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Joseph Biederman February 26, 2009	Joseph Biederman February 26, 2009
Page 1	Page 2
Page 1 VOLUME 1 SUPERIOR COURT OF NEW JERSEY LAW DIVISION - MIDDLESEX COUNTY In re: Risperdal/Seroquel/Zyprexa litigation Case Code 274 Alma Avila, as next friend of Amber N Avila. an individual case v. Civil Action Docket Number Johnson & Johnson Company, Janssen Pharmaceutical Products, L.P. a/k/a Janssen, L.P., et al. Video Deposition of Joseph Biederman. M.D.	Page 2 Counsel for Plaintiffs: Fletch Tranmell, Esq. Leslic LaMacchia, Esq Jennifer Ho, Esq. Bailey Perin Bailey LLP The Lyric Centre Building Ad0 Louisiana Street - Suite 2100 Houston, Texas 77002 S 713.425.7100 - Fax 713.292.2714 frammell@bpblaw.com Intermell@bpblaw.com Intermell@bpblaw.com Houston, Texas 77016 713.751.0025 - Fax 713.751.6030 Houston, Texas 7716 Kenneth W. Smith, Esq Kenneth W. Smith, Esq Sheller, P.C IS28 Walnut Street - 3rd Floor Flidelphia, Pernsylvania 19102
 Video Deposition Gr Joseph Fiderman. H D Thursday, February 26, 2009 Dwyer & Collora, LLP Federal Reserve Plaza - 12th Floor 600 Atlantic Avenue Boston. Massachusetts 02210 	 215,790/3300 - Fax 215 546.0942 14 ksmith@sheller com 15 16 Counsel for Defendants Johnson & Johnson Company. Janssen Pharmaceutical Products L P 17 Jeffrey A. Peck, Esq 18 Drinker Biddle & Reath LLP 500 Campus Drive 19 Florham Park, New Jersey 07932 973,360,1100 - Fax 973,360,01801 20 jeffrey.peck@dbr.com deirdre kole@dbr.com 21 22 William V. Essig. Esq Drinker Biddle & Reath, 1.LP 23 191 North Wacker Drive - Suite 3700 Chicago, Illinois 60606 24 312,569,1000 - Fax 312,569,30%0 william esig@dbr.com
Stratos Legal Services 800-971-1127	25 Stratos Legal Services 800-971-1127
Joseph Biederman February 26, 2009	Joseph Biederman February 26, 2009
Page 3	Page 4
 Counsel for Defendant AstraZeneca: Donald C LeGower. Esq Dechert LLP Cira Centre 2929 Arch Street Philadelphia, Pennsylvania 19104 215 994 4000 - Fax 215 994 2222 donald legower@dechert com Counsel for the deponent. Dr Biederman: Peter S. Spivack, Esq Keith Burney, Esq Hogan & Hartson, L L P Columbia Square 555 Thirteenth Street, N.W Washington, D C. 20004 202 637.5600 - Fax 202 637 5910 psspivack@hhlaw com Videographer: William R Slater, Legal Video Specialist Stratos Legal Services LP HO01 West Loop South - Suite 809 Houston, Texas 77027 Also Present: George Döbrentey, Videographer on behalf of Hogan & Hartson 	1 IN D E X 3 DEPONENT PAGE 4
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			2 (Pages 5 to 8
1	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	-		Page 6
	Page 5		rage 6
1 2	BIEDERMAN EXHIBITS FOR IDENTIFICATION	1	
3		2	BIEDERMAN EXHIBITS FOR IDENTIFICATION
4	8	4	14 PowerPoint slide printouts, first slide 277
5			reading New Initiative! J&J Pediatric
67	9 Article entitled Risperidone Treatment 204	5	Research Center at Mass General Hospital,
	for Juvenile Bipolar Disorder, A	6	Gahan J Pandina. Ph D (Bates JJRE 03857473 - 480)
8	Retrospective Chart Review, Jean A. Frazier M.D., Journal of The American Academy of	17	15 E-mail sent Friday, March 22, 2002. at 289
9	Child and Adolescent Psychiatry. August 1999 pages 960 through 965		9:38 a.m. from Gahan Pandina to Christine
10		8	Cote. subject: Feedback regarding MGH
11	10 Document headed Case Report, Treatment 208 of Risperidone-Induced Hyperprotactinemia	9	pediatric seminar (Bates JJRIS 00566318)
12	with a Dopanine Agonist in Children, Louise Glassner Cohen and Joseph Biederman, M.D.	9	16
13	Journal of Child and Adolescent Psychopharmacology, Volume 11. Number 4,	10	
	2001: pages 435 through 440		
14	11 Article entitled No Seizure Exacerbation 210	11	•
15	From Risperidone in Youth With Comorbid Epilepsy and Psychiatric Disorders: A Case	12	:
16	Series, Joseph Gonzalez-Heydrich, M.D.	13	
17	Journal of Child and Adolescent Psychopharmacology, Volume 14. Number 2.	14	(ORIGINAL EXHIBITS RETURNED TO ATTORNEY 1 aMACCHIA)
18	2004, pages 295 through 310	15	
1	12	16	
19		18	
20		19	
21		20	
22		21	
23	13 Sheet headed Key Points From 2003 Child 264 & Adolescent Business Planning Session	22	
24	2-4/12/02 (Bates JJRE 00057039)	24	
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 7		Page 8
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1		1	MS. LaMACCHIA: Leslie LaMacchia,
1 2	MORNING SESSION	2	plaintiffs.
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			3 (Pages 9 to 12
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 9	[Page 10
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1	questioner leave the room	1	MR. SPIVACK: You can tell him whatever
2	MR SPIVACK: Your objection is noted	2	you want.
3	And you know since the purpose of videotaping a	3	MR FIBICH: All right
4	deposition is to replicate for the courtroom, we	4	Mr. Videographer
5 6	think it's appropriate to have a videographer focused on the questioner. I'm not going to direct	5 6	MR. SPIVACK: Since he's hired by us, he
7	the videographer to leave the room; I'm going to ask	7	will unfortunately not pay attention to what you tell him.
8	him to stay. If you don't want to proceed with the	8	MR. FIBICH: Well, he may not.
9	deposition, that's fine	9	Are you the videographer that is focusing
10	MR. FIBICH: No, we're going to proceed	10	on the questioner?
11	with the deposition. But I am going to direct the	11	MR. SLATER: I am, yes, the questioner.
12	videographer, the second one, to place the camera on	12	I mean, not the questioner, the witness
13	Mr. Biederman's feet so that we can replicate what	13	MR DÖBRENTEY: I'm the videogrpaher
14	it looks like in a courtroom and we can see him	14	focusing on the questioner.
15	moving around nervously when he's asked questions	15	MR FIBICH: And I am telling you there is
16	So, Mr. Videographer, I want you to find a	16	no such notice that allows that, and I am asking you
17	way to videotape the witness's feet. Will you do	17	not to do it.
18	that, sir?	18	MR DÖBRENTEY: I have to defer to the
19	MR_DÖBRENTEY: That would be the	19	person who hired us.
20	I can't do that.	20	MR. FIBICH: So you're going to take
21	MR SPIVACK: If you want to stop the	21	directions from Hogan & Hartson?
22	deposition, that's fine	22	MR DÖBRENTEY: Yes
23	MR FIBICH: No. I'm going to tell the	23	MR FIBICH: Okay
24	videographer not to focus on Mr. Trammell as he	24 25	My initial comment, Mr. Spivack, was a
25	starts the questioning. Stratos Legal Services	25	request because I don't think it's right. It's a Stratos Legal Services
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	Joseph Biederman February 26, 2009	†	Joseph Biederman February 26, 2009
	Page 11		Page 12
1	request Now I'm going to make And I presume	1	behalf, so that is something we disagree on.
2	you're not going to accommodate my request?	2	MR SPIVACK: Okay
3	MR SPIVACK: You are correct	3	MR. FIBICH: We may have the opportunity
4	MR. FIBICH: Okay. For the record, I am	4	on many other occasions to take Dr. Biederman's
5	now going to object for the record and we will raise	5	deposition. I was hoping today would be the only
6	this issue with the Court and we will proceed with	6	day. But if this is the sort of activity that we're
7	the understanding that these sorts of things will	7	going to have to deal with, then we'll do it the
8	just be the first shot over the bow.	8	best way we can. For the purpose of the record, I
9	MR. SPIVACK: If that's a threat, go	9	intend to be as professional as I know how to be and
10 11	ahead, take your best shot. MR. FIBICH: We intend to, sir.	10 11	I'm sure you will too MR. SPIVACK: Absolutely.
12	MR. SPIVACK: I think that, as we all	12	Since we are making objections for the
13	will, I'm sure you will abide by the laws governing	13	record, I would like to object for the record to
14	the lawyers in Texas and you just had a nice	14	you, Mr. Trammell and Mr. Fibich, asking any
15	statement of how lawyers are supposed to behave in	15	questions in this deposition since I understand you
16	depositions and otherwise I'm sure that you'll be	16	haven't complied with the New Jersey rules on
17	polite, and I will as well, when we have our	17	admission pro hac vice as an attorney. I know that
18	disagreements, but we can do so respectfully	18	you have made your application, you have been
19	MR FIBICH: Well, I think so too, and	19	accepted, but my understanding is that you have not
20	I intend to do that. My point is that insofar as	20	paid the fees required into the New Jersey Client
21	obeying the law, we've got a rule that applies to	21	Trust Account.
22	videotaping and I don't appreciate what you're doing	22	MR FIBICH: Anything else?
23	today, because my option is to proceed or	23	MR. SPIVACK: Not at this moment.
24	alternatively come back and raise this as an issue	24	MR FIBICH: Let's swear the witness in
25	I don't find that to be very professional on your	25	and get on the videotape
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 13		Page 1
1	MR. LeGOWER: Counsel, before we swear in	1	
			documents and, as far as I know, no one else knew
2	the witness, I think I have something a lot less	2	what he was going to produce I don't know what he
3	controversial, though I could be wrong.	3	had in his possession.
4	AstraZeneca has reviewed Dr. Biederman's	4	MR. FIBICH: Thank you.
5	document production and has identified a few	5	MR. SPIVACK: And I have one more matter
б	documents that we believe contain confidential	6	to put on the record I talked to Ms. LaMacchia
7	information that AstraZeneca would like to mark as	7	before the deposition. There are documents that we
8	protected documents under the Court's protective	8	produced pursuant to the Court's order after the
9	order I have exchanged with counsel for all the	9	hearing that contain Dr Biederman's personal
10	parties and for the witness a document that lists	10	financial information; for example, his Social
11	those documents by Bates number, and I would just	11	Security number, bank account information, home
12	like to mark it for the record and preserve it in	12	address, et cetera
		13	
13	this deposition Any objections?		What we would like to do is replace those
14	MR FIBICH: I would like to know when you	14	documents with redacted copies We had anticipated
15	first saw the production	15	that the Court would entertain a protective order
16	MR. LeGOWER: I first saw the production	16	Since at least at this juncture it has indicated
17	when Brian McCormick delivered it to me on Tuesday	17	it's not, we make that request
18	night at 5:00 p.m.	18	MR FIBICH: Well, that camera over there
19	MR FIBICH: And Janssen or Who do you	19	sure bothers me. I don't think we can agree to that
20	represent, again?	20	request, mainly because I don't know of any
21	MR. LeGOWER: I represent AstraZeneca.	21	privilege that he has to protect that information
22	MR FIBICH: Okay So prior to that time	22	MR. SPIVACK: I mean, in that case, then
