypothetically attributable to elevated prolactin6levels, SHAP."7Did I read that correctly?8A Correct.9Q What's a post-hoc analysis?10A This wasn't the primary analysis done at11the time the original study was done. These studies12were put together, and the data was done after the13study was over.14Q So just so the jury understands, these five15At So those who are over 10 and had16A Yes.17Q And somebody made a decision to combine18these five studies and do an analysis of the data and19publish it?20A Yes.21Q Okay. What does it mean when it's written,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>A Correct.</li> <li>Q "That prolactin levels above 18 but less, below 30 NG/ML, are rarely if ever associated with clinical manifestations or alterations of the hypothalamic pituitary gonadal axis"; did I read that correctly?</li> <li>A Correct.</li> <li>Q What does that mean?</li> <li>A There's an area in the sentence, either less than 30 or below 30 is one of the other.</li> <li>Q Is a prolactin level between 18 and 30 considered abnormal?</li> <li>A So the normal range in males under 18 and normal females under 30 considered in the normal range. But it's been changing over time. And in our experience and it's still my experience to this day that levels under 30, in fact, probably under 15 are rarely if ever associated with any significant side effects.</li> <li>Q And following up on that statement, "Prolonged elevations between 18 and 30 can lead to side effects." Is it more likely that they can lead to side effects based on a longer duration?</li> </ul>	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	I can't give you the answer to that. It would be speculation. Q Five minutes left on the tape. We might as well change the tape real quick. Let's do that. MR. ESSIG: Sure. VIDEOGRAPHER: This marks the end of videotape No. 1 in the deposition of Dr. Denis Daneman. Going off the record at 10:45 a.m. (Discussion off the record.) VIDEOGRAPHER: Here begins videotape No. 2 in the deposition of Dr. Denis Daneman. Going back on the record at 10:48 a.m. BY MR. GOMEZ: Q Dr. Daneman, we're looking at continuing to look at the July what's titled July '03. We'll call it a draft, that was attached to the email you produced in your deposition today. You and Dr. Moshang were asked to look at the adverse events possibly associated with prolactin elevation in risperidone; correct? A Yes. Q And you came up with was it your decision to or whose decision was it to come up with a
1objective of this post-hoc analysis was to investigate2serum prolactin levels in children and adolescents3with long-term risperidone treatment and to explore4any possible correlation with side effects5hypothetically attributable to elevated prolactin6levels, SHAP."7Did I read that correctly?8A7Did I read that correctly?8A7Did I read that correctly?9Q9Q9Q9What's a post-hoc analysis?10A11the time the original study was done. These studies12were put together, and the data was done after the13study was over.14Q15studies had already been completed?16A17Q18these five studies and do an analysis of the data and19publish it?20A21Q21Q21Q21Q21Q21Q2121Q21212121212121212121212121212121212121 <td></td> <td></td> <td></td> <td></td>				
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23talking about a correlation test? Or are they using 2423AWell, age 10, if you take Tanner stage two, 2423the word interchangeably with "association"?23AWell, age 10, if you take Tanner stage two, 10 to 13 and a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>objective of this post-hoc analysis was to investigate serum prolactin levels in children and adolescents with long-term risperidone treatment and to explore any possible correlation with side effects</li> <li>hypothetically attributable to elevated prolactin levels, SHAP."</li> <li>Did I read that correctly?</li> <li>A Correct.</li> <li>Q What's a post-hoc analysis?</li> <li>A This wasn't the primary analysis done at the time the original study was done. These studies were put together, and the data was done after the study was over.</li> <li>Q So just so the jury understands, these five studies had already been completed?</li> <li>A Yes.</li> <li>Q Okay. What does it mean when it's written, "and to explore any possible correlation"? Are they talking about a correlation test? Or are they using</li> </ul>	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>had gynecomastia at a time when pubertal gynecomastia was likely to be at its height. And we felt that there needed to be an analysis that included those children and excluded those children to see what the outcome was.</li> <li>Q Can you define or do you remember before we look at this what the cutoff was in terms of age or SHAP A and SHAP B gynecomastia?</li> <li>A I think we said 10 in boys.</li> <li>Q Was there ever any discussion to include ages less than 10; do you remember?</li> <li>A To include them?</li> <li>Q As SHAP B.</li> <li>A So those who are over 10 and had gynecomastia were excluded for SHAP B.</li> <li>Q Right. Do you remember any discussion to make that age cutoff lower than age 10?</li> <li>A I can't recall the exact nature of the discussion.</li> <li>Q And why age 10 when there's discussions earlier that we saw regarding ages 12 to 14?</li> <li>A Well, age 10, if you take Tanner stage two,</li> </ul>

17 (Pages 62 to 65)

	Page 66		Page 68
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>Page 66</li> <li>be Tanner stage two pubertal development in boys. That would be the range. So you wouldn't want to go much below 10.</li> <li>Q I'm reading from page 13. It says, "An alternate definition of SHAP was used for the SHAP B population."</li> <li>A Which one?</li> <li>Q I'm looking at the bottom of page 13, second-to-last sentence. It says, "An alternate defense of SHAP was used for the SHAP B population."</li> <li>A Yes.</li> <li>Q So it's fair to say SHAP A was all inclusive of all ages in adverse events; correct?</li> <li>A Yes, correct.</li> <li>Q "SHAP B also excluded patients with amenorrhea less than one week in males 10 years of age or older with gynecomastia and females with less than 31 days of breast development." Did I read that right?</li> <li>A Correct.</li> <li>Q Then it's written, "It is considered normal for males to have gynecomastia at some point in the evolution of puberty, with the frequency estimated as high as 50 percent."</li> </ul>	$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>Page 68</li> <li>puberty who develop gynecomastia, males, the principle is that you have to investigate it very thoroughly to find a cause. It's going to very likely be a reason for it because males under the age of 10 don't produce enough estrogen to be converted to don't produce enough testosterone to be converted to estrogen in the peripheral tissues to allow the gynecomastia to develop.</li> <li>Q Going through the rest of this article or this draft, if you could go to page 17, do you see where it says, "Insert table one"?</li> <li>A Yes.</li> <li>Q Do you remember seeing, prior to publication in 2003, any of the tables that were originally included in the final published article?</li> <li>A I must have seen the tables.</li> <li>Q If you had seen them, you would have reviewed them?</li> <li>A I make that presumption.</li> <li>Q Okay. Fair enough. If you go over to page 18, it reads, the top sentence, "The PA population." What is a PA population?</li> <li>A I'd have to go back and look. PF often stands for primary analysis. But there must be somewhere where that is described.</li> </ul>
	Page 67		Page 69
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>Q It goes on to read, "Adolescent gynecomastia" and when it says "adolescent gynecomastia," that means pubertal gynecomastia?</li> <li>A Same thing.</li> <li>Q May be unilateral, one-sided, or bilateral?</li> <li>A Correct.</li> <li>Q And occurs most frequently during stages three and four of puberty?</li> <li>A Yes.</li> <li>Q And lasts a few months to two years?</li> <li>A Yes.</li> <li>Q 27 percent in one series lasted a year, and</li> <li>7 percent lasted two years?</li> <li>A Yes.</li> <li>Q Stages three and four of puberty, that's the equivalent of ages 12 to 14?</li> <li>A Yes.</li> <li>Q Why then are you excluding between the ages of 10 and 12?</li> <li>A That's what our discussions led us to. I can't tell you 11 years later the reason for that.</li> <li>Q So any children under the age of 10 who got gynecomastia, we can just all together exclude puberty as a cause?</li> <li>A So if you have children who have gone into</li> </ul>	$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>Q Just for purposes of my question, I'll represent PA is primary analysis, so we can save some time.</li> <li>A Okay.</li> <li>Q And we'll see that later on in the final published article. But the sentence reads, "The PA population included 489 boys or 82.6 of the subjects in the PA population and 103 girls, 17.4 percent."</li> <li>Did I read that right?</li> <li>A Correct.</li> <li>Q What's the purpose of writing in the article the distinction between boys and girls and the number of each?</li> <li>A There may be differences in the likelihood of complications, side effects in each.</li> <li>Q You would want, for example, gynecomastia as something only seen in boys; correct?</li> <li>A It's the equivalent of breast development in girls, yes.</li> <li>Q However, if we're looking at gynecomastia, we only want to look at the boys. Is that one reason why the numbers are being put here; would you agree?</li> <li>A That attribute is the only reason this was done. Gender differences are always put in papers.</li> <li>Q And the purpose of an article like this is</li> </ul>

	Page 70		Page 72
1	to educate physicians or give them at least a source	1	A Yes.
2	to go look for information about safety. And if you	2	Q I'll read it again. "The percentage of
3	were having a prescriber who was concerned about side	3	children with SHAP was assessed for SHAP B patients
4	effects in girls, this is an article he could go to to	4	with prolactin levels above the ULN." That's upper
5	get information about it; correct?	5	limits of normal?
6	MR. ESSIG: Objection to form and	6	A Yes.
7	foundation.	7	Q "Versus children with prolactin levels
8	THE WITNESS: Correct.	8	within the normal range at the various analysis time
9	BY MR. GOMEZ:	9	periods." Did I read that right?
10	Q Did you say correct?	10	A Yes.
11	A I said correct.	11	Q Do you remember whether or not what was
12	Q Okay. If you could go to page 21. I'm	12	going on here is that they were at different time
13	sorry, Doctor. Please back up to page 20, if you	13	periods, weeks one to four, four to eight, et cetera,
14	could do that for me. There's a section called "Side	14	the comparison was being done of kids with elevated
15	effects hypothetically attributable to prolactin	15	prolactin above normal versus children with normal
16	SHAP." Do you see that?	16	prolactin levels.
17	A Yes.	17 18	And they were looking at whether or not there was a difference between those who suffered side
18 19	Q As we discussed earlier, it reads in the third sentence, "As such, two analysis were performed.	18	effects; is that a fair assessment of what's being
20	The first analysis, SHAP A, used a more inclusive	20	written there?
20	definition of SHAP. And the second analysis, SHAP B,	20	A It's a fair assessment, but I can't recall
22	excluded additional symptoms that the pediatric	22	the discussion in any detail at all.
23	endocrinologist authors TM and DD attributed to	23	Q And what they're reporting here in the last
24	puberty."	24	sentence is that there was no statistical difference
25	A Correct.	25	in the percentage of patients who reported SHAP for
	Page 71		Page 73
1	Q Okay. The second sentence reads,"Many	1	any analysis time period whether or not prolactin
2	Q Okay. The second sentence reads,"Many children in this analysis were at the age of puberty.	2	any analysis time period whether or not prolactin levels were normal or above the upper limits of
2 3	Q Okay. The second sentence reads,"Many children in this analysis were at the age of puberty. So the cause of SHAP could be uncertain." Did I read	2 3	any analysis time period whether or not prolactin levels were normal or above the upper limits of normal. Did I read that correctly?
2 3 4	Q Okay. The second sentence reads,"Many children in this analysis were at the age of puberty. So the cause of SHAP could be uncertain." Did I read that right?	2 3 4	any analysis time period whether or not prolactin levels were normal or above the upper limits of normal. Did I read that correctly? A Correct.
2 3 4 5	Q Okay. The second sentence reads,"Many children in this analysis were at the age of puberty. So the cause of SHAP could be uncertain." Did I read that right? A You did.	2 3 4 5	<ul><li>any analysis time period whether or not prolactin levels were normal or above the upper limits of normal. Did I read that correctly?</li><li>A Correct.</li><li>Q Do you know what they mean when it's</li></ul>
2 3 4 5 6	<ul> <li>Q Okay. The second sentence reads,"Many children in this analysis were at the age of puberty.</li> <li>So the cause of SHAP could be uncertain." Did I read that right?</li> <li>A You did.</li> <li>Q So what the article is saying is we're</li> </ul>	2 3 4 5 6	<ul><li>any analysis time period whether or not prolactin levels were normal or above the upper limits of normal. Did I read that correctly?</li><li>A Correct.</li><li>Q Do you know what they mean when it's written here the authors, including yourself, in that</li></ul>
2 3 4 5 6 7	<ul> <li>Q Okay. The second sentence reads, "Many children in this analysis were at the age of puberty.</li> <li>So the cause of SHAP could be uncertain." Did I read that right?</li> <li>A You did.</li> <li>Q So what the article is saying is we're going to do two analysis, one all inclusive, and one</li> </ul>	2 3 4 5 6 7	<ul> <li>any analysis time period whether or not prolactin levels were normal or above the upper limits of normal. Did I read that correctly?</li> <li>A Correct.</li> <li>Q Do you know what they mean when it's written here the authors, including yourself, in that last sentence we just read, when they're talking about</li> </ul>
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2 3 4 5 6 7 8	<ul> <li>Q Okay. The second sentence reads,"Many children in this analysis were at the age of puberty. So the cause of SHAP could be uncertain." Did I read that right?</li> <li>A You did.</li> <li>Q So what the article is saying is we're going to do two analysis, one all inclusive, and one is excluding subjects based on age and so forth; is</li> </ul>	2 3 4 5 6 7 8	<ul> <li>any analysis time period whether or not prolactin levels were normal or above the upper limits of normal. Did I read that correctly?</li> <li>A Correct.</li> <li>Q Do you know what they mean when it's written here the authors, including yourself, in that last sentence we just read, when they're talking about SHAP, are they talking about SHAP A or SHAP B?</li> </ul>
2 3 4 5 6 7 8 9 10 11	<ul> <li>Q Okay. The second sentence reads,"Many children in this analysis were at the age of puberty.</li> <li>So the cause of SHAP could be uncertain." Did I read that right?</li> <li>A You did.</li> <li>Q So what the article is saying is we're going to do two analysis, one all inclusive, and one is excluding subjects based on age and so forth; is that right?</li> <li>A Correct.</li> <li>Q And you would expect the results of both</li> </ul>	2 3 4 5 6 7 8 9 10 11	<ul> <li>any analysis time period whether or not prolactin levels were normal or above the upper limits of normal. Did I read that correctly?</li> <li>A Correct.</li> <li>Q Do you know what they mean when it's written here the authors, including yourself, in that last sentence we just read, when they're talking about SHAP, are they talking about SHAP A or SHAP B?</li> <li>MR. ESSIG: Objection to the form. THE WITNESS: I believe this is SHAP A. BY MR. GOMEZ:</li> </ul>
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19 (Pages 70 to 73)

	Page 74		Page 76
1		1	
1	A Yes.	1	A Correct.
2	Q It reads, "Only 13 of 592, 2.2 percent of	2	Q Let's look over on the left-hand side
3	children, develop symptoms hypothetically attributable	3	between the two black lines. That's the abstract;
4	to prolactin for SHAP, with nine out of the 13	4	correct?
5	children showing resolution of these symptoms at study	5	A Correct.
6	end." Did I read that correctly?	6	Q And we looked at the background again. And
7	A Yes.	7	again, the analysis was being designed to investigate
8	Q Okay. The next sentence reads, "No	8	prolactin levels in children and adolescents on
9	correlation was found between SHAP and prolactin	9	long-term risperidone treatment and explore any
10	levels even when male gynecomastia during puberty was	10	relationships with side effects hypothetically
11	included." Did I read that right?	11	attributed to the prolactin SHAP.
12	A Yes.	12	No change from the draft; right?
13	Q Is what the authors are trying to say here	13	A Correct.
14	is that no correlation was found even in a SHAP A	14	Q Okay. And under the "Results" section of
15	analysis; correct?	15	the abstract, it reads, "At least one SHAP was
16	A Correct.	16	reported by 13 of 592 children. There was no direct
17	Q As well as the SHAP B analysis which	17	correlation between prolactin elevation and SHAP." Is
18	excludes children over the sage of 10; correct?	18	that right?
19	A Correct.	19	A Correct.
20	Q And what sort of tests would they have done	20	Q Okay. When it reads, "At least one SHAP
21	to determine whether or not there was a correlation?	21	was reported by 13 out of 592 children," when they say
22	A There were chi-squares, and there were	22	SHAP, they mean SHAP A or SHAP B?
23	correlation coefficients, as far as I can recall from	23	A This gives you the more conservative
24	reading the method section.	24	outcome, which would be let me just check SHAP
25	Q Based on your experience and your	25	B. This gives you at least this gives you the
	Page 75		Page 77
1	Page 75 knowledge, a chi-square test is for an association,	1	Page 77 minimum.
1 2		1 2	-
	knowledge, a chi-square test is for an association,	-	minimum.
2	knowledge, a chi-square test is for an association, not a correlation; correct?	2	minimum. Q And then it says there was no direct
2 3	knowledge, a chi-square test is for an association, not a correlation; correct? A It's better for an association, yes.	2 3	minimum. Q And then it says there was no direct correlation between prolactin elevation and SHAP?
2 3 4	<ul><li>knowledge, a chi-square test is for an association, not a correlation; correct?</li><li>A It's better for an association, yes.</li><li>Q Doctor, you can put that aside. Let me</li></ul>	2 3 4	minimum. Q And then it says there was no direct correlation between prolactin elevation and SHAP? A Yes.
2 3 4 5 6 7	<ul> <li>knowledge, a chi-square test is for an association, not a correlation; correct?</li> <li>A It's better for an association, yes.</li> <li>Q Doctor, you can put that aside. Let me mark as Exhibit 5 the published version of the article we were just looking at. And I have a few questions about it.</li> </ul>	2 3 4 5	<ul> <li>minimum.</li> <li>Q And then it says there was no direct</li> <li>correlation between prolactin elevation and SHAP?</li> <li>A Yes.</li> <li>Q Okay. Is there anything in the abstract</li> <li>that defines the difference between SHAP A and SHAP B?</li> <li>A No.</li> </ul>
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20 (Pages 74 to 77)