23	AstraZeneca didn't have any notice of what he had in	23	we'll go forward with the motion for the protective
24	his possession?	24	
	MR LeGOWER: Prior to that time I had no	25	order if you're not agreeing to that. I mean, it
OF	WIK LEGUWEK: Phor to that time I had no	12.7	seems entirely
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 17		- Page 18
1	MR LeGOWER: Don LeGower, Dechert, for	1	O. Yes
2	AstraZeneca	2	A. It's 523 Boylston Street, Brookline,
3	MS KOLE: Deirdre Kole, Drinker Biddle &	3	Massachusetts 02445
4	Reath, Janssen and Johnson & Johnson	4	Q. Can you speak up a little bit? I'm not
5	MR ESSIG: William V Essig, Drinker	5	sure
6	Biddle, Johnson & Johnson and Janssen	6	A. I'm a little bit hoarse. I can't. But if
7	MR. PECK: Jeffrey Peck, Drinker Biddle,	7	you want me to say it again? 523 Boylston Street,
8	Johnson & Johnson and Janssen	8	B-o-y-l-s-t-o-n Street, Brookline, Massachusetts
9	MR. BURNEY: Keith Burney, Hogan &	9	02445.
10	Hartson, representing Dr. Biederman	10	MR TRAMMELL: Are you able to hear him?
11	MR SPIVACK: Peter Spivack of Hogan &	11	THE VIDEOGRAPHER: Yes
12		12	MR. TRAMMELL: Good
13		13	BY MR. TRAMMELL:
14		14	Q And where do you work?
15		15	A. The Massachusetts General Hospital.
16	e i <i>i</i>	16	Q Is that here in Boston?
17	was examined and testified as follows:	17	A. In Boston
18	EXAMINATION	18	Q. Doctor, who is representing you here
19	BY MR TRAMMELL:	19	today?
20	· · ·	20	A. Mr. Spivack and Mr. Burney.
21	-	21	Q. From the firm of Hogan & Hartson?
22	Q Please state your name for the record	22 23	A. Correct.
23	A Joseph Biederman	23 24	Q. Are you paying these lawyers? A. The Yes.
24 25	Q. And where do you live, Dr Biederman?A. You want my address?	25	
2.5	Stratos Legal Services	2.5	Q. Do you have a malpractice insurer that's Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009	1	February 26, 2009
	Page 19		Page 20
1	paying them or are you paying them directly out of	1	MR TRAMMELL: Okay So we're on the
2			the framewart only be worth on the
14	your pocket?	2	record right now, the video record. We've just
3	your pocket? A. Well, it's paid through the Massachusetts	2 3	
		l	record right now, the video record We've just started. We noticed this deposition, as you know,
3 4 5	 A. Well, it's paid through the Massachusetts General Hospital (Mr Fibich interrupted, holding up a 	3 4 5	record right now, the video record We've just started. We noticed this deposition, as you know, under the New Jersey rules to be a videotaped
3 4 5 6	 A. Well, it's paid through the Massachusetts General Hospital (Mr Fibich interrupted, holding up a BlackBerry speakerphone in his hand. A voice, later 	3 4 5 6	record right now, the video record We've just started. We noticed this deposition, as you know, under the New Jersey rules to be a videotaped deposition and complied with all the New Jersey
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 21		Page 22
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1	something You mean they want to videotape the		the deposition. The notice shall further state that
2	lawyer when the lawyer is asking the question?	2	the deposition is to be videotaped "And that was
3	MR. TRAMMELL: Right That's correct,	4	done here?
4	your Honor.		MR. TRAMMELL: No.
5	THE COURT: I see. You're cutting out	5	THE COURT: Was that done by plaintiff?
6	Is that the issue, that the defendant wants to	6	MR TRAMMELL: That was done by
7	videotape the questioner?		plaintiffs, not by Dr. Biederman's counsel.
8	MR. TRAMMELL: That's correct, your Honor.	8	THE COURT: Okay And then section (c)
9	THE COURT: Okay. For the record let's	9 10	has to do with the transcript. Section (d) has to
10	agree 4:14-9 is the rule in New Jersey which states		do with the filing of the copies. (e) has to do
11	"Videotaped depositions may be taken for discovery	11 12	with the use. (f) is counsel's objections (g) is
12	purposes or for use at trial in accordance with the	12 13	the cost of the videotaped dep. And (h), also the
13	applicable provisions of these discovery rules	14	record on appeal Bear with me. I'm just reading the notice
14	subject to the following further requirements and		· · ·
15	conditions: (a) Time for Taking Videotaped	15 16	here. (Pause)
16	Depositions. The provisions of Rule 4:14-1 shall	16 17	I have never seen a videotaped deposition
17 18	apply to videotaped depositions except that such a deposition of a treating physician or expert witness	18	where the lawyers were actually shown to the jurors neither in my tenure as a judge or trial lawyer If
19	which is intended for use in lieu of trial testimony	19 19	the defendants want to do that, give me a rule or
20	should not be noticed for taking until 30 days"	20	give me some case law and specifically cite me to a
21	well, that portion is not relevant here	20	rule or some case law which says you can just use
22	"(b) Notice. A party intending to	21 22	recording technology without giving your adversary
23	videotape a deposition shall serve the notice	23	notice of it so if there is an objection, it can be
24	required by Rule 4:14-2(a) not less than ten days	23 24	presented to the Court Because under our video
25	prior to the date therein fixed for the taking of	25	rule 4:14-9(a), it's important pursuant to this rule
2.5	Stratos Legal Services	Ĩ	Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 23		Page 24
1	that the parties be given notice so obviously if		
		1	MR_PECK: Doesn't the rule specifically
2	there is some problem, the Court can deal with it.	1	MR PECK: Doesn't the rule specifically state parties? It says any
2	there is some problem, the Court can deal with it.	2	state parties? It says any
3	Due to the fact that it is not customary	2 3	state parties? It says any THE COURT: Any party intending to
3 4	Due to the fact that it is not customary at least in my experience either as a judge or trial	2 3 4	state parties? It says any THE COURT: Any party intending to videotape. Well, there's a party intending to
3 4 5	Due to the fact that it is not customary at least in my experience either as a judge or trial lawyer to have the videographer actually taking a	2 3	state parties? It says any THE COURT: Any party intending to videotape. Well, there's a party intending to videotape. But where does it state that this rule
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			7 (Pages 25 to 28
Joseph Biederm			Joseph Biederman
February 26, 2			February 26, 2009 Page 26
	Page 25		Page 20
1been involved in2MR SPIVACK: Your Ho.3don't think that custom and practid4dictate here. I think it's the rule.5respectfully, your Honor, I have H6videotapes of the lawyers, the que7been undertaken8THE COURT: What rule,9rule? We're talking New Jersey r10said pursuant to the rule What rule11referring to?12MR SPIVACK: I'm referring13that your Honor quoted14THE COURT: 4:14-9?15MR SPIVACK: Yes16THE COURT: Well, tell rule17that you can take the video of the18MR SPIVACK: Well, you19exclude it.20THE COURT: You're not21frankly, you're not giving me a go23MR SPIVACK: All right24the record I certainly understand25disagree with it. I think that the rule	ice is what should And been in cases where estioners, have counsel? What ules here. You ule are you ring to the rule me where it says questioner. ar Honor, it doesn't giving me Quite bod reason why it Your Honor, for your ruling I ule provides	$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\0\\11\\12\\13\\14\\15\\6\\7\\8\\9\\0\\22\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\$	for such videotaping I think given that this is intended to replicate a courtroom setting, if it's introduced into evidence, I think that the jury should see both the questioner and the witness THE COURT: Have you ever done that in New Jersey? MR SPIVACK: Your Honor, it's MR PECK: Judge Happas, this is Jeffrey Peck for Janssen and Johnson & Johnson I believe Judge Corodemus and I know Judge Garruto has permitted cameras for exactly that reason, two cameras: a videotape camera obviously on the witness and a videotape second camera on the questioner. And orders have been entered in either Janssen-Ortho or HRT, one of the other mass torts, on exactly the same issue; and the reason being that the dual cameras do replicate the courtroom if in fact the deposition THE COURT: You've got to come in closer to the phone because you're fading in and out Now I can't hear you at all MR PECK: Okay, I'm coming around the table I know that Judge Garruto and perhaps Judge Corodemus before him have ordered dual cameras
Stratos Legal Ser 800-971-1127	vices		Stratos Legal Services 800-971-1127
Joseph Biederm February 26, 2			Joseph Biederman February 26, 2009
	Page 27		Page 28
1for depositions that are videotaped2where Well, the argument is to r3courtroom environment. And what4when these videotapes are shown r5as a split screen. It shows the quest6shows the witness just as one wout7courtroom. And that is the rational8it I don't see how it prejudices an9I don't understand the nature of the10THE COURT: Well, let me11something12MR. PECK: But it's been de13New Jersey.14THE COURT: For these put15think it's important that you get state16deposition, what would be the prol17today's purposes of letting the defet18in that fashion and this is an issue19bring up at the time of trial?	replicate the ut's been done is that at trial, it is done stioner and it ld see in the le for allowing ybody at all. e objection e ask you one before in proses, because I urted with this blem at least for endants proceed that we'll	1 3 4 5 6 7 8 9 10 11 12 13 14 5 16 7 8 9 10 11 12 3 14 5 16 7 8 9 10 11 12 3 14 5 10 11 12 13 14 5 14 5 14 5 14 5 14 5 14 5 14 5 1	situation in which this occurred, we don't know what those orders said We don't know whether they relate to the circumstances here THE COURT: And that could be the case But here we are. Okay? Here we are at the point where everybody, all fifteen lawyers are seated in that room, you have Dr Biederman, and everybody is ready to go So at this point I'm not going to put the deposition off That doesn't make a lot of sense MR TRAMMELL: No, and we don't want to do that I mean, as silly as it is, the purpose is to intimidate the questioner THE COURT: No, it's not to intimidate Come on You're lawyers If you're going to be intimidated by a camera, which I doubt that you will be, that's not to intimidate And that I don't buy I mean, a lawyer is not going to be intimidated by a camera
 MR. TRAMMELL: Well, y MR. TRAMMELL: Well, y obviously had they raised their into this, we would have objected to it. said, that's the purpose of complyi Jersey rule, which they haven't do Mr Peck can give us an allegorica 	Your Honor, I mean, ention to do As your Honor ng with the New ne Even if I account of a	20 21 22 23 24 25	MR TRAMMELL: Okay Well, I certainly can't imagine what the purpose would be. And I agree with you there's nobody that's going to be intimidated by that but I don't know what the purpose of it is They didn't comply with the rules

25 Mr Peck can give us an allegorical account of a Stratos Legal Services 800-971-1127

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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 29		Page 30
		1.	_
1	THE COURT: Well, this is what we're going	1	MR. SPIVACK: Thank you, your Honor
2	to do I think there's no harm, they've got the	2	THE COURT: Have a good day Thank you
3	video equipment there, it will give us time to	3	(End of BlackBerry speakerphone conference
4	review it and see whether or not it is appropriate.	4	with Judge Happas.)
5	I'm not really happy, quite frankly, that you didn't	5	BY MR. TRAMMELL:
6	at least give the courtesy to the other side. I	6	Q. Dr. Biederman, you understand you're still
7	think there's courtesy involved here If you were	7	under oath?
8	going to bring in a videographer, I don't know why	8	MR. FIBICH: Are we on the record?
9		9	
	you couldn't have picked up the phone and said, by	1	MR TRAMMELL: I don't think we were ever
10	the way, we're going to do this Okay? To come in	10	off.
11	carting this equipment, I just think as a courtesy	11	BY MR. TRAMMELL:
12	it should have been done And maybe even more.	12	Q. You said the hospital you work for is
13	But at this point we're past that. You	13	paying for your lawyers here today. Is that right?
14	have everything set up, everybody's ready for the	14	A. Correct.
15	deposition, and I think we'll save the argument for	15	Q. So no money is coming out of your pocket?
16	another day I'll look into some of those other	16	A. No.
17	situations that occurred. And let's get the	17	Q. Do you know if the hospital has any
18	deposition started. Everybody's been waiting a long	18	arrangement with Janssen or any other drug company
19		19	to reimburse the hospital for the cost of your
	time for this deposition to be completed and we'll		•
20	deal with the issue when it comes up before trial as	20	lawyers?
21	to whether or not you'll get to show both the	21	A. I do not know.
22	questioner and the witness or just the witness.	22	MR TRAMMELL: I guess this is 2 now,
23	Okay?	23	isn't it?
24	MR TRAMMELL: Yes Thank you, your	24	MR. PECK: What's marked?
25	Honor	25	MR. BURNEY: This other document
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	300-971-1127 Joseph Biederman February 26, 2009		300-971-1127 Joseph Biederman February 26, 2009
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 33		Page 34
	-		-
1	A. All the time.	1	Q. How many times?
2	Q. Do you use your folders in your Outlook?	2	A Yesterday and the day and half of the
3	A. I use some folders for current things that	3	day before
4	are pending.	4	Q. So today is Thursday. You met with them
5	Q. Did you search any folders for documents	5	all day on Wednesday?
6	responsive to this subpoena?	6	A. All day on Wednesday and half of the day
7	A Yes, I searched all the folders that I	7	on Tuesday.
8	have.	8	Q. Where did you meet?
9	Q So you searched your entire system?	9	A. In my house
10	A I searched my entire system	10	
1			
11	Q Did you give all those documents to your	11	A. Yes.
12	lawyers?	12	Q. How many hours did you meet?
13	A. Yes.	13	A. Probably about two hours on Tuesday and
14	Q. Did you withhold any?	14	about I would say four or five on Wednesday.
15	A. No.	15	Q. Did you look at any documents?
16	Q Number 5 is all communications between you	16	A I looked at some documents, yes.
17	and Janssen. Have you provided all those?	17	Q. Do you know which documents you looked at?
18	A. Yes	18	A. No. I don't remember.
19		19	Q You don't remember any of the documents
20		20	that you looked at?
21		21	A. I don't remember
22		22	Q. I want to look at your C.V., but Well,
23		23	I'll get it. We're done with that, with the
24		24	subpoena, Doctor
25		25	A Where do you want it to go?
	Stratos Legal Services		Stratos Legal Services
	800-971-1127	1	000 071 1107
	000 971 1127		800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Joseph Biederman		Joseph Biederman
1	Joseph Biederman February 26, 2009 Page 35	1	Joseph Biederman February 26, 2009 Page 36
1 2	Joseph Biederman February 26, 2009 Page 35 Q. Put it right here for the court reporter.	1	Joseph Biederman February 26, 2009 Page 36 Q. Hasn't been revised since?
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			10 (Pages 37 to 40)
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
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	Page 37		Page 38
1	MR SPIVACK: Right	1	Q What was of interest to you in Jerusalem?
2	BY MR. TRAMMELL:	2	A. I like their medical training and I wanted
3		3	
4	Q. So when you were six months old you left	4	to have that experience
5	Prague for Argentina. Right?	5	Q Did you apply to any other internship
	A. Right.	1	programs?
6	Q Went to all your grade school and high	6	A. No.
7	school in Argentina?	7	Q. Just the Hadassah University in Jerusalem?
8	A. Correct.	8	A. Yes
9	Q Passed an entrance exam and went to	9	Q. What did you do after your internship?
10	medical school?	10	A. I did my residency in psychiatry
11	A. Yes.	11	Q. Immediately after?
12	Q. And how old were you at that point?	12	A. Immediately after
13	A. I was 16.	13	Q. Stayed in Jerusalem?
14	Q And how old were you when you got out of	14	A. Yes.
15	medical school?	15	Q. And after that?
16	A 22	16	A. After that, I came to Boston to train in
17	Q What did you do after that?	17	child psychiatry.
18	A. I did my internship in Hadassah Medical	18	Q You weren't a research fellow at the
19	Center, Hebrew University, Jerusalem.	19	Jerusalem Medical Health Center?
20	Q Why did you go to Jerusalem?	20	A Yes, that was part of the residency.
21	A. Because I wanted to	21	Q. Then you came to Boston to do your
22	Q. Why did you want to?	22	clinical training?
23	A. Because I felt like it.	23	A. I came to Boston to train in child
24	Q. And why did you feel like it?	24	psychiatry.
25	A. That was my choice	25	Q Did you have any child psychiatry training
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009		
	February 26, 2009 Page 39		February 26, 2009 Page 40
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2	February 26, 2009 Page 39 in Jerusalem? A. No.	2	February 26, 2009 Page 40 Q. But your first pediatric psychiatry training was at the Children's Hospital at Harvard.
2	February 26, 2009 Page 39 in Jerusalem? A. No. Q. What was the nature of the child	2	February 26, 2009 Page 40 Q. But your first pediatric psychiatry training was at the Children's Hospital at Harvard. Right?
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 41		Page 42
ī	A. Since the mid '90s. Or, I don't remember,	1	Q Just once?
2	but it's listed in the C V., I think A few years	2	A. No
3	after my training, so in the '80s I completed. You	3	Q. You were married before?
4	first need to pass the adult psychiatry board and	4	A. Yes.
5	then you are ready to go to the child psychiatry	5	Q For how long?
6	board. It's a lengthy process.	6	A Seven years
7	Q. Do you have any other kind of scientific	7	Q. How old were you when you first got
8	training at school, any kind of training in	8	married?
9			
10	epidemiology or biostatistics or anything like that?	9 10	A 23
11	A Not specifically. But I published 650	11	Q Was that in Israel?
12			A No, in Argentina.
	field of child psychiatry.	12	Q How old were you when you got married the
13	Q Despite being very well-known and	13	second time?
14	prolifically published, do you have any training in	14	A. 31 or 32
15	epidemiology or biostatistics?	15	Q And how old are you today?
16	ç	16	A 61
17	Q There is training that exists for purposes	17	Q How many articles did you say you've
18	of specializing in epidemiology, though, isn't	18	written over the course of your career, Doctor?
19		19	A. More than 600.
20		20	Q It says in your C.V. that during the
21		21	decade of the '90s you were the fourth highest
22		22	producer of high-impact papers in psychiatry as
23		23	determined by the Institute of Scientific Medicine
4		24	Is that correct?
25	, , ,	25	A That's correct.
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	Joseph Biederman February 26 2009		Joseph Biederman
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	February 26, 2009 Page 43		Joseph Biederman
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2345678901234567890	February 26, 2009 Page 43 Q. What does that mean? What's a high-impact paper? A. That is a formula that includes a citation and some other factor that I don't exactly remember, but has two components, a part of what's called the citation index Q And why does the number of times a paper is cited make a paper a high-impact paper? A Because the paper is cited when other people consider it important. Q. And so it's because other authors, other people that write on similar subjects, are relying on your paper in making whatever points they're making in their paper Right? A You can say so. I think that the quotations are when you are trying to make a case of what is the evidence for a scientific factor. I only write scientific papers, so they are used, for example, if somebody does epidemiological research and says that depression affects 10 percent of the	2 3 4 5 6 7 8 9 10 11 12 13 4 5 6 7 8 9 10 11 2 13 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 2 3 4 5 6 7 8 9 10 11 12 13 14 5 16 7 8 9 10 11 12 13 14 5 16 7 8 9 10 11 12 13 14 5 16 7 8 9 10 11 12 13 14 5 16 7 8 9 10 11 12 13 14 5 16 7 8 9 10 11 12 13 14 5 16 17 10 11 12 11 11 11 12 11 11 11 11 11 11 11	Joseph Biederman February 26, 2009 Page 44 familial, so that will be quoted Q. Now, it is a way of saying that your papers are influential in the scientific community. Right? A. The papers are quoted because the reader of the paper consider the paper as having scientific value Q. You don't think your papers are influential? A. I do not know what you mean by influential. But the papers are cited. When I cite a paper, it's because I consider the information of the paper that I am citing of scientific value and that's the reason I cite the paper. Q Okay Your papers are considered to be of high scientific value to other people that write papers. Right? A Yes. Q What is your problem with agreeing that your papers influence other scientific authors?
23456789012345678901	February 26, 2009 Page 43 Q. What does that mean? What's a high-impact paper? A. That is a formula that includes a citation and some other factor that I don't exactly remember, but has two components, a part of what's called the citation index Q And why does the number of times a paper is cited make a paper a high-impact paper? A Because the paper is cited when other people consider it important. Q. And so it's because other authors, other people that write on similar subjects, are relying on your paper in making whatever points they're making in their paper Right? A You can say so. I think that the quotations are when you are trying to make a case of what is the evidence for a scientific factor. I only write scientific papers, so they are used, for example, if somebody does epidemiological research and says that depression affects 10 percent of the population, so a paper would start "And depression	$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 1\\ 1\\ 1\\ 2\\ 1\\ 1\\ 1\\ 1\\ 1\\ 1\\ 1\\ 1\\ 1\\ 1\\ 1\\ 1\\ 2\\ 2\\ 2\\ 1\end{array}$	Joseph Biederman February 26, 2009 Page 44 familial, so that will be quoted Q. Now, it is a way of saying that your papers are influential in the scientific community. Right? A. The papers are quoted because the reader of the paper consider the paper as having scientific value Q. You don't think your papers are influential? A. I do not know what you mean by influential. But the papers are cited. When I cite a paper, it's because I consider the information of the paper that I am citing of scientific value and that's the reason I cite the paper. Q. Okay Your papers are considered to be of high scientific value to other people that write papers. Right? A. Yes. Q. What is your problem with agreeing that your papers influence other scientific authors? A. Because influence, as I understand the
234567890123456789012	February 26, 2009 Page 43 Q. What does that mean? What's a high-impact paper? A. That is a formula that includes a citation and some other factor that I don't exactly remember, but has two components, a part of what's called the citation index Q And why does the number of times a paper is cited make a paper a high-impact paper? A Because the paper is cited when other people consider it important. Q. And so it's because other authors, other people that write on similar subjects, are relying on your paper in making whatever points they're making in their paper Right? A You can say so. I think that the quotations are when you are trying to make a case of what is the evidence for a scientific factor. I only write scientific papers, so they are used, for example, if somebody does epidemiological research and says that depression affects 10 percent of the population, so a paper would start "And depression affects 10 percent of the population and I would	2 3 4 5 6 7 8 90 112 13 4 5 6 7 8 90 112 13 4 15 6 7 8 90 12 22 22 22 22 22	Joseph Biederman February 26, 2009 Page 44 familial, so that will be quoted Q. Now, it is a way of saying that your papers are influential in the scientific community. Right? A. The papers are quoted because the reader of the paper consider the paper as having scientific value Q. You don't think your papers are influential? A. I do not know what you mean by influential. But the papers are cited. When I cite a paper, it's because I consider the information of the paper that I am citing of scientific value and that's the reason I cite the paper. Q Okay Your papers are considered to be of high scientific value to other people that write papers. Right? A Yes. Q What is your problem with agreeing that your papers influence other scientific authors? A Because influence, as I understand the word, has a variety of meanings; and that is not
23456789012345678901223	February 26, 2009 Page 43 Q. What does that mean? What's a high-impact paper? A. That is a formula that includes a citation and some other factor that I don't exactly remember, but has two components, a part of what's called the citation index Q And why does the number of times a paper is cited make a paper a high-impact paper? A Because the paper is cited when other people consider it important. Q. And so it's because other authors, other people that write on similar subjects, are relying on your paper in making whatever points they're making in their paper Right? A You can say so. I think that the quotations are when you are trying to make a case of what is the evidence for a scientific factor. I only write scientific papers, so they are used, for example, if somebody does epidemiological research and says that depression affects 10 percent of the population, so a paper would start "And depression affects 10 percent of the population and I would like to cite this source " So if somebody does a	2 3 4 5 6 7 8 9 0 1 1 2 3 4 1 5 6 7 8 9 0 1 1 2 3 1 1 5 6 7 8 9 0 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Joseph Biederman February 26, 2009 Page 44 familial, so that will be quoted Q. Now, it is a way of saying that your papers are influential in the scientific community. Right? A. The papers are quoted because the reader of the paper consider the paper as having scientific value Q. You don't think your papers are influential? A. I do not know what you mean by influential. But the papers are cited. When I cite a paper, it's because I consider the information of the paper that I am citing of scientific value and that's the reason I cite the paper. Q Okay Your papers are considered to be of high scientific value to other people that write papers. Right? A Yes. Q What is your problem with agreeing that your papers influence other scientific authors? A Because influence, as I understand the word, has a variety of meanings; and that is not appropriate to science. So in science you build on
234567890123456789012234	February 26, 2009 Page 43 Q. What does that mean? What's a high-impact paper? A. That is a formula that includes a citation and some other factor that I don't exactly remember, but has two components, a part of what's called the citation index Q And why does the number of times a paper is cited make a paper a high-impact paper? A Because the paper is cited when other people consider it important. Q. And so it's because other authors, other people that write on similar subjects, are relying on your paper in making whatever points they're making in their paper Right? A. You can say so. I think that the quotations are when you are trying to make a case of what is the evidence for a scientific factor. I only write scientific papers, so they are used, for example, if somebody does epidemiological research and says that depression affects 10 percent of the population, so a paper would start "And depression affects 10 percent of the population and I would like to cite this source " So if somebody does a paper on ADHD and says that ADHD is familial, I	2 3 4 5 6 7 8 9 0 1 1 2 3 4 1 5 6 7 8 9 0 1 1 2 3 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Joseph Biederman February 26, 2009 Page 44 familial, so that will be quoted Q. Now, it is a way of saying that your papers are influential in the scientific community. Right? A. The papers are quoted because the reader of the paper consider the paper as having scientific value Q. You don't think your papers are influential? A. I do not know what you mean by influential. But the papers are cited. When I cite a paper, it's because I consider the information of the paper that I am citing of scientific value and that's the reason I cite the paper. Q Okay Your papers are considered to be of high scientific value to other people that write papers. Right? A Yes. Q What is your problem with agreeing that your papers influence other scientific authors? A Because influence, as I understand the word, has a variety of meanings; and that is not appropriate to science. So in science you build on blocks, one step at a time. So you want to go to
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2 3 4 5 6 7 8	February 26, 2009 Page 43 Q. What does that mean? What's a high-impact paper? A. That is a formula that includes a citation and some other factor that I don't exactly remember, but has two components, a part of what's called the citation index Q And why does the number of times a paper is cited make a paper a high-impact paper? A Because the paper is cited when other people consider it important. Q. And so it's because other authors, other people that write on similar subjects, are relying on your paper in making whatever points they're making in their paper Right? A. You can say so. I think that the quotations are when you are trying to make a case of what is the evidence for a scientific factor. I only write scientific papers, so they are used, for example, if somebody does epidemiological research and says that depression affects 10 percent of the population, so a paper would start "And depression affects 10 percent of the population and I would like to cite this source " So if somebody does a paper on ADHD and says that ADHD is familial, I	2 3 4 5 6 7 8 9 0 1 1 2 3 4 1 5 6 7 8 9 0 1 1 2 3 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Joseph Biederman February 26, 2009 Page 44 familial, so that will be quoted Q. Now, it is a way of saying that your papers are influential in the scientific community. Right? A. The papers are quoted because the reader of the paper consider the paper as having scientific value Q. You don't think your papers are influential? A. I do not know what you mean by influential. But the papers are cited. When I cite a paper, it's because I consider the information of the paper that I am citing of scientific value and that's the reason I cite the paper. Q Okay Your papers are considered to be of high scientific value to other people that write papers. Right? A Yes. Q What is your problem with agreeing that your papers influence other scientific authors? A Because influence, as I understand the word, has a variety of meanings; and that is not appropriate to science. So in science you build on blocks, one step at a time. So you want to go to