	Page 78		Page 80
1	Q Yes. What does it mean when the authors	1	studies?
2	wrote, "There was no direct correlation between	2	A I can't give an answer to that question.
$\frac{2}{3}$	prolactin elevation and SHAP"?	$\frac{2}{3}$	There was discussion of these protocols, and I can't
4	A That you couldn't define at a certain level	4	remember whether I did or I didn't. It's too long ago
5	of prolactin that there would be a side effect of	5	to remember the details.
6	prolactin.	6	Q Let's break down the studies. There's two
7	Q Specifically as to things like	7	six-week studies; right?
8	gynecomastia, that's the analysis we talked about	8	A Yes.
9	earlier where they were looking at	9	Q Double-blind placebo control studies?
10	A Yes.	10	À Yes.
11	Q Those were the upper limits of normal	11	Q We can agree that those trials are not long
12	versus normal and then looking at side effects to see	12	enough to look for safety data?
13	if there was a difference?	13	A Absolutely.
14	A Yes.	13 14	
			Q Those are short-term trials; correct?
15	Q If they had found a correlation, you would	15	A But they can give you prolactin data.
16	expect that to be here in the abstract as well as the	16	Q Agreed.
17	article; correct?	17	A Yes.
18	A Correct.	18	Q But if we're looking at adverse events
19	Q Let's turn the page and go to the section	19	A Correct.
20	under "Method." Are you there?	20	Q Okay.
21	A I am there.	21	MR. ESSIG: Object to the form, but go
22	Q It says under here under "Pooled Study	22	ahead.
23	Databases" that five study databases of	23	BY MR. GOMEZ:
24	risperidone-treated children and adolescents were	23 24	Q Let me ask the question again. The two
			six-week trials are not ideal to look at to determine
25	merged. "There were two six-week DB placebo control	23	six-week trials are not ideal to look at to determine
	Page 79		Page 81
1	trials." DB is double blind?	1	safety data or to gather safety data; correct?
2	A Correct.	2	A Correct.
3	Q "With two 48-week OL extensions of those	3	Q And then we have two 48-week open label
4	trials." Correct?	4	extensions of those trials. Is that a sufficient time
		5	frame to look at safety data?
5			
6	Q What's "OL"?	6	A It's better than six weeks, and it's the
7	A Open label.	7	best data we have, which is why it was reported. Is
8	Q Okay. And then a stand-alone one year OL	8	it the ideal way to do it? The ideal way is to have a
9	or open label trial to collect safety data; correct?	9	double-blind placebo controlled, randomized trial that
10	A Correct.	10	went for long enough to be able to be sure of that.
11	Q Were you aware that the one-year open label	11	But that wasn't the case. So this is the best
12	trial to collect safety data had over 500 subjects in	12	available, but it's not the best possible.
13	it?	13	Q Okay. We can agree that the 48-week
14	A Where is that? I went through the	14	extensions are long term?
15	different study numbers at the time. I couldn't have	15	A Yes.
16	quoted you today what the numbers were in each trial.	16	Q Are you aware of whether or not they paid
17	Q Okay. All I'm asking is, as you sit here	17	special attention to side effects like gynecomastia in
18	today, are you aware that there was over 500 subjects	18	those open label extensions?
19	alone in the stand-alone, one-year open label trial to	19	A My understanding is that there was
20	collect safety data?	20	attention paid to any potential side effects.
21	A Yes.	21	Q In comparison with the stand-alone,
22	Q Were you aware that there were 24 cases of	22	one-year open label extension, were you aware that in
23	gynecomastia seen in that study?	23	the protocols of that study that the particular
24	A No.	24	special attention was paid to side effects like
25			
23	Q Did you ever review the protocols of these	25	gynecomastia?

	Page 82		Page 84
1	A I cannot recall the details.	1	A Correct.
2	Q Were you aware when you reviewed these five		Q Is that correct?
3	studies when physical exams were done to look for	3	A Correct.
4	gynecomastia?	4	Q Okay. And then in figure 1, we have a
5	A We were I was aware of when the patients	5	chart or a graph entitled "Prolactin Levels in
6	were seen.	6	Children Receiving Long-Term Risperidone Treatment."
7	Q And really the only way you can look for	7	Do you see that?
8	gynecomastia is to do a physical exam; correct?	8	A Correct.
9	A Correct.	9	Q And then it has again, it's broken down
10	Q Staying with the final article, can we turn	10	by weeks. You see weeks four to seven there? That's
11	the page. And under "Outcome Measures" on the	11	where it's at the highest; is that right?
12	right-hand side, if you go down to the third	12	A Correct.
13	paragraph, you see there beginning with adverse	13	Q Then at weeks eight to 12, it's declined
14	events?	14	some way; right?
15	A Yes.	15	A Correct.
16	Q The first part of this paragraph talks	16	Q And then we see it declining over time all
17	about how the adverse events were looked at or how	17	the way up through the end of weeks 40 to 48; is that
18	they were assessed; is that fair?	18	what the graph is telling the reader?
19	A Yes; correct.	19	A Correct.
20	Q Okay. The sentence beginning with	20	Q If you go down to the section beginning
21	"patients," it says, "Patients with SHAP were	21	"Side effects hypothetically attributed to prolactin";
22	classified according to two sets of criteria, SHAP A	22	do you see that?
23	and SHAP B."	23	A Yes.
24	A Correct.	24	Q It reads, "Many of the side effects
25	Q So this is the article telling the reader	25	hypothetically attributable to elevation in prolactin
	Decc 92		Dece 95
	Page 83		Page 85
1	about the distinctions between SHAP A and SHAP B?	1	levels are also commonly seen during puberty." Did I
2	A Yes.	2	read that right?
3	Q Okay. And then it's written down within	3	A Correct.
4	the paragraph, "It is considered normal for males to	4	Q You agree with that?
5	have gynecomastia at some point in the evolution of	5	A Yes.
6	puberty, with the frequency estimated as high as	6	Q Okay. And then it reads, "Many of the
7	50 percent"?	7	children and adolescents in this analysis were at the
8	A Yes.	8	age of puberty. So the cause of SHAP could be
9	Q And that's consistent with the language we	9	uncertain."
10	saw in the earlier draft; correct?	10	A Correct.
11	A Yes.	11	Q "As such, because of this, as such, two
12	Q If you can go to page 1366 of the article,	12	analysis were performed." Did I read that right?
13	the page number is on the bottom right, Dr. Daneman.	13	A Correct.
14	A Yes.	14	Q Okay. And then it talks about the first
15	Q This is where we see table 1 and figure 1.	15	analysis, SHAP A, used a more inclusive definition.
16	Do you see that?	16	And the second analysis, SHAP B, excluded additional
17 18	A Correct.	17	symptoms based on, in the case of gynecomastia, age.
1 I X	Q Okay. And table 1 is describing the	18	Is that right?
		19	A Yes.
19	studies; do you see that?	$\gamma \gamma$	I I IVAV ANA TRAP IT VALLAA AVAT TA TRA PAVT
19 20	A Yes.	20	Q Okay. And then if you go over to the next
19 20 21	<ul><li>A Yes.</li><li>Q And then what we talked about earlier, we</li></ul>	21	column okay you see the percentage of patients
19 20 21 22	A Yes. Q And then what we talked about earlier, we see PA as primary analysis, and there's 592	21 22	column okay you see the percentage of patients sentence there, three down from the top? Do you see
19 20 21 22 23	A Yes. Q And then what we talked about earlier, we see PA as primary analysis, and there's 592 correct in table 1; do you see that?	21 22 23	column okay you see the percentage of patients sentence there, three down from the top? Do you see that?
19 20 21 22 23 24	A Yes. Q And then what we talked about earlier, we see PA as primary analysis, and there's 592 correct in table 1; do you see that? A Yes.	21 22 23 24	column okay you see the percentage of patients sentence there, three down from the top? Do you see that? A First paragraph?
19 20 21 22 23	A Yes. Q And then what we talked about earlier, we see PA as primary analysis, and there's 592 correct in table 1; do you see that?	21 22 23	column okay you see the percentage of patients sentence there, three down from the top? Do you see that?

	Page 86		Page 88
1	A Yes.	1	to look at it in the raw data as well.
2	Q Underneath table 4?	2	Q Okay. Again, the purpose I mean, we can
3	A Yes.	3	agree the main purpose of this article is to talk
4	Q It reads, "The percentage of patients with	4	about and look at any relationship?
5	SHAP was assessed for SHAP B patients with prolactin	5	A Yes, yes.
6	levels above the upper limits of normal versus	6	Q Okay. And if the relationship was found
7	patients with prolactin levels within the normal range	7	doing this comparison, you would expect to see it in
8	at the various analysis time periods."	8	the article; is that fair?
9	Did I read that correctly?	9	A Correct.
10	A Yes.	10	Q And we can agree what we just read was only
11	Q So that's talking about the SHAP B	11	the SHAP B analysis, which excludes kids over the age
12	analysis; correct?	12	of 10; right?
13	A Correct.	13	A Yes.
14	Q And when they compared kids with elevated	14	Q Okay. Now, if we turn the page to 1368
15	prolactin with kids who didn't have elevated prolactin	15	under the discussion section are you there?
16	and they were looking at side effects to determine	16	A I am there.
17	whether or not there was a relationship; is that fair?	17	Q Let's go over to the right-hand column and
18	A Correct.	18	then the second full paragraph or the first full
19	Q Then it says, "There was no statistical	19	paragraph beginning with, "Only 13 of 592." Are you
20	difference" okay "in the percentage of patients	20 21	there?
21 22	who reported SHAP for any analysis time period." And then it reads. "whather or not prologin levels were	21	A Yes, I am there.
22	then it reads, "whether or not prolactin levels were	22	Q Okay. So the reader is going to this
23 24	normal or above the upper limits of normal." Did I read that correctly?	23 24	section in the discussion and would read, "Only 13 of 592, 2.2 percent of children and adolescents, develop
24 25	A Yes.	24	symptoms hypothetically attributable to prolactin or
23	11 1 Co.	23	symptoms hypothetically attributable to profactil of
	Page 87		Page 89
1	Q What's a statistical difference? What's	1	SHAP." Did I read that right?
2	that?	2	A Correct.
3	A Probability.	3	Q "With nine of the 13 showing resolution of
4	Q Is that where they do the chi-square test?	4	these symptoms at study end"?
5	A Whatever statistical analysis is done will	5	A Yes.
6	tell you if it's a P value less than whatever you've	6	Q No difference from what we saw in that
7	set for your study, that the probability of these two	7	draft we looked at earlier; correct?
8	being different by chance alone is exceeded or not	8	A Yes.
9	exceeded.	9	Q It goes on, "No correlation was found hot was SUAD and malastin lavels even when mala
10	Q And if the P value is statistically significant, what does the reader learn from that?	10	between SHAP and prolactin levels even when male
11 12	significant, what does the reader learn from that? A That the chances of having X, Y, or Z is	11 12	gynecomastia during puberty was included." A Yes.
12	greater than by chance alone.	12	Q So that's an all inclusive. They're
13	Q In other words, if the P value is	13	talking about the SHAP A analysis or everything;
14	statistically significant, a reader could look at that	14	correct?
16	and say kids with elevated prolactin have a higher	16	A Yes.
17	propensity to develop SHAP throughout the trial; is	17	Q And they're telling the reader that they
18	that fair?	18	looked at that and they saw no correlation?
19	A You have to be a little careful in terms of	19	A Correct.
20	statistical significance and clinically meaningful	20	Q "This finding is in keeping with other
21	because sometimes the difference is tiny, but it	21	studies in adults that also showed no correlation
22	reaches statistical significance. So you know,	22	between prolactin levels and SHAP." So this analysis
23	statistics are statistics.	23	in this paper is reinforcing the adult analysis and
24	They just give you the probability. They don't	24	reassuring the physician; correct?
25	give you the impact of what's going on. And you have	25	A As one puts together ones discussion, one

Page	92
1 uge	

	Page 90		Page 92
1	looks at what there is in the literature and balances	1	BY MR. GOMEZ:
2	ones finding against that and then deals with the	2	Q I don't think you answered my question,
3	shortcomings of the particular study involved.	3	though. You want to put in both sides for balance; is
4	Q Now, in this final paper, if there had been	4	that fair? If you had information that showed an
5	an internal analysis done of SHAP A that showed a	5	
	•		association or a correlation, you would want that in
6	correlation, we would expect to see that in the paper;	6	the paper?
7	correct?	7	MR. ESSIG: Objection.
8	A You'd expect to see that in the paper, yes.	8	THE WITNESS: Yes.
9	Q And we would also expect to see that, if	9	BY MR. GOMEZ:
10	statements are being made that there's no direct	10	Q If we can go back to page 1367, I want to
11	correlation between elevated prolactin levels and	11	specifically look at the tables. Why do you have
12	SHAP, that the type of test to determine whether or	12	what's the purpose of these, table 2 and table 3?
13	not there's a correlation would be in the paper;	13	A To provide the actual numbers, to be able
14	correct?	14	to look at them.
15	A Correct.	15	Q And when you say provide actual numbers,
16	Q And if it's not possible to do a	16	you're talking about the rates of side effects?
17	correlation test okay the statement of no	17	A Yes.
18	correlation is kind of misleading; would you agree?	18	Q And prescribing physicians or anybody who
19	MR. ESSIG: Objection to the form.	19	reads the article, this is one place where they can go
$\frac{1}{20}$	THE WITNESS: It's not misleading if you	20	quickly to find that information; correct?
20	read the last two paragraphs of the discussion, which	20	A The prescribing physician is very unlikely
$\frac{21}{22}$	clearly indicate the shortcomings of any analysis of	21	
		22	to go to the tables. He's much more likely to go to
23	this sort. The clinical implications of the study are		the conclusions.
24	many.	24	Q Okay. But it's put in here for a reason.
25	What clinicians can expect, it gives an accurate	25	Hold on. Let me just finish my question. The reason
			D 02
	Page 91		Page 93
1	assessment, and what the deficiencies are here. And	1	it's put in the article is to show the rates of side
2	C C	1 2	
	assessment, and what the deficiencies are here. And		it's put in the article is to show the rates of side
2	assessment, and what the deficiencies are here. And so if you're a physician about to prescribe something,	2	it's put in the article is to show the rates of side effects; correct?
2 3	assessment, and what the deficiencies are here. And so if you're a physician about to prescribe something, a medication in a situation, you're going to look at	2 3	it's put in the article is to show the rates of side effects; correct? A Yes.
2 3 4	assessment, and what the deficiencies are here. And so if you're a physician about to prescribe something, a medication in a situation, you're going to look at the conclusions more than you will look at correlation	2 3 4	<ul><li>it's put in the article is to show the rates of side effects; correct?</li><li>A Yes.</li><li>Q Let's look at table 2. Under the PA or the</li></ul>
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2 3 4 5 6	assessment, and what the deficiencies are here. And so if you're a physician about to prescribe something, a medication in a situation, you're going to look at the conclusions more than you will look at correlation coefficient.	2 3 4 5 6	<ul><li>it's put in the article is to show the rates of side effects; correct?</li><li>A Yes.</li><li>Q Let's look at table 2. Under the PA or the primary analysis, we have a number of 592; do you see that?</li><li>A Correct.</li></ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>assessment, and what the deficiencies are here. And so if you're a physician about to prescribe something, a medication in a situation, you're going to look at the conclusions more than you will look at correlation coefficient.</li> <li>And it very clearly says, "Only a small percentage of children and adolescents treated with risperidone in this fashion will develop SHAP that requires intervention." And no matter what statistic you apply or not, that's something that holds very accurately.</li> <li>BY MR. GOMEZ:</li> <li>Q Okay. And that's within the article under that paragraph. But we can agree that, if you're going to do an analysis okay comparing children who had elevated prolactin and those who didn't and look at the relationship between prolactin and side effects, you want to be balanced and put in information that shows a correlation or shows an association?</li> <li>A You want to put in the best available information.</li> <li>Q Okay.</li> </ul>	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>it's put in the article is to show the rates of side effects; correct? <ul> <li>A Yes.</li> <li>Q Let's look at table 2. Under the PA or the primary analysis, we have a number of 592; do you see that?</li> <li>A Correct.</li> <li>Q Okay. And we saw earlier that 489 are males, and 103 are females. Do you remember that?</li> <li>A I do.</li> <li>Q That adds up to 592; correct?</li> <li>A Yes.</li> <li>Q Okay. So if you go down here where it says, "Reports of SHAP by preferred term," it says gynecomastia and says males; right?</li> <li>A Correct.</li> <li>Q Okay. And then you go over to the PA analysis, and it has 22. And I'll represent to you that 22 into 592 is 3.7 percent. That's what that's saying; correct?</li> <li>A Correct.</li> <li>Q Okay. If we're looking for gynecomastia in males, wouldn't we want the number under the PA to be</li> </ul> </li> </ul>

24 (Pages 90 to 93)

	Page 94		Page 96
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\end{array} $	<ul> <li>Q Okay. Do you think it's incorrect to measure or to put forth the percentage of gynecomastia in males and count females in the denominator?</li> <li>A So when you don't count females in the denominator, the number changes from 3.7 to 4.5, I believe.</li> <li>Q Something like that, yes.</li> <li>A Something like that; yes?</li> <li>Q Yes.</li> <li>A And that's a very small differential.</li> <li>Ideally, you'd like to separate the two. It's a small differential.</li> <li>Q It's not correct, though; agree?</li> <li>A It's 22 of the 592 of both sexes. This is</li> <li>peer reviewed on more than one occasion and left to stand by erudite reviewers. So I'm not going to</li> <li>Q So the authors missed it and</li> <li>MR. ESSIG: Can you let him answer his</li> <li>question. He was almost done.</li> <li>THE WITNESS: I'm not going to reject it on</li> </ul>	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	<ul> <li>there, in your opinion?</li> <li>A Galactorrhea and substantial breast enlargement, especially in males.</li> <li>Q Let's look at the same table. Reproductive disorders in females. Do you see that?</li> <li>A Going back? Yes.</li> <li>Q And it says, "Eight reproductive disorders, adverse events, in females"; do you see that?</li> <li>A Yes, I do.</li> <li>Q They're delineated underneath that;</li> <li>correct?</li> <li>A Correct.</li> <li>Q It says 1.4. That's 1.4 percent; right?</li> <li>A Correct.</li> <li>Q And that's eight into 592?</li> <li>A Or eight into 120, whatever the number.</li> <li>Q Shouldn't it be eight into 103? That would be correct?</li> <li>A I can't go back and tell you what the discussion was around it. I have no recollection.</li> <li>Q Listen carefully to my question. I'm not</li> </ul>
21 22	the basis of that.	21 22	asking about the discussion around it. I'm asking if
23	BY MR. GOMEZ:	23	you agree with me that it should be eight into 103.
24 25	Q Okay. But we can agree that the reviewers missed it and the authors missed it? It would be	24 25	And that percentage, that would be correct? A In 2012, if you put it that way, that's how
	Page 95		Page 97
1	ideal to have 22 into 489 to get the true and accurate	1	I would do the analysis.
2	percentage rate for gynecomastia; you agree with that?	2	Q Do you know whether or not anybody has ever
3	A Yes.	3 4	taken any steps to correct these calculations? A To provide a different analysis?
4 5	Q Okay. Now, you were talking about the difference between 4.5 and 3.7 is not significant, in	4 5	Q No. Has anybody do you know of anybody,
6	your opinion; correct?	6	authors, company representatives from Janssen, calling
7	A You have to be careful about the word	7	the Journal of Clinic Psychiatry and saying, "In our
8	"significant." It's the probability of	8	2003 Findling article, we have some mathematical
9	additional of a serious number of other patients	9	mistakes on the adverse event rates in females and
10	developing it and changing the recommendations that	10	males. We want to correct it"?
11	come in the end of the paper is going to be very small	11	MR. ESSIG: Object to the form.
12	indeed.	12 13	THE WITNESS: The term would be, "We have a different englysis" rather than an error
13 14	And I'll read those to you, if I may. "There's little justification for the discontinuation or	13 14	different analysis" rather than an error. BY MR. GOMEZ:
15	reduction in dose of risperidone (INAUDIBLE) since the	15	Q I'm specifically
16	dose of risperidone did not (INAUDIBLE) If a highly	16	A I have no knowledge whatsoever.
17	distressing hypothetically as attributable to	17	Q As one of the authors, do you think maybe
18	prolactin" (INAUDIBLE) gives examples.	18	you might do that? Could you do that if you wanted,
19	"Clinicians must balance the risk benefit ratio	19	say to the journal that this needs to be corrected?
20	prescribing risperidone, especially in the face and	20	A Since I'm not the primary author
21	the effect and outcome of untreated disruptive	21	Dr. Findling is I would discuss it with him.
22	behavior disorder." That's a very balanced	22	Q You would discuss it with him first?

- You would discuss it with him first? Q
- A Absolutely.
- 24 Q And then -- okay. Let's go down to table
- 25 3, which is SHAP B patients. Do you see that?

23

24

25

conclusion.

Q Okay. When we're talking about highly

distressing side effects, is gynecomastia included

	Page 98		Page 100
1	A Correct.	1	A Yes.
2	Q Now, we can agree when we looked at this	2	Q You can put that aside.
3	earlier that what a table does is it gives you the	$\frac{2}{3}$	MR. ESSIG: We've been going for about an
4	number of subjects, the number of adverse events, and	4	hour. This is probably a good time for a break.
5	you get a percentage. And that's what we see in the	5	MR. GOMEZ: Sure. Short break.
6	table; correct?	6	VIDEOGRAPHER: Going off the record at
7	A Correct.	7	11:33 a.m.
8	Q Okay. Now, we can also agree that we	8	(Recess from 11:33 a.m. to 11:41 a.m.)
9	looked at earlier the cutoff of age 10	9	VIDEOGRAPHER: Going back on the record at
10	A Correct.	10	11:41 a.m.
11	Q in terms of gynecomastia; correct?	11	BY MR. GOMEZ:
12	A Correct.	12	Q Dr. Daneman, before we get into the next
12	Q Okay. If you look at the number of	12	exhibit, have you reviewed in the course of getting
14	patients with at least one SHAP do you see that?	14	ready for this deposition or at any time any of the
15	A Yes.	15	expert reports in this case? By both sides?
16	Q Okay. It says 13 or 2.2 percent.	16	A No.
17	A Yes.	17	Q No? Looking at Exhibit 6, it's an email
18	Q Now, do you agree with me that the 592	18	and an attachment. Do you see that?
19	number is keeping in those male subjects over the age	19	A I do.
20	of 10 with gynecomastia?	20	(Whereupon, Exhibit No. 6 was marked for
20	A Both the tables are done with the same	20	identification.)
21	analyses, yes.	22	BY MR. GOMEZ:
23	Q Okay. And if you look at the reports of	23	Q And it's from Carin Binder on Tuesday,
23	SHAP by preferred terms, gynecomastia in males would		July 16, 2002, to Gahan Pandina; do you see that?
24	have five cases or .8 percent; correct?	24	A I do.
23	have five cases of is percent, context?	23	A 1 00.
	Page 99		Page 101
1	A Correct.	1	Q Do you know Dr. Pandina?
2	Q I'll represent to you that the number of	2	A No.
3	males under the age of 10 is 255. If that's correct,	3	Q Have you ever met him?
4	assuming for purposes of my question, that should be	4	A I'm unaware of that.
5	the number for the denominator; would you agree?	5	Q Do you know Vincent Nys?
6	A That's another way of doing the analysis,	6	A No.
7	yes.	7	Q In the subject is "Draft Prolactin
8	Q It is the more accurate manner to do the	8	Manuscript"; do you see that?
9	analysis; would you agree?	9	A I do.
10	A It's a manner in which I would do it in	10	Q And you're not on this email; correct?
11	2012.	11	A Correct.
12	Q And again in table 3, we have the female	12	Q It reads, "Hi Gahan, as promised. If there
13	analysis. Again, it's eight into 592 or 1.4. It	13	are glaring omissions, please let me know. Thanks,
14	should be eight into 103 in 2012; would you agree?	14	Karen." Do you see that?
15	A I understand what you're saying.	15	A I do.
16	Q Now, the readers of this article, if they	16	Q And then if we turn the page, it's the
17	went to this article and went to this table, are going	17	attachment; do you agree?
18	to get a percentage of less than one of males	18	A I do.
19	developing gynecomastia under the age of 10 who are on		Q Going down to the bottom left side, it
20	Risperdal.	20	says, "Revised July 16, 2002"; do you see that?
21	That's what they're going to glean from this	21	A I do.
22	table; correct?	22	Q It's entitled "Prolactin Levels in Children
23	A Yes.	23	and Adolescents with Long-Term Risperidone Use"?
24	Q If it was accurate and had 255 males, it	24	A Yes.
25	would almost double; is that right?	25	Q And again, the authors that are in the 2003

26 (Pages 98 to 101)

	Page 102		Page 104
1	final published version that we just looked at in	1	A Correct.
2	Exhibit 5; do you see that?	2	Q If I go do here, it says, "Correlation
3	A Yes.	3	coefficients were calculated to assess correlation
4	Q Do you remember seeing a July 16, 2002,	4	between prolactin levels and age and score on the
5	draft of the final article?	5	conduct problem subscale of the NCBRF." And a
6	A I saw drafts of the articles. I can't	6	correlation coefficient is a test for whether or not
7	recall any one with a specific date.	7	there's a correlation; correct?
8	Q If we go to I believe if you look on the	8	A Correct.
9	right-hand corner, Doctor, there's a JJRE number; do	9	Q If you could go to the page ending in
10	you see that?	10	page Bates stamp ending in the JJRE number and 40.
11	A Yes.	11	Are you there?
12	Q If you go to the JJRE number ending in	12	A I'm there.
13	22	13	Q If you go down to the paragraph beginning
14	A Got it.	14	with, "The percentage of children with SHAP." Do you
15	Q in the shaded portion, it reads, under	15	see that?
16	the "Conclusion" section, "There was no direct	16	A Yes.
17	correlation between prolactin elevation and the	17	Q It reads, "The percentage of children with
18	occurrence of SHAP, EPS, or efficacy." And then it	18	SHAP was assessed for patients with prolactin levels
19	says in parenthesis "Ann confirm." Do you see that?	19	above the ULN versus patients with prolactin levels
20	A I do.	20	within the normal range at the various analysis time
21	Q Do you know who Ann is?	21	periods."
22	A No.	22	Did I read that right?
23	Q If you could go to page ending in 33. Are	23	A Yes.
24	you there?	24	Q "The proportions were all comparable except
25	A I'm there.	25	for the weeks eight to 12 time period, in which
	Page 103		Page 105
1		1	-
1	Q Okay. See the paragraph beginning "Patient	1 2	7.8 percent of patients who had prolactin above the
2	Q Okay. See the paragraph beginning "Patient demographics"?	1     2     3	7.8 percent of patients who had prolactin above the ULN had SHAP at some point during the trial, while
2 3	Q Okay. See the paragraph beginning "Patient demographics"? A Yes.	3	7.8 percent of patients who had prolactin above the ULN had SHAP at some point during the trial, while 2.9 percent of patients with prolactin levels within
2 3 4	<ul><li>Q Okay. See the paragraph beginning "Patient demographics"?</li><li>A Yes.</li><li>Q Okay. It reads, "Patient demographics and</li></ul>	3 4	7.8 percent of patients who had prolactin above the ULN had SHAP at some point during the trial, while 2.9 percent of patients with prolactin levels within the normal range at weeks eight to 12 experience SHAP
2 3 4 5	<ul> <li>Q Okay. See the paragraph beginning "Patient demographics"?</li> <li>A Yes.</li> <li>Q Okay. It reads, "Patient demographics and pre-dose characteristics were compared between the PA</li> </ul>	3 4	7.8 percent of patients who had prolactin above the ULN had SHAP at some point during the trial, while 2.9 percent of patients with prolactin levels within the normal range at weeks eight to 12 experience SHAP at some time during the study. P is less than 0.02."
2 3 4	<ul> <li>Q Okay. See the paragraph beginning "Patient demographics"?</li> <li>A Yes.</li> <li>Q Okay. It reads, "Patient demographics and pre-dose characteristics were compared between the PA and non-PA populations using the chi-square test for</li> </ul>	3 4 5	7.8 percent of patients who had prolactin above the ULN had SHAP at some point during the trial, while 2.9 percent of patients with prolactin levels within the normal range at weeks eight to 12 experience SHAP
2 3 4 5 6	<ul> <li>Q Okay. See the paragraph beginning "Patient demographics"?</li> <li>A Yes.</li> <li>Q Okay. It reads, "Patient demographics and pre-dose characteristics were compared between the PA</li> </ul>	3 4 5 6	7.8 percent of patients who had prolactin above the ULN had SHAP at some point during the trial, while 2.9 percent of patients with prolactin levels within the normal range at weeks eight to 12 experience SHAP at some time during the study. P is less than 0.02." Do you remember seeing this, what we just read?
2 3 4 5 6 7 8 9	<ul> <li>Q Okay. See the paragraph beginning "Patient demographics"?</li> <li>A Yes.</li> <li>Q Okay. It reads, "Patient demographics and pre-dose characteristics were compared between the PA and non-PA populations using the chi-square test for categorical data or T test for continuous data."</li> <li>A Yes.</li> <li>Q "The chi-square test was also used to</li> </ul>	3 4 5 6 7 8 9	<ul> <li>7.8 percent of patients who had prolactin above the ULN had SHAP at some point during the trial, while</li> <li>2.9 percent of patients with prolactin levels within the normal range at weeks eight to 12 experience SHAP at some time during the study. P is less than 0.02." Do you remember seeing this, what we just read? A No.</li> <li>Q Is this the first time you've ever seen it? A I can't answer that question.</li> </ul>
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	Page 106		Page 108
1		1	
1	So it's not a sentence that I would like to keep		statistically significant association between elevated
2	in a paper.	2	prolactin and SHAP for kids that went on to the rest
3	Q We can agree that what's being written here	3	of the study?
4	is the results of the chi-square analysis comparing	4	A Yes.
5	children with prolactin levels above the upper limits	5	Q Is that fair? Is that a fair
6	of normal versus children with prolactin levels below	6	interpretation?
7	the upper limits of normal.	7	A That's fair. But they don't but those
8	And it's showing that kids with elevated	8	statistics don't tell you the relationship between the
9	prolactin had a much higher percentage or a higher	9	timing of the SHAP and the actual prolactin level at
10	percentage of side effects versus those with prolactin	10	that time. $O = P$ tifthe analysis is had inset the
11	levels below the upper limits of normal; is that fair?	11	Q But if the analysis is looking at the
12	MR. ESSIG: Objection to form and	12	relationship that we talked about at various analysis
13	foundation.	13	time periods, this is a relationship that was found at
14	THE WITNESS: I don't think it's fair. My	14	weeks eight to 12.
15	analysis here is the SHAP and the prolactin level are	15	A Okay. So one has to be very careful in
16	not comparable because they don't the statement	16	statistics at how you interpret them. When you do a
17 18	there doesn't tell you that the complication occurred	17 18	huge number of statistical analyses in a study and there were a huge number done here a something is
	at the time that the prolactin level was higher. BY MR. GOMEZ:		there were a huge number done here something is
19 20		19 20	going to come up that shows you relationships that may or may not exist.
20	Q Okay. Do you remember when we looked at the chart of the prolactin level where it peaked at	20	Q I'm not trying to argue with you. I guess
21		21	my question is this. That is an association that was
22	weeks four to eight and then eight to 12 at just below the near level? So they were above the upper limits	22	found?
23 24	the peak level? So they were above the upper limits	23 24	A Yes.
24 25	of normal at weeks eight to 12; is that correct? A Yes. Yes.	24 25	Q Correct?
23	A ICS. ICS.	23	Q Contect?
	Page 107		Dec. 100
			Page 109
1	Q Okay. The P is less than 0.02. Is that	1	A Correct.
1 2		1 2	A Correct.
	Q Okay. The P is less than 0.02. Is that statistically significant? A It is.		A Correct.
2	statistically significant?	2	<ul><li>A Correct.</li><li>Q Would you expect to see that in the final</li></ul>
2 3	statistically significant? A It is.	2 3	A Correct. Q Would you expect to see that in the final paper based on what you testified earlier about, that
2 3 4	<ul> <li>statistically significant?</li> <li>A It is.</li> <li>Q What does that mean?</li> <li>A That the chance of finding this difference</li> <li>by chance alone is less than 2 percent.</li> </ul>	2 3 4	A Correct. Q Would you expect to see that in the final paper based on what you testified earlier about, that medical literature should be balanced?
2 3 4 5	<ul><li>statistically significant?</li><li>A It is.</li><li>Q What does that mean?</li><li>A That the chance of finding this difference</li></ul>	2 3 4 5	A Correct. Q Would you expect to see that in the final paper based on what you testified earlier about, that medical literature should be balanced? MR. ESSIG: Objection to the form.
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	Page 110		Page 112
1	A Correct.	1	A Correct.
2	Q Correct? The draft that we looked at,	2	Q You would agree with me that you can't do a
3	which was entitled July, 2003, that was attached to	3	correlation coefficient for prolactin levels versus
4	the email that Mr. Essig sent me did not discuss that	4	SHAP?
5	association; correct?	5	A You can do it. It has a different
6	A Correct.	6	connotation.
7	Q And in the final paper, there's no mention	7	Q Don't you need two continuous variables to
8	of it as well; correct?	8	do a correlation coefficient?
9	A Correct.	9	A You do.
10	Q And can we agree that the final paper said	10	Q If you're comparing prolactin levels versus
11	that the analysis at all the various analysis time	11	SHAP, one of those is not a continuous variable;
12 13	periods of SHAP B showed no relationship? And even		therefore, you cannot do a correlation coefficient.
13	when kids with puberty were included, the same was found; is that correct?	13 14	You would agree? A Correct.
15	A Correct.	15	Q You can put that aside, Dr. Daneman. Thank
16	Q Okay. And that's the complete opposite of	16	you. I'm going to mark as Exhibit 7 another email and
17	what we see in this draft; correct?	17	attachment, sir.
18	MR. ESSIG: Objection to the form. And	18	(Whereupon, Exhibit No. 7 was marked for
19	foundation.	19	identification.)
20	BY MR. GOMEZ:	20	BY MR. GOMEZ:
21	Q Correct?	21	Q Dr. Daneman, I've marked as Exhibit 7
22	A Correct.	22	another email and attachment. Do you see that in
23	Q Let's go to page Bates stamp ending in 41.	23	front of you?
24	Now, this was an attachment to a Carin Binder email;	24	A I do.
25	correct?	25	Q Okay. Let's take a moment and look at the
	Page 111		Page 113
1	A Correct.	1	email before we go to the attachment. And this email
2	Q After the sentence that we just read in	2	is from at the top, again, somebody forwarding the
3	brackets, there's some comments. Do you see that, at	3	pooled prolactin manuscript. And it's from Carmen
4	the top?	4	Deloria; do you know who that is?
5	A Correct.	5	A No.
6	Q It reads, "How do you want to handle the	6	Q To Joseph Lynn; do you know him?
7	one significant value?" Do you agree that what she's	7	A No.
8	asking about there or whoever wrote this is asking	8	Q No?
9	about is the significant value mentioned in the	9	A No.
10 11	preceding sentence?	10 11	Q Okay. They're forwarding an email from Dr.
	A I presume so, yes. O "The poster states there was no direct		Pandina that was sent on August 21, 2002. Do you see that below?
12	Q "The poster states there was no direct	12	that below?
12 13	Q "The poster states there was no direct correlation with prolactin elevation in SHAP. What		that below? A Yes.
12	Q "The poster states there was no direct correlation with prolactin elevation in SHAP. What analysis was used for this?" Did I read that	12 13	that below? A Yes.
12 13 14	Q "The poster states there was no direct correlation with prolactin elevation in SHAP. What	12 13 14	<ul><li>that below?</li><li>A Yes.</li><li>Q Okay. And he was sending it to Carin</li></ul>
12 13 14 15 16 17	Q "The poster states there was no direct correlation with prolactin elevation in SHAP. What analysis was used for this?" Did I read that correctly? A Correct. Q We know, based on what we read earlier,	12 13 14 15 16 17	<ul> <li>that below?</li> <li>A Yes.</li> <li>Q Okay. And he was sending it to Carin</li> <li>Binder and Goedele DeSmedt, who was one of the authors or two of the authors of the 2003 article; correct?</li> <li>A Correct.</li> </ul>
12 13 14 15 16 17 18	Q "The poster states there was no direct correlation with prolactin elevation in SHAP. What analysis was used for this?" Did I read that correctly? A Correct. Q We know, based on what we read earlier, that the chi-squared analysis was done to look for the	12 13 14 15 16 17 18	<ul> <li>that below?</li> <li>A Yes.</li> <li>Q Okay. And he was sending it to Carin</li> <li>Binder and Goedele DeSmedt, who was one of the authors or two of the authors of the 2003 article; correct?</li> <li>A Correct.</li> <li>Q And Magali Reyes-Harde, do you see her</li> </ul>
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12 13 14 15 16 17 18 19 20 21 22 23	Q "The poster states there was no direct correlation with prolactin elevation in SHAP. What analysis was used for this?" Did I read that correctly? A Correct. Q We know, based on what we read earlier, that the chi-squared analysis was done to look for the relationship between elevated prolactin levels and SHAP; right? Yes? A Correct. Q Okay. "Can we get correlation coefficients for prolactin levels versus SHAP, as was done for	12 13 14 15 16 17 18 19 20 21 22 23	<ul> <li>that below?</li> <li>A Yes.</li> <li>Q Okay. And he was sending it to Carin</li> <li>Binder and Goedele DeSmedt, who was one of the authors or two of the authors of the 2003 article; correct?</li> <li>A Correct.</li> <li>Q And Magali Reyes-Harde, do you see her</li> <li>name?</li> <li>A Yes.</li> <li>Q Okay. And then Albert Derivan is carbon</li> <li>copied as well as Ivo Caers; do you see their names?</li> <li>A I do.</li> </ul>
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29 (Pages 110 to 113)