			IZ (Fages 45 CO 46)
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 45		Page 46
			-
1	I want to know the next	1	Q. So in 2005 you were number one in terms of
2	Q. So your papers serve as a building block	2	total citations to your papers on ADD and ADHD over
3	for a lot of other papers out there. Is that right?	3	the course of the past decade Is that right?
4	A. My papers are used for people that are	4	A. That is correct.
5	writing scientific papers to expand the scientific	5	Q. You had a total of 6,866 cites Let me
6	knowledge	6	start over. Over the course of the decade between
7	Q. But a lot of people who write papers on	7	1995 and 2005, there were a total of 6,866 cites to
8	subjects similar to yours rely on your papers as	8	your papers on ADD and ADHD. Is that right?
9	building blocks. Right?	9	A. That's correct
10	MR SPIVACK: Objection, asked and	10	Q That means that among the articles that
11	answered	11	were written on the subjects of ADD and ADHD, your
12	BY MR TRAMMELL:	12	papers were cited more than any other papers?
13	Q You have to answer.	13	A I would guess that's the interpretation.
14	A I do not know what you mean, rely. Could	14	Q. Do you know whether citations to your
15	you expand on that?	15	papers that disagree with what your papers say also
16	Q Well, what is the purpose of citing a	16	count?
17	paper?	17	A Yes In science you are allowed to
18	A The purpose of citing a paper is to	18	disagree. So a citation could be in a paper that
19	provide evidence that there is some factual	19	failed to replicate what I found
20	information that somebody has done the work before.	20	Q Do you know of any studies where that
21	And the example I used perhaps is the simplest to	21	occurred?
22	illustrate my point. If somebody does work on, say,	22	A. I do not know on top of my head, but there
23	depression will cite a paper that says depression is	23	are many in science. There is always different
24	prevalent. So that's not to influence; the paper is	24	opinions and different views; and when somebody is
25	a fact.	25	writing a scientific paper on a subject that I
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	Joseph Biederman	1	We have the second second second second
	February 26, 2009		Joseph Biederman February 26, 2009
1	February 26, 2009 Page 47	1	February 26, 2009
1 2	February 26, 2009	12	February 26, 2009 Page 48
	February 26, 2009 Page 47 address and they have different results, they will		February 26, 2009 Page 48 A. God.
2	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found	2	February 26, 2009 Page 48 A. God. Q Did you say God?
2 3	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.?	2 3	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah.
2 3 4 5 6	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of	2 3 4 5 6	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.?
2 3 4 5	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude.	2 3 4 5 6 7	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of
2 3 4 5 6 7 8	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to?	2 3 4 5 6 7 8	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing.
2 3 4 5 6 7 8 9	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what?	2 3 4 5 6 7 8 9	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical
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2 3 4 5 6 7 8 9 10 11 12	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic	2 3 4 5 6 7 8 9 10 11 12	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a
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2 3 4 5 6 7 8 9 10 1 12 13 14	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic promotions Q. What does that mean?	2 3 4 5 6 7 8 9 10 11 12 13 14	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a pharmaceutical company? A. I don't remember.
2 3 4 5 6 7 8 9 10 12 13 14 5	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic promotions Q. What does that mean? A. To move in the ranks from one rank, for	2 3 4 5 6 7 8 9 10 12 13 14 15	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a pharmaceutical company? A. I don't remember. Q. But you remember that you do or you have?
2 3 4 5 6 7 8 9 0 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 1 1 2 3 4 5 6 7 8 9 1 1 2 3 4 5 6 7 8 9 1 1 2 3 4 5 6 7 8 9 1 1 2 3 4 5 6 7 8 9 1 1 2 3 4 5 6 7 8 9 1 1 2 3 4 5 6 7 8 9 1 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 1 2	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic promotions Q. What does that mean? A. To move in the ranks from one rank, for example at Harvard there is instructor, from	2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 1 1 2 3 4 5 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 1 2 3 1 2 3 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 1	February 26, 2009 Page 48 A. God. Q. Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a pharmaceutical company? A. I don't remember. Q. But you remember that you do or you have? A. I remember that it is my practice if
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234567890123456789012 11234567890122222	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic promotions Q. What does that mean? A. To move in the ranks from one rank, for example at Harvard there is instructor, from instructor you move to assistant professor, from assistant professor you move to associate professor, and from associate professor? A. Mm-hmm.	2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 9 0 1 2 3 1 2 3 1 2 1 2 2 1 2 2 1 2 2 1 2 2 1 2 2 2 2	February 26, 2009 Page 48 A. God. Q. Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a pharmaceutical company? A. I don't remember. Q. But you remember that you do or you have? A. I remember that it is my practice if somebody asks for my C.V. for a reason, I send my C.V. Q. Do you recall whether any pharmaceutical companies have asked you for your C V.? A. Not specifically. Q. Is this something that's well-known about
234567890123456789012345678901223	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic promotions Q. What does that mean? A. To move in the ranks from one rank, for example at Harvard there is instructor, from instructor you move to associate professor, and from associate professor you move to full professor Q. Full professor? A. Mm-hmm Q. What rank are you?	234567890112345678901223	February 26, 2009 Page 48 A. God. Q Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a pharmaceutical company? A. I don't remember. Q. But you remember that you do or you have? A. I don't remember. Q. But you remember that you do or you have? A. I remember that it is my practice if somebody asks for my C.V. for a reason, I send my C.V. Q. Do you recall whether any pharmaceutical companies have asked you for your C V.? A. Not specifically. Q. Is this something that's well-known about you, that you are a prolific writer of high-impact
23456789012345678901234567890123456789012234	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic promotions Q. What does that mean? A. To move in the ranks from one rank, for example at Harvard there is instructor, from instructor you move to assistant professor, from assistant professor you move to associate professor, and from associate professor? A. Mm-hmm. Q. What rank are you? A. Full professor	23456789012345678901234 112345678901234	February 26, 2009 Page 48 A. God. Q. Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a pharmaceutical company? A. I don't remember. Q. But you remember that you do or you have? A. I remember that it is my practice if somebody asks for my C.V. for a reason, I send my C.V. Q. Do you recall whether any pharmaceutical companies have asked you for your C V.? A. Not specifically. Q. Is this something that's well-known about you, that you are a prolific writer of high-impact papers?
234567890123456789012345678901223	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic promotions Q. What does that mean? A. To move in the ranks from one rank, for example at Harvard there is instructor, from instructor you move to assistant professor, from assistant professor you move to associate professor, and from associate professor you move to full professor Q. Full professor? A. Mm-hmm Q. What rank are you? A. Full professor Q What's after that?	234567890112345678901223	February 26, 2009 Page 48 A. God. Q. Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a pharmaceutical company? A. I don't remember. Q. But you remember that you do or you have? A. I don't remember. A. I remember that it is my practice if somebody asks for my C.V. for a reason, I send my C.V. Q. Do you recall whether any pharmaceutical companies have asked you for your C V.? A. Not specifically. Q. Is this something that's well-known about you, that you are a prolific writer of high-impact papers? MR. SPIVACK: Objection, calls for
2345678901123456789012234 10123456789012234	February 26, 2009 Page 47 address and they have different results, they will say that contrary to what I reported, they found differently. Q. Why did you put this information in your C.V.? A. Because it's an honor to have citations of this magnitude. Q. Who do you send this C V to? A To what? Q To whom do you send this C V.? What do you use it for? A The C.V s are largely used for academic promotions Q. What does that mean? A. To move in the ranks from one rank, for example at Harvard there is instructor, from instructor you move to assistant professor, from assistant professor you move to associate professor, and from associate professor? A. Mm-hmm. Q. What rank are you? A. Full professor	23456789012345678901234 112345678901234	February 26, 2009 Page 48 A. God. Q. Did you say God? A. Yeah. Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.? A. Because a C.V. is a running notation of what is my work and what I'm doing. Q. Do you send this to pharmaceutical companies? A. Only if they ask me. Q. When was the last time you sent it to a pharmaceutical company? A. I don't remember. Q. But you remember that you do or you have? A. I remember that it is my practice if somebody asks for my C.V. for a reason, I send my C.V. Q. Do you recall whether any pharmaceutical companies have asked you for your C V.? A. Not specifically. Q. Is this something that's well-known about you, that you are a prolific writer of high-impact papers?

	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 49		Page 50
	· · · · ·		-
1	speculation	1	of all the plaintiffs at this proceeding that your
2	MR FIBICH: The objection, I think, is	2	word "objection" preserves for the record any
3	"objection" only under the rules. So if you would	3	objection you want to raise as to the matter that
4	please not suggest answers to your witness by going	4	you've just objected to
5	further than saying "objection."	5	MR. SPIVACK: On any basis?
6	MR. SPIVACK: I am stating my basis for	6	MR. TRAMMELL: As to the form of the
7	the record; I'm not suggesting to the witness	7	question.
8	MR. TRAMMELL: It's improper.	8	MR SPIVACK: All right. And there may be
9	MR. FIBICH: Well, Mr. Spivack, we have	9	situations, for example if you ask a question that
10	the right to ask you to state the basis for your	10	calls for privileged information
11	objection, but in the absence of that, I think the	11	MR. TRAMMELL: Sure That's different.
12	proper way to object and preserve your objections	12	MR SPIVACK: So on that, you're saying I
13	for the record is to say one word, "objection "	13	can
14	MR. SPIVACK: Are you referring to the New	14	MR. FIBICH: Sure. Anything that you
15	Jersey rules or the Massachusetts rules?	15	think is improper that we're inquiring into, you can
16	MR. FIBICH: Yes, sir, New Jersey	16	instruct the witness not to answer on the basis of
17	MR SPIVACK: And to which rule are you	17	privilege
18	referring?	18	MR. SPIVACK: All right
19	MR FIBICH: I'll pull it out for you, if	19	BY MR TRAMMELL:
20	you'd like, at the break. I truly want to proceed	20	Q Doctor, do you know whether you have a
21	in this deposition without any interruptions, but	21	reputation for writing high-impact papers?
22	I find those to be speaking objections that are	22	A. The high-impact paper is determined by
23	intended to suggest answers to the witness, and I	23	others So the listed data that is in the C V is
24	would ask that you not do it	24	what others compiled about me, not me
25	For the record, I am stipulating on behalf	25	Q. Okay But you recognize and the reason
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	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 51		Page 52
	-		-
1	you put this in here is you want people who read	1	Q. So this is in there so that the people who
2	your C V to know you write papers that doctors read	2	read your C V know who they're dealing with, that
3	and rely on Right?	3	you are a great scientist Right?
4	A. I put it in the C V. because it's an honor	4	MR SPIVACK: Objection, argumentative
5	to be recognized by my peers as my scientific work	5	MR. TRAMMELL: I'll object to your
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in your C V ?

Q.

Α.

being of importance to them positively

Q. I don't understand. Are you just bragging

or is there some purpose for having this information

A No The purpose of the information is

saying that I'm great. I'm saying that this is the

information for anybody that reads your C.V.?

Because I think -- I am very proud of that

recognized by your peers through my scientific work.

Since I am a scientist, science has the peer-review

So why have it in your C.V.?

and I consider that it is a great honor to be

process, which is a very critical part of the

practice of science. To be recognized that the

papers that I write have scientific utility to my

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factual This is stating the facts I am not

Q. What's the practical use of that

facts that were compiled about me.