	Page 114		Page 116
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>A Yes.</li> <li>Q Okay. He writes, "Dear Team" before I read the email, you're not on this email, are you?</li> <li>A No.</li> <li>Q Okay. Do you ever let me read it.</li> <li>"Dear Team, attached please find my comments. I think the paper is overall constructed well and well written. I think we need to include the lack of association between Tanner height delay and prolactin level with SHAP, as our advisors tell us that this is one serious concern about prolactin."</li> <li>"If we can demonstrate that the transient rise in prolactin does not result in abnormal maturation or SHAP, this would be most reassuring to clinicians. I realize that these manuscripts are being developed in parallel, but the relationship here is important."</li> <li>Is he talking about the 2004 Dunbar article as well, if you know?</li> <li>A I don't know. I would presume so.</li> <li>Q "We have also had many concerns about patients who are maintained on stimulants, as this might affect prolactin level, and no subanalysis were included. Perhaps we can discuss prior to the next revision."</li> </ul>	$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	<ul> <li>that, if it's high at this eight to 12 week period, at some point in the later period, you may have SHAP. And if it's normal there, you would have one third or whatever 7.8 versus 2.9. And that was .02. Okay? Q Right.</li> <li>A And that's one of many investigations. And that doesn't give a sense of security that there's a good association or relationship in any way because you've got a point here and something there. So if you can demonstrate that there's normal physical maturation in patients receiving any medication, it would make the it would sort of smooth out those levels of prolactin.</li> <li>Q When you say "physical maturation," you're talking about another analysis, though, that was the focus of the Dunbar paper that looked at the same five studies; correct?</li> <li>A Abnormal maturation is what I would expect and that's what we mean, yes. Maybe I'm attributing too much information there.</li> <li>Q My questions are focused solely on the relationship between SHAP and elevated prolactin levels.</li> <li>A I don't think I would be attributing things that I'm not sure I can.</li> </ul>
		-	
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\\23\\24\\25\end{array} $	Page 115 accepted. Great news. Maybe this will make it easier for us to include this as a sub-analysis in this paper. Gahan." Did I read that right? A You did. Q Okay. Do you remember any discussion about one serious concern about prolactin was the levels in SHAP? A No. Q Do you know what he means when he said, "If we can demonstrate that the transient rise in prolactin does not result in SHAP, this would be most reassuring to clinicians"? MR. ESSIG: Objection to the form. You just skipped the first part of that sentence. BY MR. GOMEZ: Q Fair enough. I'll read it again. Thank you, Bill. "If we can demonstrate that the transient rise in PRL does not result in abnormal maturation or SHAP, this will be most reassuring to clinicians." Do you know what he means when he writes that? A So I have to attribute what I think he means to ten years and three months later. So you're okay with that? Q Yes. Your best answer. A So in that chi-square where you showed	6 7 8	<ul> <li>Q Sure. I don't want you to speculate. If the message of the paper was that there was no that prolactin rise is transient and not related to side effects hypothetically attributable to prolactin, does the significant value that we looked at in the previous draft fly in the face of that key message?</li> <li>A It argues against the key message. It's not the whole story against it because of the timing and the relationship.</li> <li>Q Understood. But it goes against the key message?</li> <li>A Yes. Often in any multiple analyses that you're going to do, you're going to get intuitive and counterintuitive answers. And you have to deal with them.</li> <li>Q If you have a significant value at weeks eight to 12 in looking at all SHAP, it also is in direct correlation between prolactin levels and SHAP; is that fair?</li> <li>MR. ESSIG: Objection to the form. THE WITNESS: Yes. BY MR. GOMEZ:</li> <li>Q Let's go to the email from Carin Binder below that; do you see that?</li> </ul>

1 A I do. 1 comparable except for v	
	weeks eight to 12 time period,
	patients who had prolactin
	of normal had SHAP at some
	hile 2.9 percent of patients
	ithin the normal range at weeks
	I SHAP at some time during the
7 A No. 7 study." 9 Do you can be seen d none graph? "Kay	ton of 02. compat?
8QDo you see her second paragraph? "Key8And it has the P fac9Message. Prolactin rise is transient and not related9ACorrect.	ctor of .02; correct?
	other comment, and it's
	ndina, based on his name. Do
12 that?	
13 A I do. 13 A I do.	
14 Q Okay. And on the second page of the email, 14 Q And he writes,	"This may be notable as this
	st that patients who show an
	eak period above upper limits
	gher propensity for SHAP. I
	ss this somewhere in the
19QDo you know if this was ever forwarded to19manuscript."20you?20What does he mean	by a higher propensity for
21 A No. 21 SHAP?	i by a higher propensity for
	bjection to the form.
23 the first page. Are you there? 23 BY MR. GOME	
24 A Yes. 24 Q You can answe	
25 Q I'm sorry. I do that too fast sometimes. 25 A I think he mean	ns a higher propensity for
Page 119	Page 121
1 Again, we can agree, if you look at the bottom, it's 1 SHAP.	
2 July 30th, 2002. The authors are all the same. We 2 Q What does that	z mean?
3 can agree it's another draft of the final article that 3 A A higher likelih	
	rote, "I think we need to
	e in the manuscript"; correct?
	ssed in the final manuscript
8 Let me know when you're there, sir. 8 that we looked at?	ssed in the final manuscript
9 A I'm there. 9 A No.	
10 Q Okay. Let me point your attention to the 10 Q Do you think it	t should have been?
11 second or the first full paragraph beginning, "The 11 A I don't know w	hat was submitted to the
	cept in and what they removed.
13 that? 13 So I don't know the ans	
	your opinion, as one of the
	ng that you would have liked suscript in terms of being
17 A Correct. 17 balanced?	iuseript in terms of being
	bjection to the form.
	: Nine-plus years later or
20 levels above the upper limits of normal versus 20 ten-plus years later, pro	
21 patients with prolactin levels within the normal range 21 BY MR. GOME	
	o Bates stamp ending in 196.
	second third full paragraph
24ACorrect.24beginning, "As a post-h25QIt says, "The proportions were all25AI do.	noc analysis"?
25QIt says, "The proportions were all25AI do.	

Q It reads, "As a post-hoc analysis of pooled data, these results should be considered exploratory in nature. However, the fact that the initial rise in prolactin levels with risperidone was transient and subsided to normal values reduces the safety concerns regarding long-term treatment in children." "This is reinforced by the lack of direct correlation between elevated prolactin levels in SHAP and EPS." That sentence, "This is reinforced by the lack of direct correlation," is that a correct statement? A Well, there was an association between SHAP between prolactin levels at the peak eight to 12 week and SHAP some time along the way. Q If he's saying here that a lack of direct correlation okay if he's specifically talking about correlation, it's not possible because the test is impossible to do; is that correct? MR. ESSIG: Objection to the form. Calls for speculation. THE WITNESS: So there's a statistical interpretation of the world "correlation." BY MR. GOMEZ: Q Let me rephrase the question, if you were done with your answer.	<ul> <li>A Correct.</li> <li>Q Do you agree with that?</li> <li>A I'd have to reflect on it a long period of</li> <li>time because it's the first time I'm seeing that.</li> <li>Q When he means hurt the overall impact of</li> <li>the paper strike that. The purpose of the paper is</li> <li>to educate the medical community; correct?</li> <li>A Correct.</li> <li>Q Is the purpose of the paper to impact the</li> <li>number of sales for a drug?</li> <li>A No.</li> <li>MR. ESSIG: Objection to the form.</li> <li>BY MR. GOMEZ:</li> <li>Q Should it ever be the purpose of a medical</li> <li>paper?</li> <li>A No.</li> <li>Q So how could it hurt the overall impact of</li> <li>the paper if the statistically significant association</li> <li>at weeks eight to 12 was discussed in the final</li> <li>manuscript?</li> <li>MR. ESSIG: Objection to the form.</li> <li>Foundation. Calls for speculation.</li> <li>THE WITNESS: I'd have to speculate.</li> <li>BY MR. GOMEZ:</li> <li>Q Okay. Would doctors who saw that, if they</li> </ul>
<ul> <li>A Yes.</li> <li>Q Maybe it was a poor question. The statement is made, "There was no direct correlation between elevated prolactin levels in SHAP." Correct?</li> <li>A Correct.</li> <li>Q Yet we can agree that a correlation coefficient is impossible to do for that analysis?</li> <li>A Correct.</li> <li>Q So the term that there's no direct correlation is not correct MR. ESSIG: Objection. BY MR. GOMEZ:</li> <li>Q unless the word is being used interchangeably with another word for relationship or association; is that fair?</li> <li>MR. ESSIG: Objection to the form. THE WITNESS: Fair. BY MR. GOMEZ:</li> <li>Q He goes on to write, "If possible, this would be the place to specifically mention or /discuss the lack of correlation between Tanner delay and prolactin level or SHAP. I believe that if we are unable to include this, it will hurt the overall inpact of the paper."</li> </ul>	<ul> <li>Page 125</li> <li>were concerned about the relationship between</li> <li>Risperdal's prolactin elevation and things like</li> <li>gynecomastia, be less likely to prescribe the drug if</li> <li>there was a direct correlation?</li> <li>MR. ESSIG: Same objections.</li> <li>THE WITNESS: Can I just have the final</li> <li>manuscript back for a second?</li> <li>BY MR. GOMEZ:</li> <li>Q Sure.</li> <li>Can you read my question back. And see if you</li> <li>can answer it.</li> <li>(The reporter read the record as requested.)</li> <li>MR. ESSIG: Same objections.</li> <li>BY MR. GOMEZ:</li> <li>Q Can you answer that?</li> <li>A So in the actual manuscript that's</li> <li>published, the last paragraphs are different from</li> <li>this. And they do warn about the deficiencies in the</li> <li>analysis in the long-term group with the control</li> <li>group</li> <li>Q Can you specifically point me where you're</li> <li>going to?</li> <li>A 1168, last paragraph on the right-hand</li> <li>column.</li> <li>Q Okay. Let me read that out loud.</li> </ul>