A. There is no practical use

peers is of great honor to me.

objection. It's improper under the rules. MR. SPIVACK: Well, actually, my colleague here shows me the New Jersey rules, which say under 4:14 dash -- I think it was 3 -- 4:14-3 that if 10 there is an objection to the form of the question, the objector shall state the basis for the objection so as to allow the questioner to amend the question. So that appears to be the reverse of what Mr. Fibich said

15 MR FIBICH: No Under 4:14-3(c), "No 16 objection shall be made during the taking of a 17 deposition except those addressed to the form of a 18 question or to assert a privilege, a right to 19 confidentiality, or a limitation pursuant to a 20 previously entered court order. The right to object 21 on other grounds is reserved and may be asserted at 22 the time the deposition testimony is proffered at 23 trial." 24 MR. SPIVACK: Would you read the next

sentence? Stratos Legal Services

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Joseph Biederman February 26, 2009 Page 53 MR FIBICH: "An objection to the form of a question shall focus attament by the objector a sto why the form is objectionable is as to allow the interregator to anend the question. No 5 objection shall focus on the question. No 5 objection shall focus on the question. No 6 objection shall focus on the question. No 7 Well, still think I interpret this to 9 suggest an answer. 10 MR SPIVACK: I am not suggesting the 11 answer. Suggesting an answer would be improper 11 know what a speaking objection is, Mr Fibh. In 12 know what a speaking objection is, Mr Fibh. In 13 order to allow Mr Tranmell to amend the form of his 14 question, a she rule states, if if is an objection 15 to the form of the question, I will state a short 16 Q Doctor, with which drug companies do you 14 may have utility for the management 16 objection that write in my scientific papers. 17 BPY MR. TRAMMELL: 18 work with a speaking objection is, Mr Fibh. In 19 OV is so that everyhody will know that you are an 19 forfloamial, improvant scients. Rujh? 20 in infloamiation that I write in my scientific papers 20 wefful. 21 consulting relationship? 25 ueffel. an very proud that my pares find the 21 consulting relationship? 25 ueffel. an very proud that my pares find the 21 consulting relationship? 25 ueffel. an very proud that my pares find the 21 consulting relationship? 26 A ley list in the CV because as a 27 professional relationship? 27 and what is the nature of that 28 of ensulting relationship? 28 A call why that you mean by 25 trat cos Legal Services 29 Q With which do you not have a consulting 20 one drug. Some of the pharmaccutical companies have 29 of whis which anse a professional relationship with dozens of drug manufacturers. 20 of any charter tell you There are multiple 29 drught and you have a professional 20 on drugs. Some of the pharmaccutical companies have 20 A drught is the nature of that 20 on drugs. Some of the pharmaccutical companies have 20 or tha very side drught any protecond that the sp			1	
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 57		Page 58
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1	which you've worked with Janssen or any of the	1	that medical education is delivered It's delivered
2	affiliated companies that are responsible for	2	in the form of lectures, it's delivered in the form
3	Risperdal?	3	of seminars, it's delivered in the form of grand
4	A. I do essentially two things. I do medical	4	rounds.
5	education and consulting.	5	Q So when you say medical education, you're
6	Q. What is medical education?	6	talking about grand rounds, lectures, and seminars.
7	A Medical education are CME activities,	7	Right?
8	talks.	9	A Mm-hmm, correct
10	Q. And what that means is that there is a continuing medical education event attended by	10	Q. Anything else?A. That's the majority of it.
11	doctors at which you will speak on Janssen's behalf.	11	Q. What are grand rounds?
12	Right?	12	A. Grand rounds are academic talks that
13	A. The CME activities are sometimes funded by	13	academic institutions organize to educate their
14	different pharmaceutical companies. The content is	14	faculty
15	not necessarily dictated by the pharmaceutical	15	Q Who pays for those?
16	companies. For example, I may be invited to give	16	A. I don't know who pays for that. Sometimes
17	grand rounds at the medical center and that program	17	it's paid by funds that the institution has
18	or that grand round series is supported by	18	Sometimes the institution solicits outside funding
19	pharmaceuticals, but not necessarily a one-to-one	19	Q But if you go speak at grand rounds,
20	correspondence	20	somebody pays you for your time Right?
21	Q. Well, okay When you talk about medical	21	A. Yes
22	education, what are you talking about? Are you	22	Q. And when you go to grand rounds to talk
23	talking about CMEs or grand rounds or is that the	23	about Risperdal, who pays you for your time?
24	same thing in your opinion?	24	A I never talk on Risperdal I talk on the
25	A No. CME is a larger category of the way	25	diseases that risperidone may treat, like pediatric
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009		February 26, 2009
	February 26, 2009 Page 59		February 26, 2009 Page 60
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2	February 26, 2009 Page 59 bipolar illness in this case To my recollection, I talk on the diseases that risperidone may treat.	1 2	February 26, 2009 Page 60 Q. What are lectures in the context of your medical education activities?
2 3	February 26, 2009 Page 59 bipolar illness in this case To my recollection, I talk on the diseases that risperidone may treat. I never talk of my knowledge on risperidone as a	1 2 3	February 26, 2009 Page 60 Q. What are lectures in the context of your medical education activities? A. Could you explain the question? I'm not
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2 3 4 5	February 26, 2009 Page 59 bipolar illness in this case To my recollection, I talk on the diseases that risperidone may treat. I never talk of my knowledge on risperidone as a talk on risperidone Q When you go talk about the diseases which	1 2 3 4 5	February 26, 2009 Page 60 Q. What are lectures in the context of your medical education activities? A. Could you explain the question? I'm not sure what are you asking? Q. Sure I asked you what medical education
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 61		Page 62
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1	twelve child psychiatrists kind of discussing cases O And this is all Your medical education	1	has been limited to ADHD and pediatric bipolar disease. Right?
3	Q And this is all Your medical education is separate from your consulting relationship with	3	A. That is the predominance of my scientific
4	Janssen. Right?	4	work, not the only. I have been interested in
5	A Yes.	5	children that have psychopathology and I have done
6	Q Who pays you to go talk at seminars?	6	work on children at risk for bipolar disease. I
7	A Depending on who has invited me.	78	have been interested in children with autism
9	Q. When was the last time you did it? A. About a year ago	9	spectrum, children with anxiety. But the bulk of my papers have been on ADHD and pediatric bipolar
10	Q. And who invited you?	10	illness.
11	A. I don't remember.	11	Q. How many times a year do you think you
12	Q. Do you know where it was?	12	participate in medical education events as a
13	A. No.	13	speaker?
14 15	Q Do you know what you talked about? A Say again?	14 15	A. It's hard to know. I think last year I have done much less than in the past. I would say a
16	Q Do you know what you talked about?	16	dozen times or so.
17	A I talk about two subjects, ADHD or	17	Q A dozen times a year?
18	pediatric bipolar illness	18	A I really cannot tell you an exact number.
19	Q Is your specialty limited to ADHD and	19	Q. Does that mean in the last year you've
20	pediatric bipolar disease?	20 21	gotten fewer invitations to do these things? A. Yes.
21 22	A. Pretty much. I treat all conditions in child psychiatry, but those are the conditions that	22	Q. Do you have any idea why that is?
23	my scientific work has focused on.	23	A. There has been some accusation by Senator
24	Q So your study to the extent you've studied	24	Grassley about issues of conflict of interest; and
25	these diseases and drugs that treat them, your study	25	while the investigation is going on, I agreed not to
	Stratos Legal Services 800-971-1127		Stratos Legal Services 800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009	1	February 26, 2009
			2 .
	Page 63		Page 64
1	speak.	1	Page 64 in issues of conflict of interest and is interested
2	speak. Q What is the nature of Senator Grassley's	1 2	Page 64 in issues of conflict of interest and is interested in making sure that the universities have tight
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 65		Page 66
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1	Q. Did you destroy any?	1 2	Mr Fibich, you are here representing the same party Under New Jersey rules and procedures,
3	Q. Did you destroy any? A. No.	3	you are not permitted It's two lawyers for the
4	Q Were the documents you gave them produced	4	same party
5	to us here?	5	MR TRAMMELL: I think, just to be clear,
6	A. Say that again?	6	I think I'm also pro hac'd in the in re case, and so
7	Q. Were the documents you gave to the school	7	I represent all plaintiffs in addition to this
8	in response to Senator Grassley's investigation	8	plaintiff particularly
9	produced to us here?	9	MR PECK: I think you're wrong I think
10	A I believe that anything that has to do	10	the pro hac application was for the Avila case as
11	with risperidone was produced	11	well as for Mr Fibich Now, we can check easily
12	MR FIBICH: Objection, nonresponsive	12	MR TRAMMELL: Sure Well, in any event,
13	BY MR TRAMMELL:	13	your objection is noted
14	Q Were the documents you gave	14	BY MR TRAMMELL:
15	MR PECK: Excuse me, Mr Trammell I	15	Q Did you send Did you produce to the
16	think at this point I ought to raise this for the	16	plaintiffs in this litigation everything that you
17	record.	17	produced or that was produced by your school to
18	Both Mr. Fibich and yourself were admitted	18	Senator Grassley?
19 20	pro hac in the Foti case, and it is inappropriate	19 20	A The information that I produced, as I told
20 21	for two lawyers to speak for or question or object for the same party. It's been going on for the	20	you at the beginning, was sent to the lawyers and I assumed that my lawyers would produce whatever you
22	first hour or so, and I just raise this for the	22	need.
23	record. Mr. Trammell is asking the questions	23	Q. That's not the question I was asking
24	Mr. Trammell has the right to object to answers that	24	When you were requested to produce documents to
25	are nonresponsive	25	Harvard and to MGH so that they could respond to
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Jacob Diedermen		
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
1	February 26, 2009 Page 67 Senator Grassley, you produced certain documents to	1	February 26, 2009 Page 68 Q. Do you have any idea what they're charging
2	February 26, 2009 Page 67 Senator Grassley, you produced certain documents to the school and to the hospital Right?	2	February 26, 2009 Page 68 Q. Do you have any idea what they're charging the hospital?
2 3	February 26, 2009 Page 67 Senator Grassley, you produced certain documents to the school and to the hospital Right? A That's correct	2 3	February 26, 2009 Page 68 Q. Do you have any idea what they're charging the hospital? A. I have no idea
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	Joseph Biederman		Joseph Biederman
	February 26, 2009 Page 69		February 26, 2009 Page 70
	-		-
1	A. You want a list of people? I told my	1	with respect to this deposition?
2	staff because I have been absent from taking care of	2	A I just mentioned that I have this
3	my usual duties because of the time that you	3	deposition
4	required from me, so I told them that I am in a	4	Q That's it?
5	deposition.	5	A Yes
6	Q. And where does your wife think you are	6	Q Just said "By the way, I have a deposition
7	today?	7	this week"?
8 9	A. My wife?	9	A Yeah. I cannot see them; I cannot partake in some social activity
10	Q She know you're here? A. My wife knows that I am here.	10	Q What is Partners HealthCare?
11	Q. Okay. Did you talk to anybody else about	11	A Partners HealthCare is the umbrella
12	the deposition?	12	organization of several health care organizations
13	A. I do not know what you want from me What	13	such as Mass. General, Brigham and Women's, Faulkner
14	exactly ? Could you be specific about what	14	Hospital, and some other institutions
15	information you're asking?	15	Q Do you work for Partners HealthCare?
LG	Q. Sure.	16	A Indirectly. I work for Mass General
.7	A. You want a complete list of people that I	17	That is one of Partners HealthCare's institutions
18	talked to, or what do you want?	18	In fact, my ID badge says Partners
9	Q. I want a complete list of people with whom	19	Q. Who is general counsel of Partners?
20	you have spoken about this deposition.	20	A I have no idea
21	A. My children know about this deposition	21	Q Have you ever heard of Paul Cushing?
22	Some of my friends know about this deposition.	22	A. Paul Cushing? Paul Cushing is a lawyer in
23	Q. What did you and your friends	23	the office of the general counsel, yes
24	A. My staff. Say that again?	24	Q Okay Did you talk to him about the
25	Q What did you and your friends talk about	25	deposition?
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	800-971-1127 		800-971-1127 Joseph Biederman February 26, 2009
1	300-971-1127 Joseph Biederman February 26, 2009	1	800-971-1127 Joseph Biederman February 26, 2009
1 2	300-971-1127 Joseph Biederman February 26, 2009 Page 71	12	800-971-1127 Joseph Biederman February 26, 2009 Page 7
	300-971-1127 Joseph Biederman February 26, 2009 Page 71 A. This one?		800-971-1127 Joseph Biederman February 26, 2009 Page 7 the nature of your consulting relationship with Janssen? A. The nature is an ad hoc consulting
2 3 4	Joseph Biederman February 26, 2009 Page 71 A. This one? Q. Yes. A No. Not that I know of. Q When you met with Hogan & Hartson	2	300-971-1127 Joseph Biederman February 26, 2009 Page 7: the nature of your consulting relationship with Janssen? A. The nature is an ad hoc consulting arrangement that if they assemble, for example, an
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2345678901234567	Joseph Biederman February 26, 2009 Page 71. A. This one? Q. Yes. A No. Not that I know of. Q When you met with Hogan & Hartson yesterday and Tuesday, were Janssen lawyers there? A No. Q Who all was in the room? A. Myself and the two gentlemen that are here to my left. Q. And no one else? A. No Well, it was my house. My housekeeper was around and my wife was around. Q. And can you tell us who your lawyers are? A. Yes. It's Peter Spivack and Keith Burney. Q. Now, in addition to medical education activities, you said you do consulting work for Janssen Right?	2 3 4 5 6 7 8 9 0 11 2 3 4 5 6 7 11 2 3 4 5 6 7 11 2 3 4 5 6 7 11 2 3 4 5 6 7 11 2 3 4 5 6 7 11 2 12 3 14 5 6 7 8 9 0 11 2 3 14 5 6 7 8 9 0 11 2 3 14 5 6 7 8 9 0 11 2 3 14 5 6 7 8 9 0 11 2 3 14 5 6 7 8 9 0 11 2 3 14 5 6 7 8 9 0 11 2 3 14 5 1 1 2 3 14 5 1 1 2 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Joseph Biederman February 26, 2009 Page 7: the nature of your consulting relationship with Janssen? A. The nature is an ad hoc consulting arrangement that if they assemble, for example, an advisory board, I may partake if my time permits. That's the nature of the consulting. I don't have any formal title of consultant. Q. Can you tell me all the types of consulting that you've done for Janssen? A. My consultation has to do with the issues pertaining to the design of clinical trials, science, these type of things. Q. Okay, I want to be a little more specific. Do you participate in ad boards, advisory boards? A. Sometimes, yes. Q So advisory boards is one thing you do as part of your consulting relationship. Right?
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Joseph Biederman February 26, 2009 Page 74 research that is funded by Janssen, if this is t you are asking. So they fund studies that you're going to r that you're going to be involved in. Right? Yes. That will result in some sort of ication. Right? Yes. That'll be written by you. Right? Yes Is that it? Just the research, the ulting, and the medical affairs speaking? (Witness nodded) What kind of advisory boards have you cipated in for Janssen? Well, Janssen had a few years of something they called the T&S Summit that brought
Page 74 research that is funded by Janssen, if this is t you are asking. So they fund studies that you're going to r that you're going to be involved in. Right? Yes That will result in some sort of ication. Right? Yes That'll be written by you. Right? Yes Is that it? Just the research, the ulting, and the medical affairs speaking? (Witness nodded) What kind of advisory boards have you cipated in for Janssen? Well, Janssen had a few years of something
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ther hundred or so psychiatrists, adult and I psychiatrists in the country, to interchange ntific information One year was focused on stic, another year was focused on neuroimaging
hose are kind of And during those meetings e were smaller groups For example, for me it child psychiatry and things of that type And where do those meetings take place? Stratos Legal Services 800-971-1127 Joseph Biederman
February 26, 2009
Page 76
 Well, what kind of hotel did you stay at? It was a hotel that they made arrangements ay Where did you stay in Arizona? I don't remember. A hotel. They pay you for your time? Yes. How much did they pay you an hour for an sory board? I believe the advisory board, I think the brarium, I think it was two or three thousand ars for the day. I'm sorry. Didn't mean to interrupt you wo or three thousand dollars per day for For one day. The meeting was one day

			20 (Pages 77 to 80
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 77		Page 78
	raye //		-
1	A. Usually they write me a check	1	A Yeah, that's correct
2	Q To you personally?	2	Q. When did your relationship with Janssen
3	A. To me personally.	3	begin?
4	Q. And what do you do with that money?	4	A I really don't remember. Janssen
5	A. I deposit the money in my account.	5	developed risperidone, was approved in the '90s, so
б	Q. Do you know how many times you've	6	we became interested in risperidone after observing
7	participated in advisory boards for Janssen?	7	that it's a useful treatment for our patients. So I
8	A I don't remember.	8	think our paper was in the mid '90s, I would say in
9	Q. Do you think it's a hundred?A. I don't think so	9 10	the late '90s or so. Mid to late '90s it would be. Q Do you know when Risperdal was approved
10 11		11	for marketing?
12	Q. Do you think it's fifty?A I do not know.	12	A. I don't remember exactly. I think it's in
13	Q. Could it be fifty?	13	the early '90s, in the 1990s.
14	A I don't think so	14	Q. '93?
15	Q. But you don't know?	15	A '93 sounds right
16	A. I don't remember.	16	Q. Okay After it was approved, you started
17	Q Okay I asked you earlier, and just to be	17	using it in your patients Right?
18	clear, just so that we've got just so we	18	A. Not immediately. In our clinical care of
19	understand the nature of the relationship, they fund	19	children with bipolar illness we observed that the
20	your research, you do consulting which consists only	20	traditional treatments, mainly lithium, Depakote,
21	of advisory board activity or whatever other random	21	carbamazine, did not work very well. The treatment
22	questions they have for you, and you do speaking at	22	took months to unfold and was associated with very
23	medical education events, and that is the entire	23	high rates of relapse So we noted that the second-
24	scope of your relationship with Janssen Is that	24	best treatment that benefited these children were
25	right?	25	atypical neuroleptics. So at that time when we
	Stratos Legal Services 800-971-1127		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
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2 3 4 5 6 7 8 9 0 11 2 3 4 5 6 7 8 9 0 11 2 3 4 5 6 7 8 9 0 11 2 3 4 5 6 7 8 9 0 11 2 3 4 5 6 7 8 9 0 11 2 3 4 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 11 2 5 6 7 8 9 0 1 1 2 8 9 0 1 1 2 8 9 1 1 1 2 8 9 1 1 1 2 8 9 1 1 1 2 1 1 2 1 1 2 1 1 1 1 2 1 1 1 1	February 26, 2009 Page 79 finished doing analysis on this, the only atypical outside of Clozaril that was available was risperidone, so we began using risperidone in our practice And we noticed it was very helpful to our Q. You say the second-best treatment for children was atypicals? A. No, not second-best What I said, the second outside Clozaril Let me go back. We did an analysis that we published on what helps children with bipolar illness So we noted that in the paper that was published in the Journal of Clinical Psychiatry, that this is about 100 children that had the diagnosis, treated by about a dozen doctors. So we noted that the traditional treatments that were mainly lithium, carbamazine, valproic acid was helpful selectively more than anything else, but the treatment took very long to unfold and was associated with very high rates of relapse. The second-best treatment after the traditional mood stabilizers were the typical first-generation antipsychotics So at that time when we finished the analysis, it took several years to do, risperidone was available, so I would say it was mid 1990s And	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	February 26, 2009 Page 80 in our clinic when we treated children with risperidone added on to other medicines, we noticed that children improved. So we were very interested in exploring the usefulness of risperidone further as monotherapy MR FIBICH: Objection, nonresponsive MR TRAMMELL: Objection, nonresponsive BY MR. TRAMMELL: Q. Do you recall whether you initiated the contact with Janssen to begin the professional relationship that you've described or they initiated the contact? A. I approached Janssen in the mid 1990s after I noticed that risperidone worked for our patients in the paper that we published. We approached them - I approached them to see if they would be interested to do a clinical trial. Q. So you published on this subject before you approached Janssen? A. I published on the subject before I approached Janssen Q. And what paper is that? A. It was a paper, a case series that we published that is in my C.V. that we added risperidone to I think two dozen children on top of