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	Page 126		Page 128
1	A In the second last, "The clinical	1	the record at 12:17 p.m.
2	implications of the novel findings of this study are	2	BY MR. GOMEZ:
3	many. First, clinicians can expect that, in the vast	3	Q Dr. Daneman, you just said that the
4	majority of children and adolescents exposed to	4	statement that there was no direct correlation between
5	long-term therapy with risperidone in these doses"	5	elevated prolactin levels and SHAP was inaccurate;
6	Q Slow down.	6	correct?
7	A "prolactin levels will be raised early	7	A Looking back from the vantage point we are
8	in the treatment course but will revert to levels	8	at now.
9	within normal limits, in some cases (INAUDIBLE)	9	Q Were you aware that Janssen in its
10	without change of dose. Furthermore, only a very	10	communications with the United States Food and Drug
11	small percentage of children and adolescents treated	11	Administration told them that and leading up to the
12	with risperidone in this fashion will develop SHAP	12	approval for the treatments
13	that require intervention."	13	A I'm not aware of that.
14	And at 7.8 and 2.9 percent, that's still a small	14	MR. ESSIG: Objection to the form.
15	percentage. So I don't think that the outcome says	15	BY MR. GOMEZ:
16	misleads in any way, shape, or form.	16	Q Let me rephrase the question. Were you
17 18	Q Stay on that page, Doctor. If you go up to the paragraph beginning, "Only 13 of 592."	17 18	aware that Janssen, in the communications with the FDA leading up to the approval to treat the symptoms of
18 19	A Yes.	18 19	irritability associated with autism, which was
20	Q The sentence reads, "No correlation was	20	eventually approved in 2006, that Janssen told the FDA
20	found between SHAP and prolactin levels even when male		in August and December of 2005 that there was no
22	gynecomastia during puberty was included." Do you see	22	direct correlation between elevated prolactin levels
23	that?	23	and SHAP?
24	A I do.	24	MR. ESSIG: Objection. Form and
25	Q And based on the drafts that we've looked	25	foundation. Assumes facts.
	Page 127		Page 129
1	at, that is a completely untrue statement; you would	1	THE WITNESS: I'm not aware of the
2	agree?	2	submission to the FDA.
3	MR. ESSIG: Objection to the form. THE WITNESS: That's not directly according	3	BY MR. GOMEZ:
4 5	to the interpretations of the statistics we've	4 5	Q If that statement relied on the same study, the same five studies that this article relies upon,
6	discussed.	5	The same rive shores marines arricle renes noon
0		6	
7		6 7	it's still inaccurate; you would agree?
7 8	MR. GOMEZ: Can you read that back, that	7	it's still inaccurate; you would agree? MR. ESSIG: Objection to the form.
8	MR. GOMEZ: Can you read that back, that answer?		it's still inaccurate; you would agree? MR. ESSIG: Objection to the form. THE WITNESS: It depends on the efficacy
	MR. GOMEZ: Can you read that back, that	7 8	it's still inaccurate; you would agree? MR. ESSIG: Objection to the form.
8 9	MR. GOMEZ: Can you read that back, that answer? (The reporter read the record as requested.)	7 8 9	it's still inaccurate; you would agree? MR. ESSIG: Objection to the form. THE WITNESS: It depends on the efficacy and side effect ratio that's present.
8 9 10	MR. GOMEZ: Can you read that back, that answer? (The reporter read the record as requested.) BY MR. GOMEZ: Q So you would agree with me that that sentence that I just read, "No correlation was found	7 8 9 10	it's still inaccurate; you would agree? MR. ESSIG: Objection to the form. THE WITNESS: It depends on the efficacy and side effect ratio that's present. BY MR. GOMEZ:
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8 9 10 11 12 13 14	MR. GOMEZ: Can you read that back, that answer? (The reporter read the record as requested.) BY MR. GOMEZ: Q So you would agree with me that that sentence that I just read, "No correlation was found between SHAP and prolactin levels even when male gynecomastia during puberty was included," is	7 8 9 10 11 12 13 14	it's still inaccurate; you would agree? MR. ESSIG: Objection to the form. THE WITNESS: It depends on the efficacy and side effect ratio that's present. BY MR. GOMEZ: Q Let me rephrase the question. The question is it's a hypothetical question. Assume for purposes of my hypothetical that the statement by Janssen to the FDA that there was no direct
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8 9 10 11 12 13 14 15 16	MR. GOMEZ: Can you read that back, that answer? (The reporter read the record as requested.) BY MR. GOMEZ: Q So you would agree with me that that sentence that I just read, "No correlation was found between SHAP and prolactin levels even when male gynecomastia during puberty was included," is incorrect? MR. ESSIG: Objection.	7 8 9 10 11 12 13 14 15 16	<ul> <li>it's still inaccurate; you would agree?</li> <li>MR. ESSIG: Objection to the form.</li> <li>THE WITNESS: It depends on the efficacy</li> <li>and side effect ratio that's present.</li> <li>BY MR. GOMEZ:</li> <li>Q Let me rephrase the question. The question</li> <li>is it's a hypothetical question. Assume for</li> <li>purposes of my hypothetical that the statement by</li> <li>Janssen to the FDA that there was no direct</li> <li>correlation between prolactin elevation and SHAP</li> <li>relied upon the same five studies that the 2003</li> </ul>
8 9 10 11 12 13 14 15 16 17	MR. GOMEZ: Can you read that back, that answer? (The reporter read the record as requested.) BY MR. GOMEZ: Q So you would agree with me that that sentence that I just read, "No correlation was found between SHAP and prolactin levels even when male gynecomastia during puberty was included," is incorrect? MR. ESSIG: Objection. THE WITNESS: Is inaccurate.	7 8 9 10 11 12 13 14 15 16 17	it's still inaccurate; you would agree? MR. ESSIG: Objection to the form. THE WITNESS: It depends on the efficacy and side effect ratio that's present. BY MR. GOMEZ: Q Let me rephrase the question. The question is it's a hypothetical question. Assume for purposes of my hypothetical that the statement by Janssen to the FDA that there was no direct correlation between prolactin elevation and SHAP relied upon the same five studies that the 2003 Findling article relied upon, it would still be an
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	Page 130		Page 132
1	(Whereupon, Exhibit No. 8 was marked for	1	agree?
2	identification.)	2	MR. ESSIG: Objection to the form.
3	BY MR. GOMEZ:	3	THE WITNESS: My suspicion is in many
4	Q I'll show that to you. Take a quick second	4	papers there are sentences that you would focus on.
5	and look at it.	5	BY MR. GOMEZ:
6	MR. ESSIG: Take as long as you need,	6	Q Sure. But we can agree that the purpose of
7	Doctor.	7	that paper is to educate the medical community about
8	MR. GOMEZ: Yes. I didn't mean that, Bill.	8	any association or any relationship between elevated
9	He can take as long as he wants.	9	prolactin levels and SHAP; agree?
10	MR. ESSIG: Okay.	10	A Agree.
11	THE WITNESS: Would you like me to comment	11	Q Okay. And we can also agree that the
12	on this?	12	statement that there was no direct correlation between
13	BY MR. GOMEZ:	13	elevated prolactin levels and SHAP is inaccurate;
14 15	Q A quick question, and then I'd love to hear	14 15	agree?
15 16	your comment. The Exhibit 8 that I just gave you is a, for lack of a better term, an abstract of the 2003	15 16	MR. ESSIG: Objection to form. Objection. Asked and answered.
17	article that we've been talking about today; correct?	17	THE WITNESS: I'd have to state what I said
18	A Correct.	18	before. It has a certain inaccuracy to it.
19	Q And the conclusion, again, is there was no	19	BY MR. GOMEZ:
20	direct correlation between prolactin elevations and	20	Q You agree that it's inaccurate?
21	SHAP; correct?	21	MR. ESSIG: Objection to the form.
22	A It's not the conclusion again. It's the	22	Objection. Asked and answered.
23	2003 publication. This is not an updated publication.	23	THE WITNESS: Yes.
24	It will never be updated. This is the way it will sit	24	BY MR. GOMEZ:
25	for the rest of time in memorium. It's done. It's	25	Q And this statement, "There's no direct
	Page 131		Page 133
1	finished.	1	correlation" on Exhibit 8 is from 2012; correct?
2	Q Do you feel an obligation as a pediatric	2	A It's going to be there forever.
3	endocrinologist and an author of this page to correct	3	Q Does the drug company whose studies were
4	the inaccurate statement	4	the impetus for this paper and where three or two to
5	MR. ESSIG: Objection to form.	5	three of the authors were company employees have an
6	MR. GOMEZ: I'm not done with my question.	6	obligation to correct it?
7	MR. ESSIG: Sorry.	7	MR. ESSIG: Objection to the form.
8	BY MR. GOMEZ:	8	THE WITNESS: So when something is
9 10	Q that there was no direct correlation between prolactin elevations and SHAP?	9 10	submitted to the FDA or Health Canada, there is a very
	1	10	careful analysis that's done by the in-house people that looks at a whole variety of different things,
		11	
11 12	A Sir, I felt an obligation all along to follow part of the literature in this area to see what	12	
12	follow part of the literature in this area to see what	12 13	looks at the source documents, looks at a huge number
	follow part of the literature in this area to see what would happen to it. And unless I've missed a huge	12 13 14	looks at the source documents, looks at a huge number of things, and turns down a huge variety of different
12 13	follow part of the literature in this area to see what	13	looks at the source documents, looks at a huge number
12 13 14	follow part of the literature in this area to see what would happen to it. And unless I've missed a huge amount, there's precious little that informs	13 14	looks at the source documents, looks at a huge number of things, and turns down a huge variety of different pharmaceutical agents.
12 13 14 15	follow part of the literature in this area to see what would happen to it. And unless I've missed a huge amount, there's precious little that informs physicians since 2003.	13 14 15	looks at the source documents, looks at a huge number of things, and turns down a huge variety of different pharmaceutical agents. They didn't turn this down. BY MR. GOMEZ: Q Right. But were you aware that, in
12 13 14 15 16 17 18	follow part of the literature in this area to see what would happen to it. And unless I've missed a huge amount, there's precious little that informs physicians since 2003. And any paper that appears in the literature is merely a snapshot in time. I'm sure many people would change a sentence or two or an interpretation going	13 14 15 16 17 18	looks at the source documents, looks at a huge number of things, and turns down a huge variety of different pharmaceutical agents. They didn't turn this down. BY MR. GOMEZ: Q Right. But were you aware that, in August in May of 2005, the FDA sent a non-approval
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	Page 134		Page 136
1	BY MR. GOMEZ:	1	Q I believe you responded in your response
2	Q Were you aware that, within that same	2	that you were not at liberty I'm paraphrasing, of
3	letter in May of 2005, the FDA specifically addressed	3	course. And correct me if I'm wrong.
4	or focused to Janssen their concerns with elevated	4	A I said
5	prolactin and long-term sequelae? Were you aware of	5	Q Why don't you read what you said.
6	that?	6	A "Since the issues you raised are currently
7	A No.	7	sub judice, I think the only prudent response to this
8	MR. ESSIG: Objection to the form and the	8	at this time is to thank you for your email and to
9	characterization of the letter.	9	promise to reflect further on your comments."
10	BY MR. GOMEZ:	10	Q My question is straightforward and simple.
11	Q Were you aware that Janssen in response	11	Do you have any comments now on what he wrote you?
12	stated that, based on the review of the same five	12	A I find this to be an unprofessional
13	studies that we talked about here today, stated there	13	behavior.
14	was no direct correlation between elevated prolactin	14	Q By Dr. Rosenbloom?
15	levels and SHAP?	15	A Absolutely and completely.
16	MR. ESSIG: Objection to form.	16	Q Okay.
17	THE WITNESS: I'm not aware of the format	17	A Unprofessional to the extent that I think
18	of the FDA submission.	18	perhaps he should be reported to his local medical
19	BY MR. GOMEZ:	19	association for tampering with a witness.
20	Q Sure. And we agree that the I asked you	20	Q Okay. Even if he had no knowledge that you
21	earlier the question or the statement to the FDA, if	21	were a witness?
22	based on the same five studies, is inaccurate;	22	A How would something arrive on a Monday
23	correct?	23	morning or Sunday night at 11:00 when I'm going to be
24	A That statement is inaccurate.	24	giving a deposition later the same week nine years
25	Q Let me mark as Exhibit 9 an email sent to	25	after its publication? Please help me.
	Page 135		Page 137
1	Page 135	1	
1	you from Dr. Arlan Rosenbloom.	1	Q Are you implying that I asked him to send
2	you from Dr. Arlan Rosenbloom. A Thank you.	2	Q Are you implying that I asked him to send that to you?
2 3	you from Dr. Arlan Rosenbloom. A Thank you. (Whereupon, Exhibit No. 9 was marked for	2 3	Q Are you implying that I asked him to send that to you? A I'm implying that he must have had
2 3 4	you from Dr. Arlan Rosenbloom. A Thank you. (Whereupon, Exhibit No. 9 was marked for identification.)	2 3 4	Q Are you implying that I asked him to send that to you? A I'm implying that he must have had information that I'm not implying that you asked
2 3 4 5	you from Dr. Arlan Rosenbloom. A Thank you. (Whereupon, Exhibit No. 9 was marked for identification.) MR. ESSIG: Do you have an extra copy?	2 3 4 5	Q Are you implying that I asked him to send that to you? A I'm implying that he must have had information that I'm not implying that you asked him to send it to me, but I'm implying that he must
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13       correlation between SHAP and prolactin levels.         14       Q       Is there anything else?         15       A       He does believe that there's a strong         16       correlation between gynecomastia and risperidone.         17       Q       Do you disagree with that?         18       A       I think, at most, there's a weak         19       correlation or association.         20       Q       But association or correlation nonetheless;         21       correct?         22       A       But it's quite weak. It's put in the         23       balance of efficacy versus side effects.         24       Q       When you say "efficacy," efficacy in         25       treating the issues that are being treated         2       With the risperidone, which is not the side effects.         3       It's the indications for its use.         4       Q       What if risperidone is being prescribed for         5       sleep? Does the benefits outweigh the risks?         6       MR. ESSIG: Objection. Form and         7       foundation.         8       THE WITNESS: I have no comments on that         9       use.         10       BY MR. GOMEZ:         11	2 3 4	Page 138		Page 14
2       nothing, nothing, some breast development, nothing,       in Comparison       in Comparison         3       nothing, nothing, some breast development, nothing,       in Comparison       in Comparison         3       nothing, nothing, some breast development, nothing,       in Comparison       in Comparison         3       nothing, nothing, some breast development, nothing,       in Comparison       in Comparison         4       The mean height and weight there was a long       in Comparison       in Comparison         5       discussion about standard deviation scores. And this       in Comparison       in Comparison         6       and the data the further data do not answer       in Comparison       in Comparison       in Comparison         9       And the data the further data do not answer       in Comparison       process from 12:31 p.m.       in Camparison         11       Q       Answer what question?       in Comparison       process from 12:31 p.m.       in Camparison         12       A       The question on cassocation?       Q       Good afternoon, Dr. Daneman. My name is       in Bill Essign. Terpresent the lanssen defendants. And         11       Q       Do you disagree with that?       in the rocess by which the manuscript was preparison of the things is what do the could is welve bace       in the process by which the manuscript was preparison	2 3 4	visit and not on the next So if you have nothing	1	regroup and sit over here.
3       nothing, nothing, that was what we wanted to exclude.       3       VIDEOGRAPHER: Going off the record at         4       The mean height and weight, there was a long       3       VIDEOGRAPHER: Going off the record at         4       12:31 p.m.       12:31 p.m. to 12:41 p.m.)         6       was not relevant to the discussion we had to date in       12:41 p.m.)         7       large part. And the third is what we have discussed.         8       And there are data looking at the long-term outcome.       9         9       And the data the further data do not answer       10         10       Q. Answer what question?       12         11       Q. Answer what question?       11         12       A. The question of the relationship or       13         13       correlation between SHAP and prolactin levels.       14         14       Q. Is there anything else?       14         15       A. He does believe that there's a strong       16         16       correlation or association.       20         20       Q. But association or correlation nonetheless;       21         21       Q. But association or correlation nonetheless;       22         22       A. But it's quite weak. It's put in the       23         23       balance of effi	3 4			
4The mean height and weight, there was a long discussion about standard deviation scores. And this over relevant to the discussion we had to date in 7 large part. And the third is what we have discussed. 8 And there are data looking at the long-term outcome. 9 And the data - the further data do not answer 10 the question once and for all.412:31 p.m.12:31 p.m.12:3	4			
5       discussion about standard deviation scores. And this       5       (Recess from 12:31 p.m. to 12:41 p.m.)         6       was not relevant to the discussion we had to date in       6       VIDEOGRAPHER: Going back on the record         7       large part. And the third is what we have discussed.       8       And there are data looking at the long-term outcome.       8         8       And the data - the further data do not answer       10       9       BY MR. ESSIG:         10       Q Good afternoon, Dr. Daneman. My name is       11       Bill Essig. I represent the Janssen defendants. And         12       A. The question of the relationship or       12       I was going to ask you some of the things I wanted to talk about with you was         13       Correlation between gynecomastia and risperidone.       17       Q Do you disagree with that?         14       Q Do you disagree with that?       16       that led to the 2003 Findling article, as we've been         16       Do you disagree with that?       18       lot today. Okay?         17       Q Do you disagree with that?       18       lot today. Okay?         18       at think, at most, there's a weak       12       reviewing data from five of the studies of Risperdal         23       balance of efficacy versus side effects.       20       Q Okay. And we saw earlier that Carin Binder				
6       was not relevant to the discussion we had to date in       6       VIDEOGRAPHER: Going back on the record         7       large part. And the third is what we have discussed.       7       12:41 p.m.         8       And there are data looking at the long-term outcome.       9       BY MR. ESSIG:         9       And the data the further data do not answer       10       Code afternoon, Dr. Daneman. My name is         10       Q Answer what question?       11       BI Essig. I represent the Janssen defendants. And         12       A The question of the relationship or       12       was going to ask you some follow-up questions here         13       Correlation between SHAP and prolactin levels.       14       Q Is there anything else?       15         15       A He does believe that there's a strong       6       of the things I wanted to talk about with you was         16       correlation between gynecomastia and risperidone.       17       colday. Okay?         16       correlation or association or correlation nonetheless;       10       A Yes.         20       Q But association or correlation nonetheless;       10       A Yes.         21       A Treating the issues that are being treated       10       Matter with disruptive behavior disorder.         23       But it's quite weak. It's put in the       23				•
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18 all. I've never written a prescription for 18 THE WITNESS: Okay.	5 6 7 8 9 10 11 12 13 14 15 16	MR. ESSIG: Objection. Form and foundation. THE WITNESS: I have no comments on that use. BY MR. GOMEZ: Q What about autistic children? A I'm not going to comment on that either. Q But you just commented upon the efficacy versus the risks. Why won't you comment upon it when questioned with certain diagnoses? A Well, there are certain written indications	7 8 9 10 11 12 13 14 15 16	A Correct. Q Okay. And that occurred in the fall of 2001; is that right? A The timing of it, I can't give you, but I think you get that from the email trail. Q Okay. I'd like to hand you what we've marked as Exhibit 10 to your deposition. If you can take a minute to look at that, and when you'd ready to answer a question, let me know. (Whereupon, Exhibit No. 10 was marked for
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	Page 142		Page 144
1	on the "To" line and the "cc:" line?	1	spent in this meeting with these other physicians
2	A I do.	2	A Correct.
3	Q Okay. And you were not a recipient of this	3	Q to discuss the data regarding prolactin
4	email, were you?	4	from Janssen studies?
5	A Correct.	5	MR. GOMEZ: Objection to form.
6	Q And the subject here is prolactin expert	6	THE WITNESS: Yes. I can't exactly say the
7	meeting. And would it be fair to say that Exhibit 10,	7	length of it. I wouldn't put a limit to it.
8	this email, is essentially a report by Carin Binder	8	BY MR. ESSIG:
9	about what happened at the meeting about the prolactin	9	Q Okay. And do you have an independent
10	data that was held in Toronto on January 22, 2002?	10	recollection of participating in the meeting?
11 12	A Correct. Q Okay. So this was an internal summary of	11 12	A You mean of being there? Q Yes.
12	Q Okay. So this was an internal summary of what happened at the meeting; is that your	12	Q Yes. A Yes.
13	understanding?	13 14	Q And tell us what was discussed at the
15	A Yes.	15	meeting in general, to the extent that you can recall?
16	Q Okay.	16	MR. GOMEZ: Objection to form. You can
17	MR. GOMEZ: Objection. Form.	17	answer.
18	BY MR. ESSIG:	18	THE WITNESS: I think the one thing that I
19	Q And she writes, "A quick update on the	19	remember the most is that Tom Moshang and I had to
20	prolactin expert meeting held in Toronto January 22,	20	make sure that we were on the same wavelength in terms
21	2002. Attendees included two ped endos, T. Moshang	21	of thinking through different things because there was
22	and D. Daneman, and two psychs, B. Findling and V.	22	some girls in whom a breast development was reported
23	Kusumaker."	23	at one point in time and not the visit before or the
24	First of all, Doctor, do you remember attending	24	visit after.
25	a meeting here in the Toronto area in January of 2002	25	And that couldn't be looked at as a side effect
	Page 143		Page 145
1	with other physicians to discuss the prolactin data	1	because this sometimes happens with this intermittent
2	that ultimately was discussed in the Findling article?	2	type of puberty that occurs in some girls. And it was
3	A I do.	3	very difficult to evaluate what gynecomastia meant in
4	Q And in addition to the doctors listed	4	pubertal boys because of the background frequency of
5	well, first of all, do you remember these doctors	5	pubertal gynecomastia.
6	being present at the meeting?	6	And the discussion was that I think we both felt
7	A I remember Tom Moshang because I've known	/	that the levels weren't within our level of experience
8 9	of him for a long time, and this is the first time we've actually had opportunity to spend time together.	8 9	to be associated with gynecomastia. BY MR. ESSIG:
10	And I know Kusumaker was there, and there were other		Q And although you've just said this was the
11	people on the phone.	11	first time you met Dr. Moshang in person, would it be
12	I can't remember Bob Findling being there in	12	fair to say were you familiar with his writing and his
13	person.	13	stature in the pediatric endocrinology community?
14	Q But he was a participant in the meeting	14	A Absolutely.
15		15	Q And Dr. Moshang was a well respected
110	whether on the phone or in person?	15	
16	A Yes.	16	endocrinologist?
17	<ul><li>A Yes.</li><li>Q And there were other people present at the</li></ul>	16 17	endocrinologist? A Absolutely.
17 18	A Yes. Q And there were other people present at the meeting, presumably Carin Binder, because she wrote	16 17 18	endocrinologist? A Absolutely. MR. GOMEZ: Objection to form.
17 18 19	A Yes. Q And there were other people present at the meeting, presumably Carin Binder, because she wrote this summary?	16 17 18 19	endocrinologist? A Absolutely. MR. GOMEZ: Objection to form. BY MR. ESSIG:
17 18 19 20	<ul><li>A Yes.</li><li>Q And there were other people present at the meeting, presumably Carin Binder, because she wrote this summary?</li><li>A Yes.</li></ul>	16 17 18 19 20	endocrinologist? A Absolutely. MR. GOMEZ: Objection to form. BY MR. ESSIG: Q And having reviewed the email here, is
17 18 19 20 21	<ul> <li>A Yes.</li> <li>Q And there were other people present at the meeting, presumably Carin Binder, because she wrote this summary?</li> <li>A Yes.</li> <li>Q Do you recall roughly how long this meeting</li> </ul>	16 17 18 19 20 21	endocrinologist? A Absolutely. MR. GOMEZ: Objection to form. BY MR. ESSIG: Q And having reviewed the email here, is Karen Binder's summary of the meeting, at least as far
17 18 19 20 21 22	<ul> <li>A Yes.</li> <li>Q And there were other people present at the meeting, presumably Carin Binder, because she wrote this summary?</li> <li>A Yes.</li> <li>Q Do you recall roughly how long this meeting took place how long the meeting lasted, rather?</li> </ul>	16 17 18 19 20 21 22	endocrinologist? A Absolutely. MR. GOMEZ: Objection to form. BY MR. ESSIG: Q And having reviewed the email here, is Karen Binder's summary of the meeting, at least as far as what's in the email, accurate as far as you recall?
17 18 19 20 21 22 23	<ul> <li>A Yes.</li> <li>Q And there were other people present at the meeting, presumably Carin Binder, because she wrote this summary?</li> <li>A Yes.</li> <li>Q Do you recall roughly how long this meeting took place how long the meeting lasted, rather?</li> <li>A It started about 8:30 or 9:00 in the</li> </ul>	16 17 18 19 20 21 22 23	endocrinologist? A Absolutely. MR. GOMEZ: Objection to form. BY MR. ESSIG: Q And having reviewed the email here, is Karen Binder's summary of the meeting, at least as far as what's in the email, accurate as far as you recall? MR. GOMEZ: Objection.
17 18 19 20 21 22	<ul> <li>A Yes.</li> <li>Q And there were other people present at the meeting, presumably Carin Binder, because she wrote this summary?</li> <li>A Yes.</li> <li>Q Do you recall roughly how long this meeting took place how long the meeting lasted, rather?</li> </ul>	16 17 18 19 20 21 22	endocrinologist? A Absolutely. MR. GOMEZ: Objection to form. BY MR. ESSIG: Q And having reviewed the email here, is Karen Binder's summary of the meeting, at least as far as what's in the email, accurate as far as you recall?

	Page 146		Page 148
1		1	-
1 2	myself, my sort of notes to self, that No. 1. BY MR. ESSIG:	2	have an email message from Carin Binder, dated January 30, 2002; do you see that?
$\frac{2}{3}$	Q That was Exhibit No. 1. That's right. I'm	3	A I do the lower one, yes.
4	sorry. And turning back to the email here and the	4	Q Yes. And in the "To" line, there's a list
5	action items. Do you see that about two thirds of the	5	of several email addresses, and it includes your
6	way down the page?	6	address there; do you see that?
7	A I knew nothing about Brain Works being	7	A I do.
8	hired to write the manuscript.	8	Q That's your email address?
9	Q Well, let me ask you a question first. I	9	A It is.
10	just wanted to make sure you were here. Did you get	10	Q And we have other email addresses here for
11	to action items?	11	others involved in the manuscript, including the other
12	A Yes.	12	authors such as Dr. Moshang, Dr. Findling, Dr.
13	Q So let me read what she wrote here. "The	13	Kusumaker; do you see that?
14	additional analysis plan has been written up and sent	14	A I do.
15	to all participants for review. Brain Works has been	15	Q And the subject here is "Prolactin
16	hired to write the manuscript on the results and write	16	Analysis." Is that right?
17	an abstract and poster for ACAP in October."	17	A Correct.
18	"Authors will include Moshang, Daneman,	18	Q And Carin Binder writes, "Dear All, thank
19	Findling, Kusumaker. To discuss inclusion of Janssen	19	you to the people who gave input into the analysis
20	people as authors." Did I read that accurately?	20	plan. Attached please find the final plan. Miklos
21	A Yes.	21	and Ann, may I ask you to please proceed with the next
22	Q Are you familiar with Brain Works?	22	analysis and contact me if you have any questions."
23	A No.	23	"We are looking to submit an abstract by
24	Q And at the end of the meeting, I take it	24	February 15, 2002, and would appreciate if we could
25	there was a decision among the group that it would be	25	obtain some preliminary data, please." Do you see
	Page 147		Page 149
1	worthwhile to disseminate this data to other	1	that, Doctor?
2	physicians?	2	A I do.
3	A Correct.	_	
5		3	
		3 4	Q Do you remember getting this email at all?
4 5	Q And the formats that were discussed were		
4		4	<ul><li>Q Do you remember getting this email at all?</li><li>A I remember the emails going back and forth.</li></ul>
4 5	Q And the formats that were discussed were doing an abstract and poster for one of the child and	4 5	<ul><li>Q Do you remember getting this email at all?</li><li>A I remember the emails going back and forth.</li><li>The specificity, no. But getting emails, yes.</li></ul>
4 5 6	Q And the formats that were discussed were doing an abstract and poster for one of the child and adolescent psychiatry meetings; is that fair to say?	4 5 6	<ul><li>Q Do you remember getting this email at all?</li><li>A I remember the emails going back and forth.</li><li>The specificity, no. But getting emails, yes.</li><li>Q But this is part of the process in which</li></ul>
4 5 6 7 8 9	<ul> <li>Q And the formats that were discussed were doing an abstract and poster for one of the child and adolescent psychiatry meetings; is that fair to say?</li> <li>A Yes, because that is what actually was done.</li> <li>Q Okay. And the other mode of disseminating</li> </ul>	4 5 6 7 8 9	<ul> <li>Q Do you remember getting this email at all?</li> <li>A I remember the emails going back and forth.</li> <li>The specificity, no. But getting emails, yes.</li> <li>Q But this is part of the process in which</li> <li>you and the other coauthors communicated about the</li> <li>data plan and the analysis that you were performing?</li> <li>A Correct.</li> </ul>
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	D 170		D 172
	Page 150		Page 152
1	statisticians, Miklos Schulz and his associates, would	1	Q And we've talked today about some issues
2	pool from the Janssen clinical trial databases and how	2	with some of the statistical tables in the article
3	you would analyze that data; is that fair to say?	3	that in 2012 you might you might have expressed
4	A Correct.	4	differently; is that fair to say?
5	Q And the results of that analysis ultimately	5	A Correct.
6	became part of the manuscript that you and the	6	Q And aside from some of those issues that
7	coauthors prepared; is that right?	7	have been talked about earlier, do you still, as you
8	A Yes.	8	sit here today, stand behind the conclusions of the
9	MR. GOMEZ: Objection to form.	9	Findling article?
10	BY MR. ESSIG:	10	MR. GOMEZ: Objection to form.
11	Q Okay. All right. Doctor, because you were	11	THE WITNESS: So in the nine years since
12	involved in the data analysis that we've just talked	12	the publication of that article, there's not been a
13	about today, ultimately you agreed to be an author of	13	lot of information in the literature. If something is
14	what we are calling the Findling article; is that	14	going to come up as a serious complication, you would
15		14	
15 16	right? A Correct.		expect there to be a literature that develops because
		16	no one article changes the face of medicine
17	Q And as a coauthor of this article, do these	17	indefinitely.
18	conclusions in the Findling article reflect your	18	It's, if you will, held as fact or implication
19	independent clinical judgment as a pediatric	19	of fact for only as long as until the next article
20	endocrinologist?	20	that's more definitive. And I have seen precious
21	MR. GOMEZ: Objection to form.	21	little in the way of articles that have come out on
22	THE WITNESS: Yes.	22	this topic.
23	BY MR. ESSIG:	23	BY MR. ESSIG:
24	Q And I'm sorry. I'm done with that exhibit,	24	Q Doctor, I'd like to hand you what we've
25	if you want to put it aside.	25	marked as Exhibit 12 to your deposition. It's an
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	Dogo 151		Page 152
	Page 151	_	Page 153
1	A Okay.	1	article from 2007 from the Journal of Biological
2	<ul><li>A Okay.</li><li>Q Doctor, did anyone at Janssen, any</li></ul>	2	article from 2007 from the Journal of Biological Psychiatry, authored by Dr. George Anderson and
2 3	A Okay. Q Doctor, did anyone at Janssen, any personnel, whether a coauthor of the article or	2 3	article from 2007 from the Journal of Biological Psychiatry, authored by Dr. George Anderson and others.
2 3 4	A Okay. Q Doctor, did anyone at Janssen, any personnel, whether a coauthor of the article or otherwise, ever ask you to make changes to the article	2 3 4	article from 2007 from the Journal of Biological Psychiatry, authored by Dr. George Anderson and others. The title is "Effect of Short- and Long-term
2 3 4 5	A Okay. Q Doctor, did anyone at Janssen, any personnel, whether a coauthor of the article or otherwise, ever ask you to make changes to the article that you did not agree with?	2 3 4 5	article from 2007 from the Journal of Biological Psychiatry, authored by Dr. George Anderson and others. The title is "Effect of Short- and Long-term Risperidone Treatment on Prolactin Levels in Children
2 3 4 5 6	A Okay. Q Doctor, did anyone at Janssen, any personnel, whether a coauthor of the article or otherwise, ever ask you to make changes to the article that you did not agree with? A No.	2 3 4 5 6	article from 2007 from the Journal of Biological Psychiatry, authored by Dr. George Anderson and others. The title is "Effect of Short- and Long-term Risperidone Treatment on Prolactin Levels in Children with Autism."
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1       A I'm not familiar with RUP, but I know this         2       Was a multi-center study.         3       Q Okay. And the RUP group and this study is         4       Schibit 13 is?         4       Schibit 13 is?         5       Mental Health in the U.S., not by Janssen; is that         6       your understanding?         7       A Thar's my understanding?         8       Q. And of the group of patients here, as they note in the method section, 30 of them actually were followed up after 22 months of Risperdal and also assessed the patients a fact, and menstrual problems. Did you see that, Doctor?         12       A Merca are you? Procedures? Yes, yes.         13       Q And the atudors worde at the top of page 547?         14       A Time, and hand also assessed the patients in all subjects at all times, although it is possible that a drug-induced weight gain may have masked or of ogneomastin "         14       A dode shis mean that the RUP study, as a of a facilex-on study from the cartier analysis was a sociated with the two to from the antiocent and spreacemastia"         13       Q And does this mean that the RUP study, as a section and prolection in ofram.         14       Fuge 157         15       A Correct.         16       Q And hear torrectly, Doctor?         27       M Ka Loberton anticle, found no cases of of gyneomastin thesolatidentice.         1		Page 154		Page 156
2       BY MR, ESSIG:         3       Q. Okay, And the RUP group and this study is         4       something that was funded by the National Institute of         5       Mental Health in the U.S., not by Janssen, is that         6       your understanding.         7       A. Tha's my understanding.         8       Q. And of the group of patients here, as they         9       note in the method section, 30 of them actually were         10       followed up after 22 mouths of Risperdal use; do you         12       A. Mere are you? Procedures? Yes, yes.         13       Q. And the study measured prolactin in these         14       patients on Risperdal and also assessed the patients         15       for side effects such as gynecomastia.         16       and menstrual problems. Did you see that, Doctor?         17       Q. And the authors wrote at the top of         19       Q. Vay. And the authors wrote at the top of         11       and meynetices at all time, simoshibel         11       and meynetices at all time, simoshibel         11       and were heard a liftle bit about this         23       obscured gynecomastia."         11       and menstrual problems. Didyous as the study.         24       bid I read that cornectly.	1	A I'm not familiar with RUP but I know this	1	identification.)
3         Q         Dr. Daneman, can you tell us what           4         something that was funded by the National Institute of         Fishibit 13 is?           5         Mental Health in the U.S., not by Jansen; is that         Fishibit 13 is?           7         A That's my understanding.         Fishibit 13 is?           9         A The method sector, 30 of them actually were         Fishibit 13 is?           10         Re that, Doctor?         Fishibit 13 is?           11         A The method sector mote         The malysis was done by           12         A Where are you? Procedures? Yes, yes.         Fishibit 13 is?           13         a dift and so assessed the patients         Fishibit 13 is?           14         accurate?         The analysis and also assessed the patients           15         ror side effects such as gynecomasti.         The analysis			2	· · · · · · · · · · · · · · · · · · ·
4         something that was funded by the National Institute of Mental Health in the U.S., not by Janssen; is that oyour understanding?         F         A. This an assessment of the pooled databases with respect to growth and sexual maturation and the evidence that was available. The analysis was done by Mike Schulz on these databases. And I was involved in looking at the data that he had.           7         A. That's my understanding?         S. A. Mad of the group of patients here, as they note in the method section, 30 of them actually were for followed up after 22 months of Risperdal use; do you is ee that, Doctor?         So this is a copy of an article from the 1. A merican Journal of Psychiatry published in May of 12 OA and the study measured prolectin in these for side effects such as gynecomastia, glalcorthea, 16 and menstrual problems. Did you see that, Doctor, on 17 page 547. These adverse effects were rated as abasel 11 and subjects at all times, although it is possible that a drug-induced weight gain may have masked or 30 obscured gynecomastia."         16 A Tiele 19 A Yes. 20 Q And then Dr. Kusunaker and Fiona Dunbar 19 A Yes. 20 Q And we've heard a little bit about this 31 douby throw duid it be fair to say that this was 32 a ort of a follow-on study from the earlier analysis 32 of gynecomastia."           1         Q And does this mean that the RUP study, as 32 of gynecomastia."         10 of the data that had been done as part of the effort 33 obscured gynecomastia?           2         A Correct. 34 A Correct. 35 of gynecomastia."         20 Mat does this mean that the RUP study, as 32 ort of a follow-on study from the carlier analysis 33 a ort of a follow-on study from the carlier analysis 34 ort of a lobue, the find that and been done as part of the effort 35 there, Bortor. 36 Wint is che lini				
5       Mental Health in the U.S., not by Janssen; is that your understanding?       5       A It's an assessment of the pooled databases         6       with respect to growth and sexual maturation and the veidence that was available. The analysis was done by         8       Q And of the group of patients here, as they note in the method section, 30 of them actually were       6         10       followed up after 22 months of Risperdal use; do you       10         11       and mestrual problems. Did you see that, Doctor?       2004 with the title of "Growth and Sexual Maturation         12       A Where are you? Procedures? Yes, yes.       10       And the study measure prolocitin in these at a finases. Did you see that, Doctor, or an enstrual problems. Did you see that, Doctor, or a page 547?. "These adverse effects were rated as absented of the approximation in these at a finases, it shat right?       10       10       10       10       10       11			4	
7       A That's my understanding.       7       evidence that was available.         9       note in the method section, 30 of them actually were       9       Miklos Schulz on these databases. And I was involved         9       note in the method section, 30 of them actually were       9       Miklos Schulz on these databases. And I was involved         10       followed up after 22 months of Risperdal use, do you       10       Q So this is a copy of an article from the         11       A Where are you? Procedures? Yes, yes.       11       11       12       2004 with the title of "Growth and Sexual Maturation         12       and menstrual problems. Did you see that, Doctor,       12       2004 with the title of "Growth and Sexual Maturation         13       Darge 547, "These adverse effects were rated top of       16       Q And then Dr. Kusumaker and Fiona Dumbar         16       and menstrual problems. Did you see that, Doctor?       17       9       A Yeu.         21       for head at that had been done as part of the effort       18       right?         22       A You did.       10       Fuge 157         14       a Correct.       10       O And the authors on artice, found no cases         3       of gynecomastia."       11       of the data that had been done as part of the effort         2       M Correct.	5		5	A It's an assessment of the pooled databases
8       Q. And of the group of patients here, as they       9       note in the method section, 30 of them actually were       8       Miklos Schulz on these databases. And I was involved         9       note in the method section, 30 of them actually were       10       Q. So this is a copy of an article from the         11       see that, Doctor?       12       20 Where are you? Procedures? Yes, yes,       12       2004 with the title of "Growth and Sexual Maturation         12       nad menstrual problems. Did you see that, Doctor, on       16       A Correct.       12       20 And the authors wrote at the top of         19       Q. Okay. And the authors wrote at the top of       10       Q. And the authors wrote at the top of       10       Q. And the authors wrote at the top of         10       page 547?       10       Q. And the authors wrote at the top of       10       Q. And the authors on this article are       17       17       Nurself, Miklos Schulz, the statistician; is that         11       in all subjects at all times, although it is possible       11       18       right?       12       14       A Correct.         12       Q. And does this mean that the RUP study, as       12       14       Correct.       14       14       Correct.       14       14       15       14       14       Correct.       14       14	6	your understanding?	6	with respect to growth and sexual maturation and the
9       note`in the method section, 30 of them actually were 10       9       in looking at the data that he had. 0       9       in looking at the data that he had. 0       9       in looking at the data that he had. 10       10 <td>7</td> <td>A That's my understanding.</td> <td>7</td> <td></td>	7	A That's my understanding.	7	
10       followed up after 22 months of Risperdal use; do you       10       Q       So this is a copy of an article from the         11       see that, Doctor?       11       A       Where are you? Procedures? Yes, yes.       12       2004 with the title of "Growth and Sexual Maturation         13       Q       And the study measured prolactin in these       13       During Long-Term Treatment with Risperidone." Is that         14       accurate?       16       and menstrual problems. Did you see that, Doctor, on       17         16       and menstrual problems. Did you see that, Doctor, on       18       A T did.       18       right?         19       Q       Okay. And the authors wrote at the top of       19       A Yes.       20       Q       And then Dr. Kusumaker and Fiona Dunbar       21       from Janssen; is that right?         20       Doscured gynecomastia."       23       Q       And we're heard a little bit about this       23       a sort of a follow-on study from the earlier analysis         21       Page 157       1       Q       And does this mean that the RUP study, as       reported here in the Anderson article, found no cases       of the data that had been done as part of the effort         2       Page 157       1       O the data that had been done as part of the effort       that deto the Findling article?       10			8	
11       see that, Doctor?         12       A Where are you? Procedures? Yes, yes.         13       Q And the study measured prolactin in these         14       patients on Risperdal and also assessed the patients         15       for side effects such as gynecomastia, galactorrhea,         16       and menstrual problems. Did you see that, Doctor, on         17       page 547?         18       A I did.         19       Q Okay. And the authors wrote at the top of         20       page 547, "These adverse effects were rated as absent         11       and menstrual problems. Did you see that, Doctor, of         20       O And, the authors wrote at the top of         20       obscured gynecomastia."         21       that a drug-induced weight gain may have masked or         22       A Correct.         23       A You did.         24       Treported here in the Anderson article, found no cases         25       A You did.         25       A You did.         26       Page 157         1       Q And does this mean that the RUP study, as         2       reported here in the Anderson article, found no cases         3       of gynecomastia in these subjects?         4       A Correct.				-
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15for side effects such as gynecomastia, galactorrhea, and menstrual problems. Did you see that, Doctor, on page 547;15A Correct.18A I did.16Q And the authors on this article are yourself, Miklos Schulz, the statistician; is that right?19Q Okay. And the authors wrote at the top of page 547, "These adverse effects were rated as absent 21 that a drug-induced weight gain may have masked or 23 obseured gynecomastia."17N Correct.24Did I read that correctly, Doctor?23Q And then Dr. Kusumaker and Fiona Dunbar 2125A You did.23Q And we've heard a little bit about this 2426You did.23Q And we've heard a little bit about this 2427Page 15724N Correct.28reported here in the Anderson article, found no cases of gynecomastia in these subjects?13of gynecomastia in these subjects?14A Correct.35Q What is the clinical significance to you, a md this article in light of your cartier article on the Janssen data on prolactin and gynecomastia?19MR. GOMEZ: Objection to form.611BY MR, ESSIG:112Q Identical in what way, Doctor?1413A Well, it reaches the conclusions that the although these increases (INAUDIBLE)1014Risperdal treatment was associated with the two to four-fold mean increase in the (INAUDIBLE) with autism a titole.1714Risperdal treatment was associated with the two to four-fold mean increase in the (INAUDIBLE)				
16       and menstrual problems. Did you see that, Doctor, on       16       Q. And the authors on this article are         17       page 547?       yourself, Miklos Schulz, the statistician; is that         18       A. I did.       18         19       Q. Okay. And the authors wrote at the top of       19       A. Yes.         20       page 547, "These adverse effects were rated as absent       20       Q. And then Dr. Kusumaker and Fiona Dunbar         21       from Janssen; is that right?       2       A. Correct.         23       Obscured gynecomastia."       20       Q. And we've heard a little bit about this         24       Did I read that correctly, Doctor?       24       A Correct.       23         24       Did I read that correctly, Doctor?       24       a sort of a follow-on study from the earlier analysis         25       A. You did.       Page 157       1       of the data that had been done as part of the effort         25       of gynecomastia in these subjects?       3       MR. GOMEZ: Objection to form.         4       A. Correct.       4       THE WITNESS: This is the growth data on         5       Q. What is the clinical significance to you,       5       that had sorout had available.         6       Doctor, as a pediatric endocrinologist, of this study       6				
17       page 547?       17       yourself, Miklos Schulz, the statistician; is that         18       A I did.       18       right?         19       Q Okay. And the authors wrote at the top of       20       page 547, "These adverse effects were rated as absent       18       right?         20       page 547, "These adverse effects were rated as absent       20       Q And then Dr. Kusumaker and Fiona Dunbar         21       in all subjects at all times, although it is possible       20       Q And then Dr. Kusumaker and Fiona Dunbar         23       obscured gynecomastia."       20       Q And we've heard a little bit about this         24       Did I read that correctly, Doctor?       23       Q And we've heard a little bit about this         25       A You did.       26       a sort of a follow-on study from the earlier analysis         25       a You did.       26       of the data that had been done as part of the effort         2       reported here in the Anderson article, found no cases       3       of gynecomastia in these subjects?       3         3       A Correct.       3       MR. GOMEZ: Objection to form.       4       THE WITNESS: This is the growth data on         5       Q What is the clinical significance to you,       6       BY MR. ESSIG:       7       Q From the five studies that were discussed <td></td> <td></td> <td></td> <td></td>				
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19       Q       Okay. And the authors wrote at the top of       19       A       Yes.         20       page 547, "These adverse effects were rated as absert       20       Q       And then Dr. Kusumaker and Fiona Dunbar         21       in all subjects at all times, although it is possible       20       Q       And then Dr. Kusumaker and Fiona Dunbar         23       obscured gynecomastia."       20       A       Correct.         23       Q       And we're heard a little bit about this       was         24       Did I read that correctly, Doctor?       23       Q       And we're heard a little bit about this       was         25       A       You did.       23       of the data that had been done as part of the earlier analysis         7       Q       And does this mean that the RUP study, as       1       of the data that had been done as part of the effort         2       reported here in the Anderson article, found no cases       of gynecomastia in these subjects?       3       MR. GOMEZ: Objection to form.         4       A       Correct.       3       MR. GOMEZ: Objection to form.       6         9       MR. GOMEZ: Objection to form.       7       Q       From the five studies that were discussed         18       and this article about the actific; right?       9				
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5QWhat is the clinical significance to you, and this article in light of your earlier article on and this article in light of your earlier article on the Janssen data on prolactin and gynecomastia?5those that had growth data available.7and this article in light of your earlier article on the Janssen data on prolactin and gynecomastia?7QFrom the five studies that were discussed in the earlier article; right?9MR. GOMEZ: Objection to form. THE WITNESS: It's almost identical.9ACorrect.10THE WITNESS: It's almost identical.10QOkay. And Doctor, what was your conclusion11BY MR. ESSIG:11in this article about the effects of long-term12QIdentical in what way, Doctor?12treatment of Risperdal on growth and sexual13AWell, it reaches the conclusions that four-fold mean increase in the (INAUDIBLE) with autism although these increases (INAUDIBLE.)14A16although these increases (INAUDIBLE.)16be normal.17QSo17QAnd on the second page at the end of this article, Doctor, there's a listing here about the fact19question. Certainly it suggests a low order of side effects.20part in San Francisco in October of 2002 at the 2021QI just have a few more cleanup questions you what we've marked as Exhibit 13 to your23Do you see that, Doctor?24AI do.24AI do.	3	of gynecomastia in these subjects?	3	
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25 (Whereupon, Exhibit No. 13 was marked for 25 Q Do you know if you were involved in that	15 16 17 18 19 20 21 22 23	four-fold mean increase in the (INAUDIBLE) with autism although these increases (INAUDIBLE.) Q So A It doesn't answer definitively the question. Certainly it suggests a low order of side effects. Q I just have a few more cleanup questions here, Doctor. All right. Doctor, I'd like to hand you what we've marked as Exhibit 13 to your	15 16 17 18 19 20 21 22 23	risperidone, growth and sexual development appear to be normal. Q And on the second page at the end of this article, Doctor, there's a listing here about the fact that this article had been presented as a poster in part in San Francisco in October of 2002 at the meeting of the American Academy of Child and Adolescent Psychiatry. Do you see that, Doctor?
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15       same paragraph on the article, Doctor, that it notes         16       that this manuscript was received at the American         17       Journal of Psychiatry April 2, 2003. Revisions         18       received September 16th and October 28th, 2003.         19       And the article was accepted October 31, 2003.         20       Q And Doctor, does that reflect to you that         21       A You did.         22       Q And Doctor, does that reflect to you that         23       there was an exchange with the peer reviewers and with         24       the journal regarding edits to this article and that         25       ultimately, after that editorial process, the journal         26       A So what would have happened is reviewed –         3       sent in April 2, reviewed and sent back to us.         4       Changed. Went back on September 16th. Came back as accepted a month later.         7       Q Okay. And my point being that, Doctor,         8       here's a give and take in the peer-review process         9       between the authors and the reviewers and the journal         10       that may lead to changes in an article; is that fair         11       to say?         12       A Today most decent journals accept something         14       of articles submitted. So most journal		Page 158		Page 160
2       A       I vas not at that meeting.       2       A       I looked.         3       Q       Okay. And the other article, the Findling.       3       Q       And other than what you had produced         4       article, that had been presented as a poster at some       5       mixed as Exhibit I believe it's 4 did you have         6       A       I'm aware of hat. I was not at the       5       marked as Exhibit I believe it's 4 did you have         7       Poster.       5       marked as Exhibit I believe it's 4 did you have         7       poster.       7       Porcess for hese varieles?       8       A       I had none.       1         9       Poster.       9       But ultimately, it's fair to say?       8       A       I have made comments on the article.       10         10       Poster.       9       Dut ultimately, it's fair to say?       10 <t< td=""><td>1</td><td>poster presentation for this article?</td><td>1</td><td>Did you go back and look for those materials?</td></t<>	1	poster presentation for this article?	1	Did you go back and look for those materials?
3       Q       And the other article, the Findling atticle, that had been presented as a poster at some point; are you aware of that?       3       Q       And other than what you had produced at the comail that Mr. Gomez marked as Exhibit – I believe it's 4 – did you have any other materials relating to the peer-review and set has any sechage sechange in the move 10 presenting a poster for a particular article; is that fair to say?       A       I had none. I moved office in 2006, and I         10       pearetaing aposter for a particular article; is that fair to say?       I have been some kind of editorial process before the first intores the the ant cort of 200, 200, 200, 200, 200, 200, 200, 200				
4       article, that had been presented as a poster at some point; are you aware of that?       eartier today attached to the cimil that Mr. Gomez marked as Exhibit – 1 believe it's 4 – did you have any other materials relating to the peer-review process for these two articles?         7       poster.       marked as Exhibit – 1 believe it's 4 – did you have any other materials relating to the peer-review process for these two articles?         8       Q Okay. And is it not uncommon that not all the authors would necessarily be involved in presenting a poster for a particular article; is that in the authors would necessarily be involved in the trait of a say?       8         12       A Inevitably one or at the most two would be the same paragraph on the article, between the interior of Psychiatry April 2, 2003. Previous 10 form one place to the next.       0         14       Q Okay. And I also want to note here on the fits manuscript was received at the American Journal of Psychiatry April 2, 2003. Revisions 1       0         15       and the article was accepted October 31, 2003. Did I read that accurately?       10         2       Q And Doctro, does that reflect to you that the you.       20         2       A You did.       21         2       A So what would have happened is reviewed a set thack to us.       10         3       there was an exchange with the peer reviewers and the journal searce paragraph on the admiter way theory?       21         4       A So what would have happened is revieweed a set thac to us.       23				
5       point; are you aware of that?       smarked as Exhibit - 1 believe ifs 4 - did you have any other materials relating to the peer-review and the peer-review and the peer-review and end of editorial process before the functions and this time. Thank you.         10       Page 10         11       Q       Obdit of them.         12       A material published in their journals;         13       below as an exchange with the peer review and with the journal regarding edits to this article and that accurately?         14       A vo did.         24       the journal regarding edits to this article and that to this at have any questions.         25       A materid as ExAMINATION         26 <t< td=""><td></td><td></td><td></td><td></td></t<>				
6       A Tra aware of that. I was not at the       any other materials relating to the peer-review         7       poster.       any other materials relating to the peer-review         9       poster.       A I had none. I moved office in 2006, and I         9       the authors would necessarily be involved in       or more place to the next.         11       fair to say?       A I had none. I moved office in 2006, and I         2       A Nevitably one or at the most two would be       there.         13       there.       Q But ultimately, it's fair to say that, for         14       Q Okay. And I also want to note here on the       the article was accepted October 31, 2003.         16       that article was accepted October 31, 2003.       have been some kind of editorial process before the         20       A You did.       22       A They these are peer-reviewed publications,         21       A You did.       22       A They these are peer-reviewed publications,         23       bet article was an exchange with the peer reviewers and with       23       Thank you.         24       the journal regarding dids to this article and that       24       Thank you.         25       protty quickly with a few minor changes and was       6 accepted this article?       7         25       proty quickly with a few minor changes and was			-	
7       poster.       7       process for these two articles?         8       Q Okay. And is it not uncommon that not all       9         9       presenting a poster for a particular article; is that         11       fair to say?       0         12       A Inevitably one or at the most two would be       0         14       Q Okay. And I also want to note here on the       16         15       same paragraph on the article. Doctor, that it notes       16         16       that manuscript was received at the American       17         17       Journal of Psychiatry April 2, 2003.       Revisions         18       received September 16th and October 28th, 2003.         19       And the article was accepted October 31, 2003.         10       Did I read that accurately?         21       Q You did.         22       Q And Doctor, does that reflect to you that         24       there was an exchange with the peer reviewers and with         24       there was an exchange with the peer reviewers and with         24       A So what would have happened is reviewed         3       sent in April 2, reviewed and sent back to us.         4       Changed. Went back on September 16th.         4       Chady most decent journals accept sent was and the reviewers				2
8       Q       Okay. And is it not uncommon that not all       9         9       the authors would necessarily be involved in       0         10       presenting a poster for a particular article; is that       1         11       fair to say?       Q         2       A       I had none. I moved office in 2006, and I         11       fair to say?       Q         2       A       I hevitably one or at the most two would be         13       same paragraph on the article, Doctor, that it notes         16       that this manuscript was received at the American         17       Journal of Psychiatry April 2, 2003.         19       And the article was accepted October 31, 2003.         10       Did I read that accurately?         20       Q       And Doctor, does that reflect to you that         21       A You did.       20         22       Q       And bar article?         21       accepted this article?       I same archange with the peer reviewers and with         23       sent in April 2, reviewed and sent back to us.       Page 159         24       A So what would have happened is reviewed –       sent in April 2, reviewed and sent back to us.         3       sent in April 2, reviewed and sent back to us.       Q       <			_	
9       he authors would necessarily be involved in       9       culled everything that wan't necessary in the move         10       presenting a poster for a particular article; is that       11       11         12       A Inevitably one or at the most two would be       form one place to the next.         11       11       Q       But ultimately, if's fair to say that, for         12       A Inevitably one or at the most two would be       11         13       better.       Q       But ultimately, if's fair to say that, for         14       Q       Okay. And I also want to note here on the       13         15       sime paragraph on the article. Doctor, that it notes       16         16       that this manuscript was received at the American       17         17       Journal of Psychiatry April 2, 2003.       Revisitod         16       articles were ultimately published in their journals;         17       Did I read that accurately?       20         18       A They these are peer-reviewed and bit accurately?       20         21       Q       A ord uff.         22       Q       And boctor, does that reflect to you that       23         24       ther was an exchange with the peer reviewers and with       24         24       ther was an e		1	-	
10       presenting a poster for a particular article; is that       11       fair to say?         11       fair to say?       0       But ultimately, it's fair to say that, for         12       A       Inevitably one or at the most two would be       both of these articles, they would have been reviewed         13       there.       by peer-reviewed clinicians, or academics who would         14       have made comments on the article. And there would         15       same paragraph on the article. Doctor, that it notes         16       that this manuscript was received at the American         17       journal of Psychiatry April 2, 2003.         18       received September 16th and October 28th, 2003.         19       both of them.         20       Q And Doctor, does that reflect to you that         21       A       Ma the article was an exchange with the peer reviewers and with         23       there was an exchange with the peer reviewers and was       accepted this article?         2       A       So what would have happened is reviewer         3       sent in April 2, reviewed and sent back to us.         4       Changed. Went back on September 16th. Came back is accepted a month later.         5       pretty quickly with a few minor changes and was       accepted a month later.         6 <td></td> <td></td> <td></td> <td></td>				
11       fair to say?       11       Q       But ultimately, it's fair to say that, for         12       A       Inevitably one or at the most two would be       11       Q       But ultimately, it's fair to say that, for         13       arragraph on the article, Doctor, that it note here on the       14       have been some kind of editorial process before the         14       arragraph on the article, Doctor, that it note here on the       have been some kind of editorial process before the         15       same pargraph on the article, Doctor, that it note here on the       have been some kind of editorial process before the         16       that this manuscript was received at the American       have been some kind of editorial process before the         16       articles depender I of tha and Cotober 28th, 2003.       A       They these are peer-reviewed publications,         20       Did I read that accurately?       20       Q       Doctor, I don't think I have any more         21       A       You did.       21       A       Thank you.         22       Q       And the article?       MR. MOBLEY: I don't have any questions.         24       there was an exchanges and was       Page 16       EXAMINATION         2       A       Today most decent journals accept something       9       Q       Okay. If you lokon the first page,	10		10	
12       A       Inevitably one or at the most two would be       12       both of these articles, they would have been reviewed         13       there.       12       both of these articles, they would have been reviewed         14       Q       Okay. And I also want to note here on the         15       same paragraph on the article, Doctor, that it notes         16       that this manuscript was received at the American         17       Journal of Psychiatry April 2, 2003. Revisions         18       received September 16th and October 28th, 2003.         19       And the article was accepted October 31, 2003.         20       Did I read that accurately?         21       A       You did.         22       Q       And Doctor, does that reflect to you that         24       there was an exchange with the peer reviewers and with         24       the journal regarding edits to this article and that         24       Ulimately, after that editorial process, the journal         25       accepted his article?         2       A       So what would have happened is reviewed –         3       sent in April 2, reviewed and sent back to us.         4       changed. Went back on September 16th. Came back         5       pretry quickly wit a few minor changes and was				
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41 (Pages 158 to 161)