		1	
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 81		Page 82
1	other treatments that they were receiving and we	1	Q. And what's a medical liaison?
2	noted that it was very helpful.	2	A. A medical liaison is a person that
2		3	interacts on medical and scientific matters between
4	Q. Where was that published?	4	
	A. I don't recall, but I can do a computer	5	Janssen or the pharmaceutical company and academia, doctors
5	search and I can find the paper for you.	6	
6	Q I think I have it		Q. But he works for the pharmaceutical
7	So you initiated contact with Janssen to	7	company. Right?
8	let them know that you were studying the use of	8	A. Yes.
9	Risperdal in kids and you wanted to do what?	9	Q. Now, you testified earlier that you
0	A. I approached them to seek funding to do a	10	initiated a contact with Janssen in the late '90s
1	clinical trial of risperidone monotherapy	11	asking them if they would be willing to fund a study
2	MR. TRAMMELL: Let's take a break	12	of the use of Risperdal in kids Right?
3	THE VIDEOGRAPHER: The time is 10:32.	13	A I think it's in the
4	We're off the record	14	MR PECK: Object, form
5	(Short recess taken)	15	A I think it's in the mid '90s I don't
б	THE VIDEOGRAPHER: This is the beginning	16	remember the dates, but somewhere in the '90s.
7	of tape number 2 We're back on the record. Time	17	Q Did Janssen ever Now, before that time
8	is 10:53.	18	did Janssen ever request that you put together a
9	BY MR. TRAMMELL:	19	trial proposal for generally the same type of study?
0	Q. Dr. Biederman, you understand you're still	20	A. All proposals came from me to Janssen, not
1	under oath Right?	21	the other way around
2	A. Yes.	22	Q. Okay. They never requested that you put
3	Q. Who is John Bruins?	23	together a study to evaluate the use of Risperdal in
4	A John Bruins was the medical liaison person	24	kids. Right?
5	for Janssen in the '90s	25	A To my recollection, I submitted proposals
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		
	000 0/1 112/		800-971-1127
	Joseph Biederman		Joseph Biederman
	Joseph Biederman		Joseph Biederman
1	Joseph Biederman February 26, 2009 Page 83 to them. They may have asked to expand on what I	1	Joseph Biederman February 26, 2009 Page 84 kids?
	Joseph Biederman February 26, 2009 Page 83		Joseph Biederman February 26, 2009 Page 84 kids? MR.PECK: Objection to form
2	Joseph Biederman February 26, 2009 Page 83 to them. They may have asked to expand on what I submitted, but the idea of doing a trial came from me.	1	Joseph Biederman February 26, 2009 Page 84 kids?
2 3	Joseph Biederman February 26, 2009 Page 83 to them. They may have asked to expand on what I submitted, but the idea of doing a trial came from	1 2	Joseph Biederman February 26, 2009 Page 84 kids? MR.PECK: Objection to form
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2 3 4 5	Joseph Biederman February 26, 2009 Page 83 to them. They may have asked to expand on what I submitted, but the idea of doing a trial came from me. Q Do you know approximately what year you	1 2 3 4 5 6	Joseph Biederman February 26, 2009 Page 84 kids? MR PECK: Objection to form A. I don't remember. I think that my first proposal was denied, so my guess that the answer is
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2 3 4 5 6 7 8 9	Joseph Biederman February 26, 2009 Page 83 to them. They may have asked to expand on what I submitted, but the idea of doing a trial came from me. Q Do you know approximately what year you first submitted a trial proposal to Janssen? A. Somewhere in the '90s. I don't remember. In the mid '90s Q. Any of those ten years? A. Hmmm?	1 2 3 4 5 6 7	Joseph Biederman February 26, 2009 Page 84 kids? MR. PECK: Objection to form A. I don't remember. I think that my first proposal was denied, so my guess that the answer is that they refused. Q. So the first proposal you sent to them, they refused to fund the study? A. Yes. Q. Did that bother you?
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2345678901234567	Joseph Biederman February 26, 2009 Page 83 to them. They may have asked to expand on what I submitted, but the idea of doing a trial came from me. Q Do you know approximately what year you first submitted a trial proposal to Janssen? A. Somewhere in the '90s. I don't remember. In the mid '90s Q. Any of those ten years? A. Hmmm? Q. Any of those ten years? A. I don't remember the exact date. I would say somewhere in the middle of 1990s, I would guess. The answer is I don't remember the date. Q The first record I've seen is 1998, correspondence between you, from you to Janssen.	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 7 8 9 0 1 1 2 3 4 5 7 8 9 0 1 1 2 3 4 5 1 2 3 4 5 1 2 3 4 5 1 2 3 1 2 3 4 5 1 2 3 1 1 2 3 1 2 3 1 2 3 1 1 2 3 1 2 3 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 1 1 1 1	Joseph Biederman February 26, 2009 Page 84 kids? MR. PECK: Objection to form A. I don't remember. I think that my first proposal was denied, so my guess that the answer is that they refused. Q. So the first proposal you sent to them, they refused to fund the study? A. Yes. Q. Did that bother you? A. Proposals are submitted to do a study. If the study is not done, it's disappointment. Q. But it didn't bother you, did it? A. Could you define bother? Q. Sure. Were you upset? A. I don't think I was upset. I was disappointed Q. So not upset, just disappointed Right?
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 85		Page 86
ī	proposal Right?	1	A This e-mail?
2	A I think so	2	Q Yes
3	Q And did that affect your prescribing	3	A Okay
4	practices of Risperdal?	4	Q You see that?
5	A. Not at all.	5	A. Yes
6	Q. Did it affect your professional	6	Q It's dated November 17, 1999; the subject
7	relationship with Janssen?	7	is Dr Joseph Biederman payment. Do you see that?
8	A Not at all	8	A. Just one second. John Bruins, Wednesday,
9	Q How long was it between the time that they	9	November What date you are talking about?
10		10	November 17?
11	either side that you would do more research?	11	Q. November 17, 1999
12		12	 A. Subject and payment, yes
13	5 1	13	Q Okay And the subject is "Dr Joseph
14	Q. Did you ever try to get back at Janssen	14	Biederman payment " Right?
15	1	15	A Correct
16		16	Q If you go down and look at the second
17	·	17	bullet point here, it says "Three or four years ago
18	, , ,	18	Janssen H O, " which I assume means home office, but
19		19 20	maybe you know better, "requested that he put together a study to evaluate Risperdal in the shild
20 21	•	20 21	together a study to evaluate Risperdal in the child and adolescent population He submitted a thorough
22		22	and lengthy proposal which amounted to approximately
23		23	\$280,000 We dragged our heels on his request,
24		24	which we made, for over a year. He finally received
25		25	a standard ding letter. By the time I found out
	Stratos Legal Services		Stratos Legal Services
1			
	800-971-1127		800-971-1127
	800-971-1127		800-971-1127
	800-971-1127 Joseph Biederman		800-971-1127 Joseph Biederman
	800-971-1127 Joseph Biederman February 26, 2009		800-971-1127 Joseph Biederman February 26, 2009
	800-971-1127 Joseph Biederman		800-971-1127 Joseph Biederman
1	800-971-1127 Joseph Biederman February 26, 2009 Page 87	1	800-971-1127 Joseph Biederman February 26, 2009 Page 88
12	800-971-1127 Joseph Biederman February 26, 2009	1	800-971-1127 Joseph Biederman February 26, 2009 Page 88
	800-971-1127 Joseph Biederman February 26, 2009 Page 87 about it a week later I went to see him, his		800-971-1127 Joseph Biederman February 26, 2009 Page 88 Q Well, do you understand the difference?
2	300-971-1127 Joseph Biederman February 26, 2009 Page 87 about it a week later I went to see him, his secretary advised me of his fury. The sales representative who called on him and I took an hour of verbal beating. I have never seen someone so	2	300-971-1127 Joseph Biederman February 26, 2009 Page 88 Q Well, do you understand the difference? A. I am telling you that I have no idea what he's talking about. Q. You're a person of reasonable intelligence
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			23 (Payes of CO 92,
	Joseph Biederman		Joseph Biederman February 26, 2009
	February 26, 2009 Page 89		Page 90
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1	fury in my career that I recall, so I have no idea what he is referring to	12	he is talking about Q. Do you consider this kind of reaction that
3	Q. You've never been in a state of fury in	3	he's describing to be unprofessional?
4	your career. Right?	4	A I would describe it as as a behavior that
5	A. I have always been respectful and	5	is not applicable to me
6	collegial Okay? I never had a temper tantrum with	6	Q. So either Mr. Bruins misunderstood your
7	colleagues. Okay?	7	state of mind or he's lying in this document.
8	Q. Because it would be unprofessional to be	8	Right?
9	furious with people like this and give them an	9	MR SPIVACK: Objection, asked and
10	hourlong verbal beating, wouldn't it?	10	answered, misstates the witness's testimony
11 12	A. I would never have done it.	11 12	A I have no idea what Mr Bruins is saying,
13	Q It would be unprofessional, wouldn't it? A. I would never have done it	13	what his state of mind is. Q. Well, either he's wrong about how you felt
14	MR FIBICH: Objection, nonresponsive	14	about the rejection or he's lying to people at
15	MR TRAMMELL: Objection, nonresponsive	15	Janssen Right?
16	BY MR. TRAMMELL:	16	MR PECK: Objection to form
17	Q Would it be unprofessional?	17	A I have never
18	MR SPIVACK: Objection, asked and	18	MR SPIVACK: Objection, asked and
19	answered	19	answered, calls for speculation, argumentative
20	MR TRAMMELL: He hasn't answered it	20	MR. TRAMMELL: Can you wait for them to
21	BY MR. TRAMMELL:	21	fill up the record before you answer?
22 23	Q Would it be unprofessional?	22	(Pause)
23	MR SPIVACK: Objection, asked and answered.	23 24	BY MR. TRAMMELL: Q. You see there where it says in that
25	A. I have never done it. I do not know what	25	paragraph that the secretary advised Mr. Bruins of
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 91		Page 92
1.	your fury. So in fairness to you and Mr. Bruins, it	1	secretaries, receptionists and people in my staff.
2	may have been your secretary that was mistaken. But	2	Q. Who is your secretary now?
3	do you see that?	3	A Her name is Yvonne Woodward
4	MR. SPIVACK: Objection, calls for	4	Q. And how long has she been your secretary?
5	speculation, foundation	5	A. Last year and a half.
б	A I have no idea, but	6	Q. Who was your secretary before that?
7	MR SPIVACK: Just a second	7	
			A. There was a woman by the name of Julie
8	BY MR TRAMMELL:	8	Fiore.
9	Q You don't understand what this document	8 9	Fiore. Q. And how long was she your secretary?
9 10	Q You don't understand what this document says?	8 9 10	Fiore. Q. And how long was she your secretary? A. Seven years.
9 10 11	Q You don't understand what this document says? MR. SPIVACK: Objection, no foundation.	8 9 10 11	Fiore.Q. And how long was she your secretary?A. Seven years.Q. Who was your secretary before that?
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 93		Page 94
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1	MR SPIVACK: Objection, calls for	1	Q. Right?
2	speculation, no foundation	2	A. (Pause) So what was question? I don't
3	BY MR. TRAMMELL:	3	Q You don't recall being angry?
4	Q. Do you recall laying a verbal beating on	4	A. No, I don't.
5	John Bruins and the sales rep?	5	Q. The next bullet point says "Dr. Biederman
6	MR SPIVACK: Objection, asked and	67	is the head of adolescent psych at MGH. Since that
	answered		time our business became nonexistent within his area
8	A. I do not	8	of control." Do you have any idea what that's
9	Q. Certainly you would recall that if it	9 10	referring to? A. No.
10 11	happened, wouldn't you?	11	
12	A. I cannot recall things that happened so long ago.	12	Q "He now has enough projects with Lilly to keep his entire group busy for years " Do you see
13	Q. Is it customary for you to administer	13	that?
14	verbal beatings to people?	14	A. Yes.
15	A. Absolutely not.	15	Q. Now go up to the first bullet point:
16	Q. Okay. So it would be extraordinary if	16	"Dr. Biederman is not someone to jerk around He is
17	that happened, wouldn't it?	17	a very powerful national figure in child psych and
18	A It did not happen, to my recollection.	18	has a very short fuse." Did I read that reasonably
19	Q. Okay, it didn't happen. Nevertheless, it	19	correctly?
20	was his impression that he had never seen someone so	20	A. Yes
21	angry. But you don't recall being angry about it	21	Q. Do you remember telling Mr. Bruins that
22	Right?	22	you're not somebody to jerk around?
23	MR SPIVACK: Objection, no foundation,	23	A No
24	calls for speculation.	24	Q Did you have the impression that Janssen
25	BY MR. TRAMMELL:	25	was jerking you around?
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	Joseph Biederman February 26, 2009	\$	Joseph Biederman
1	representation and a second		February 26, 2009
	Page 95		February 26, 2009 Page 96
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	February 26, 2009		February 26, 2009
	Page 97		Page 98
1	objections for the same objection?	1	not a multi-layered one
2	MR. PECK: Let's proceed	2	Q. I'll object as nonresponsive. And just
3	MR. TRAMMELL: In any event, Doctor, as we	3	answer my question the best you can
4	go on, you've got to give them time to make their	4	A I submit I am a scientist. I submit
5	objections before you answer the question	5	applications all the time to various sources,
6	Otherwise we will have	6	
		7	foundations, pharmaceuticals, the Government. The
7	THE WITNESS: 1 apologize	1	most common state of affairs is rejection. Okay?
8	MR. TRAMMELL: a disastrous record	8	So what happened with Janssen is a matter of fact of
9	THE WITNESS: I apologize.	9	life in academia. Submit a proposal, they don't
10	MR. SPIVACK: And just let Mr. Trammell	10	want it, that's part of life.
11	finish That way it'll be easier for the court	11	Q. Well, the truth is it's one thing to deny
12	reporter and the videographer	12	other people's requests for proposals. It's another
13	BY MR. TRAMMELL:	13	thing to deny yours, because you're a powerful
14	Q. Now, the truth is you wanted to show	14	national figure in child psychiatry and you had the
15	Janssen you weren't somebody to jerk around and if	15	impression that they were jerking you around by
16	they were going to deny your research proposals	16	denying your request for research funding Right?
17	after they requested that you make the proposal, you	17	MR. PECK: Object to form.
18	were going to show them how powerful a national	18	MR. SPIVACK: Objection
19	figure you are by ending your business with them	19	A This is Mr. Bruins' state of mind and
20	Right?	20	interpretation of the reality. I submit
21	MR. SPIVACK: Objection, argumentative, no	21	applications all the time and to all kind of
22	foundation, calls for speculation, asked and	22	agencies, and rejection is a very common state of
23	answered	23	affairs.
24	A. I am actually not sure what is your	24	Q. How could Mr. Bruins be so mistaken?
25	question. Maybe you can do one question at a time,	25	
2.5		2.5	MR. SPIVACK: Objection, no foundation
	Stratos Legal Services 800-971-1127		Stratos Legal Services 800-971-1127
	860-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 20 21 22 3 24	February 26, 2009 Page 99 A I have no idea Q Did you find him to be a person who was not truthful? A No Q He was always honest with you, wasn't he? A I do not My interactions were strictly professional I have no basis to think one way or another Q The subject of this e-mail, though, is payment for a grand rounds you were going to do. It's not explicitly the subject but that's what the e-mail is about And the rest of this information looks like background to me. But if you go to the second page, it says, and it's the top bullet point there, it's saying generally that Dr Biederman was coming to UConn to give grand rounds in September of '99 According to him, some previous discussion had taken place between the Boston rep, the Janssen sales rep covering Dr Biederman, and the Hartford rep, who I'm assuming is a Janssen sales rep covering UConn The Boston rep was doing everything she could think of to get Dr Biederman back in our graces Anyway, they had done some behind-the- scenes negotiating to schedule this program	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 20 21 22 23 24	February 26, 2009 Page 100 Dr Huey informed me that Dr. Biederman received his commitment that Janssen would pay for this program, includes a promise of 2-1/2 thousand dollars honorarium and expenses. Dr. Huey and I were both surprised by the figure. We were not part of negotiating and stayed out of it." Have I read and summarized that bullet point reasonably correctly? A Correct Q And so this is the type of talk that you were referring to earlier when you were talking about your grand rounds duties with Janssen Right? MR SPIVACK: Objection, no foundation A. To my recollection the invitation to give grand rounds came from the chairman of the department and I did not know who was supporting the grand rounds. When the matter of payment came to be, he told me that he cannot pay me because Janssen was supposed to support it and Janssen did not pay UConn But the agreement, my discussions were between me and the university, not with Janssen. Q Did you get furious at Dr Huey? A. Absolutely not. I was disappointed that the commitment to pay for my time was not honored for six months, so I asked him to make sure that his commitment is honored.

		26 (Pages 101 to 104)
		Joseph Biederman February 26, 2009
Page 101		Page 102
hat there was behind- g the Janssen reps to s presentation? not involved in the way that these n, that there are these ns by the sales rep? o form. e upset that Janssen . Right? y that invited me and or that commitment en you were done giving is six months later ent and gave your talk d you said where's my Services	1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 7 8 9 0 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	 A. Yeah. I think after some time passed I asked if there is any problem with honoring his commitment to me. Q. And he said Janssen is supposed to pay you? A. I don't recall exactly the conversation, but something went to the extent that he cannot pay me because Janssen did not pay them. This is what I recall may have happened Q. So you went to collect from Janssen. Right? A. No. I wanted to collect from the University of Connecticut. Q. But you raised it with Janssen? A. I may have asked Janssen to make sure that that payment is received or some variation thereof. Q. Okay. You must have raised the issue with Mr Bruins, though. Right? MR. SPIVACK: Objection, calls for speculation, asked and answered A. I don't recall Q. Do you know whether you did? A. I don't recall Q. The next bullet point says "I then filled out the grant request paperwork and sent it to you Stratos Legal Services 800-971-1127
		Joseph Biederman February 26, 2009
Page 103		Page 104
betember 20, 1999. You me and requested me it." fourth from the k ago" or "Over a on his way back to Dr. Huey's office and 's feathers that we Biederman for further to him that we would get in exchange for vo lengthy voicemails and promised the hail with the check " hat he means when he ck to tirade?	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 8 9 0 1 2 3 4 5 8 9 0 1 2 3 4 5 8 9 0 1 1 2 3 4 5 8 9 0 1 1 2 3 4 5 8 9 0 1 1 2 3 1 2 3 4 5 8 9 0 1 1 2 3 1 2 1 2	 Q. Did you give the impression that you were working up to a tirade with Mr. Bruins? A. I don't recall the circumstances of what he's alluding to. Q Nevertheless, you were calling Dr. Huey's office and Janssen to try to collect the payment Right? A. I called Dr. Huey's office to ask him to honor his request and he told me that he was notdid not receive the payment from Janssen. So this is what I recall. This happened a long time ago I do not know the exact details Q. And what was it that bothered you so much? Is \$2500 a lot of money to you, or was it just that a deal is a deal? MR. SPIVACK: Objection, argumentative, misstates the witness's testimony.
	ey a verbal beating? that there was behind- ing the Janssen reps to s presentation? not involved in the way that these n, that there are these ons by the sales rep? o form. ? e upset that Janssen Right? ey that invited me and or that commitment en you were done giving s is six months later ent and gave your talk d you said where's my Services .127 derman , 2009	Page 101ey a verbal beating?1ey a verbal beating?1ey a verbal beating?1that there was behind- og the Janssen reps to s presentation?3og the Janssen reps to s presentation?6not involved in7the way that these n, that there are these on s by the sales rep?10o form.111212?13e upset that Janssen15. Right?16ey that invited me and or that commitment.17or that commitment.18en you were done giving192020s is six months later21ent and gave your talk d you said where's my2425Services.12725derman , 200920Page 1031hree months ago and ptember 20, 1999. You o me and requested me sit."1fourth from the sk ago" or "Over a on his way back to Dr. Huey's office and 's feathers that we Biederman for further to him that we would get in exchange for wo lengthy voicemails and promised the ail with the check " hat he means when he16