	Page 162		Page 164
1	Q Whether it's direct or indirect, would you	1	couple more things I want to ask you about. If you go
2	agree with me that elevated prolactin can cause	2	to page 548, it's in the top left. Are you there?
3	gynecomastia in males?	3	A I'm there.
4	A You know, I'll say two things to that. I	4	Q Okay. Up on the right-hand column, if you
5	personally have never seen it as a condition, No. 1.	5	go down the
6	And No. 2, at the levels that are present in the	6	A Okay.
7	articles that we are talking about, I've certainly	7	Q There's a sentence beginning, "Findling et
8	never seen it.	8	al. 2003"; do you see that?
9	So I would have to having seen it in those	9	A Yes.
10	levels in many different situations, I'd have to say	10	Q Okay. It reads, "Findling et al. 2003
11	that I have difficulty buying into that. And if you	11	emphasized an apparent downward trend in serum
12	notice, that statement is not referenced. So it's a	12	prolactin when examined longitudinally from weeks four
13	tough one to substantiate very easily.	13	to seven through study end point at weeks 40 to 48."
14	Q Okay. It was written by George M.	14	Did I read that correctly?
15	Anderson, Lawrence Scahill, and James T. McCracken,	15	A Correctly.
16	among others. Do you see those names?	16	MR. ESSIG: Chris, I'm lost.
17 18	A It's in the medical literature, but I'm unconvinced by it being a direct effect and at those	17 18	MR. GOMEZ: I'm sorry. 548. Right there. MR. ESSIG: Thank you.
18	lower levels. Let's leave it at that.	18 19	BY MR. GOMEZ:
20	Q Okay. In the next paragraph, do you see	20	Q In this article, there's no mention of a
20	where it says "however"?	20	statistically significant association at weeks eight
22	A However?	22	to 12?
23	Q "There's accumulating evidence that	23	A Correct.
24	children treated with typical neuroleptics and	24	Q You were asked whether or not, looking at
25	risperidone often exhibit modest to marked elevations	25	the final paper, you stand by the conclusions of the
	Page 163		Page 165
1	in prolactin?	1	article. I don't think you ever answered the
2	A Correct.	2	question. Yes or no?
3	Q And the Findling article is cited, the 2003	3	MR. ESSIG: Objection to the form.
4	article; correct?	4	THE WITNESS: The conclusions of
5	A Yes.	5	BY MR. GOMEZ:
6	Q Then it says, "Compared to adult patients,	6	<ul><li>Q Let's get the final article.</li><li>A The conclusion of the article reads as</li></ul>
7 8	there is even greater uncertainty regarding the clinical implications of elevated prolactin in	0	
8 9	children and adolescents." Do you agree with that	8 9	follows: "With long-term risperidone treatment in children and adolescents, serum prolactin levels tend
10	statement?	10	to rise and peak within the first one to two months
11	A Correct. So they didn't make an assumption	11	and then steadily decline to values within or very
12	from reading our article, the first one, that there	12	close to the normal range by three to five months."
13	was a definitive answer to the questions you've been	13	I stick by those conclusions.
14	asking today.	14	Q You stick by the conclusion that you just
15	Q Okay. You would agree with me, by reading	15	read in the abstract; correct?
16	the Findling article in 2003, the authors of this	16	A Yes.
17	article did not see the statistically significant	17	Q Okay. Can I have that for just a second?
18	association between elevated prolactin levels and side	18	Do you stand by the statement, "There was no direct
19	effects; agree?	19	correlation between prolactin elevations and SHAP"?
20	MR. ESSIG: Objection to the form.	20	A In the light of different approaches to
21	THE WITNESS: I'm not sure. They may have	21	statistical analysis, that has to be reevaluated.
22	seen the raw numbers and seen that there wasn't a huge	22	Q Do you stand by the statement, "There was
	1 0 1 1 1 1 1 1 1		no direct correlation between projectin claustion and
23	number of children with these problems.	23	no direct correlation between prolactin elevation and
23 24 25	number of children with these problems. BY MR. GOMEZ: Q Sticking with this article, there's a	23 24 25	SHAP"? MR. ESSIG: Asked and answered.

	Page 166		Page 168
1	BY MR. GOMEZ:	1	Findling, Moshang, and Daneman.
2	Q It asked for a yes or no answer. Do you	2	Q You interpret my use of the word "failed"
3	have one?	3	as malice aforethought or intentional?
4	A Given the later study which doesn't show	4	A Well, there's some suggestion of it in the
5	any of those side effects, which confirm our findings,	5	discussion that's been going on today.
6 7	it appears that to say yes, that this is a defective sentence is correct. But does it nullify	6 7	Q Assume for purposes of my question, when I say "fail," I mean that it was not in the article or
8	all the findings in that study?	8	the omission thereof. Okay?
9	I do not think so.	9	A Yes.
10	Q The study you're referring to is the 2007	10	Q Could have been done in a negligent manner,
11	article that you looked at?	11	not with malice aforethought. This article failed to
12	A So what one does	12	report the statistically significant association
13	Q Yes or no answer, and then you can answer.	13	between elevated prolactin levels and SHAP; do you
14	A Yes.	14	agree?
15	Q Okay.	15	MR. ESSIG: Objection to the form. And
16	A Okay. So the Findling article is in the	16	foundation.
17 18	literature. It's flawed by that sentence, yes. That's the answer to your question, yes. The	17 18	THE WITNESS: I think that's your
19	subsequent literature looking at a not too dissimilar	10	assessment, yes. BY MR. GOMEZ:
20	group of children comes up with very similar levels of	20	Q Do you agree with my assessment?
21	prolactin and comes up with a very similar finding in	21	A To a degree, yes.
22	terms of the side effects.	22	Q Fair enough. Thank you. That's all I
23	In fact, it finds none. So the medical	23	have.
24	literature is a series of building blocks. Sometimes	24	A Thank you.
25	the one block that's added topples the whole thing	25	MR. ESSIG: Doctor, thank you for your time
	Page 167		Page 169
1	over and you have to start again. Sometimes it adds		
	over, and you have to start again. Sometimes it augs	1	today.
	over, and you have to start again. Sometimes it adds and creates a firm foundation.	1 2	today. VIDEOGRAPHER: This marks the end of
2 3			VIDEOGRAPHER: This marks the end of videotape No. 3 and today's proceedings in the
2 3 4	and creates a firm foundation. This article and I couldn't find a whole lot of other articles that showed the reverse. This	2 3 4	VIDEOGRAPHER: This marks the end of videotape No. 3 and today's proceedings in the deposition of Dr. Denis Daneman. Going off the record
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CERTIFICATE OF SHORTHAND REPORTER I, Virlana Kardash, Registered Professional Reporter and Commissioner of Oaths in and for the Province of Ontario, before whom the foregoing proceedings were taken, do hereby certify that the witness whose testimony appears in the foregoing pages was duly sworn by me; that the testimony of said witness was taken by me stenographically at the time and place noted in the caption hereof and thereafter reduced to computer-aided transcription by me; that the foregoing transcript is a true and correct record of the proceedings; and that I am neither counsel for, related to, nor employed by any of the parties to this case and have no interest, financial or otherwise, in the outcome of the action.	
Virlana Kardash, RPR, CSR Certified Shorthand Reporter and Commissioner of Oaths	
My certificate expires: December 2, 2013	
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