1 1	for approval 1 his was about three months ago and	1 T	Q. Did you give the impression that you were
2	well before the program on September 20, 1999. You	2	working up to a tirade with Mr. Bruins?
3	then returned the paperwork to me and requested me	3	A. I don't recall the circumstances of what
4	to get the sales force to pay for it."	4	he's alluding to.
5	Just skipping down, the fourth from the	5	Q Nevertheless, you were calling Dr. Huey's
6	last bullet point says "One week ago" or "Over a	6	office and Janssen to try to collect the payment
7	week ago Dr Biederman was on his way back to	7	Right?
8	tirade He was calling me and Dr. Huey's office and	8	A. I called Dr. Huey's office to ask him to
9	was starting to ruffle Dr Huey's feathers that we	9	honor his request and he told me that he was not
10	had not paid him I asked Dr Biederman for further	10	did not receive the payment from Janssen. So this
11	documentation and committed to him that we would get	11	is what I recall. This happened a long time ago
12	his check to him by yesterday in exchange for	12	I do not know the exact details
13	documentation from him. In two lengthy voicemails	13	Q. And what was it that bothered you so much?
14	to you I explained the situation and promised the	14	Is \$2500 a lot of money to you, or was it just that
15	documentation to pass in the mail with the check "	15	a deal is a deal?
16	Do you have any idea what he means when he	16	MR. SPIVACK: Objection, argumentative,
17	says you were on your way back to tirade?	17	misstates the witness's testimony.
18	A I have no idea	18	A. A deal is a deal
19	Q What does that mean to you?	19	Q. Is \$2500 a lot of money to you?
20	MR SPIVACK: Objection, calls for	20	A. \$2500 is money.
21	speculation	21	Q. Is it a lot of money?
22	A. I don't know	22	A. I don't know. Define "lot "
23	Q. You don't know what a tirade is?	23	Q. Well, to you. Do you consider \$2500 to be
24	A I know the meaning of the word. I don't	24	a lot of money?
25	know what he means by that.	25	A. 25 dollars is a reasonable amount of
	Stratos Legal Services		Stratos Legal Services
	800-971-1127	ĺ	800-971-1127
L	الاستعاد ومعروفات والمراسية المراسيين فالمناز وروار والمراجين والمراجين والمراجع والمراجع والمراجع والمراجع والمراجع والمراجع	nukan sosta	radional da alterna y a general de la literra e l'estrate e l'alterna e l'alterna d'una sur la sur de la sur etter a an

	Joseph Biederman February 26, 2009	Joseph Biederman February 26, 2009
	Page 105	Page 10
1	money	1 A. No. This is not part of my repertoire;
2	Q. Then the next bullet point says you paged	2 I am not a moral expert.
3	Mr Bruins and wanted to know where your check was;	3 Q. Do you know the difference between right
4	and then he says "I told him to call you," which I	4 and wrong?
5	guess is reference to more of the behind-the-scenes	5 A. Ido.
6	arrangement for your payment. It says	6 Q. Is that wrong or is it right?
7	"Dr Biederman has done everything we have asked of	
8	him. Again we have jerked him around. I am truly	
9	afraid of the repercussions " And "truly" is	8 Q. What do you mean by your repertoire? What9 are you talking about?
10	misspelled, but have I read that reasonably	10 A. That I don't behave in that manner
11	correctly?	11 Q. You don't believe in what?
12	A Yes	12 A. I don't behave in
13	Q. Do you have any idea of what he means when	13 Q You mean tirades and threats?
14	he says he's truly afraid of the repercussions of	14 MR. SPIVACK: Objection, argumentative,
15	jerking you around?	15 misstates the witness's testimony, asked and
16	A I have no idea	16 answered.
17	Q Did you ever make any threats to him?	17 MR TRAMMELL: Well, now we're talking
18	A. Absolutely not	18 about his repertoire, which we haven't talked about
19	Q Would that be unprofessional?	19 before
20	A. I would never do anything like that.	20 BY MR. TRAMMELL:
21	Q Because it would be unprofessional?	21 Q It's not part of your repertoire to be
22	A. Because it's not part of my repertoire.	22 furious at people you work with and go on tirades
23	Q It's wrong, isn't it?	23 and threaten them Right?
24	A "Wrong" is a moral statement	24 A Correct
25	Q Well, can you make a moral judgment?	25 Q Are you surprised by that e-mail?
	Stratos Legal Services	Stratos Legal Services
	800-971-1127	800-971-1127
	Joseph Biederman	Joseph Biederman
	February 26, 2009	February 26, 2009
	Page 107	Page 10
1	A. Yes	Page 10 1 Q. You didn't do anything wrong. Right?
1 2		
	A. Yes	1 Q. You didn't do anything wrong. Right?
2	A. Yes.Q Does it make you angry?A. No. I'm surprised.	 Q. You didn't do anything wrong. Right? A. I did not do what he is saying here that I did. Q. So this is Exhibit 5; and we're done with
2 3	 A. Yes Q Does it make you angry? A. No. I'm surprised. Q. Are you disappointed that you gave that impression to someone? 	 Q. You didn't do anything wrong. Right? A. I did not do what he is saying here that I did.
2 3 4 5 6	 A. Yes Q Does it make you angry? A. No. I'm surprised. Q. Are you disappointed that you gave that 	 Q. You didn't do anything wrong. Right? A. I did not do what he is saying here that I did. Q. So this is Exhibit 5; and we're done with the e-mail. Oh, and by the way, is that e-mail a document you reviewed to prepare for the deposition?
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
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2		2 3	
3		4	
4 5		5	
5		6	
7		7	
8		8	
9	Q. Okay. Can you confirm or deny whether	9	
LŌ	this is other than the Well, does this have	10	
. 1	anything to do with the subject of Mr Bruins'	11	
.2	e-mail? Do you know?	12	
. 3	A I have no idea	13	Q. None of the MSLs, none of the salespeople,
L 4		14	nobody said, hey, you really ought to propose to do
15		15	research on Risperdal here at your hospital?
16		16	A Proposals for research are submitted
17		17	routinely to pharmaceutical companies, to the NIH,
18	Q. And how did you come to put this document	18	to foundations, to seek funding to advance the
19	together? What motivated you to do this?	19	scientific foundations of the diseases that I treat
20	A I am a researcher and I need Research	20	
21	is costly and I need to seek funding to do research,	21 22	
22 23	so I apply to different sources of funding,	22 23	
24	pharmaceuticals, foundations, private donors, the NIH, for different ideas to see if we can advance	23 24	
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	800-971-1127		800-971-1127
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1 2		1	MR. TRAMMELL: You sure are MR_PECK: I'm making an objection
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			29 (Pages 113 to 110)
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 113		Page 114
1 2 4 5 6 7 8 9	 Q. Are these the side effects associated with Risperdal? A. Yes. 	1 2 3 4 5 6 7 8 9	 medicines. Q. In an off-label population. Right? A. The use in children at that time was off-label and two years ago has been approved. MR. TRAMMELL: Objection, nonresponsive.
10 11 12 13 15 17 10 12 12 12 22 22 22 22 22 22 22 22 22 22	 Q. The next point And, by the way, the use of Risperdal in the pediatric population was off-label at this time, wasn't it? A. Yes Q And what does that mean? A. Off-label means that the medicine is used by physicians that is not specifically approved by the FDA for that use Q So it means a drug is being used for something that the FDA hasn't approved it for. Right? A. Yes. Q. Okay. And so you were proposing to do research on off-label uses of Risperdal Right? A. I was proposing to do research on the efficacy and safety of risperidone relative to other Stratos Legal Services 800-971-1127 	10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	 Q. One of the things you wanted to study was the efficacy of Risperdal in preschoolers Right? A. Yes. Q. And how old are preschool kids? A. Could you repeat the question? Q. How old are preschool kids? A Four to six. Q. And what age range was Risperdal approved for at that time? Stratos Legal Services 800-971-1127
1	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 115		Page 116
1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 5 7 8 9 0 1 1 2 3 4 5 7 8 9 0 1 1 2 3 4 5 7 8 9 0 1 1 2 3 4 5 8 9 0 1 1 2 3 4 5 8 9 0 1 1 2 3 4 5 1 2 3 4 5 1 2 3 5 7 8 9 0 1 1 2 3 3 1 2 3 1 2 3 1 2 3 1 2 3 3 1 2 3 1 2 3 3 1 2 3 1 2 3 1 2 3 1 2 9 0 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 2 3 1 1 1 1	 A. It was approved, to my recollection, for individuals older than 18. Q. So what you're saying is there's evidence that is accumulating that kids or that pediatric bipolar disorder onsets in these preschool kids, who have are three and four years old? 	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	from this disease or it's possible that they're suffering from this disease in the preschool years, the drug is used a lot in these kids, we ought to have some data to instruct doctors about whether it's safe and effective to be doing this? A. Yes. Q Who makes Wellbutrin? A. Bupropion was initially made by Glaxo or Wellcome Burrouchs Wellcome and then when they
15 16 17 18 20 21 22 23 24 25	 I assume are three and four years old? A Usually four to six. Q Okay. So pediatric bipolar disorder onsets in four- to six-year-old kids coupled with the fact that the drugs are widely used, despite that, there's not a lot of data on efficacy. Right? MR. PECK: Object to form. It's a compound question. A On efficacy and safety, yes. Q. And so basically what you mean is, what you're trying to say is that we have kids suffering Stratos Legal Services 800-971-1127 	15 16 17 18 20 21 22 23 24 25	 Wellcome, Burroughs Wellcome, and then when they merged I don't know who owns Wellbutrin. I think GlaxoSmithKline, I think. Q. Did Janssen fund any studies that you did to study other companies' drugs? Stratos Legal Services 800-971-1127

		(30 (Pages 117 to 12
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 117		Page 11
1	A. Not that I know	1	product development. There was no treatment in the
2	Q In the absence of Risperdal.	2	J&J Center
3	A. Not that I know of.	3	Q When did the center start?
1	Q. So is this really kind of the origins of	4	A. The center, to my recollection, started in
5	the J&J Center at MGH?	5	2002.
ŝ	A Well, not really This was a treatment	6	Q. Does it still exist?
7	program The J&J Center was centered on	7	A. No.
3 3	understanding the diseases, not the treatment of the	9	Q. When did it cease operations? A. In 2005
)	diseases. This is a program to treat the condition, pediatric bipolar illness at different ages and to	10	Q. And why?
L	treat the components of the illness, depression and	11	A. It was not refunded.
2	ADHD.	12	Q Janssen decided to stop?
3	Q. And just so the record is clear, can you	13	A Yes
ł	tell us what the J&J the Johnson & Johnson	14	Q. Okay.
,	Center is at Massachusetts General Hospital?	15	A. By the way, the center was funded by
5	A. The Johnson & Johnson Center was	16	McNeil and Janssen, not just Janssen
1	structured on the basis of an NIH center that has	17	Q Because McNeil, the McNeil-Janssen group
}	components, or we call them cores, and focused on	18	makes other drugs that you're studying for kids
)	studying the two conditions that we're interested:	19	Right?
)	ADHD and bipolar illness The center had a core	20	A McNeil makes Concerta. We study ADHD and
•	that was neuroimaging, a core that was focused on	21	bipolar illness
2	genetics, a core that was focused on data analysis	22	Q Did you say it was an NIH center before it
3	of existing data, a core that we call assessment	23 24	was a A. No I said it was modeled after centers
1	that had a core of trained psychometricians to do	24	that the NIH funds.
J	structured interviews, and a core that was in Stratos Legal Services	2.5	Stratos Legal Services
	800-971-1127		800-971-1127
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 119		Page 12
1	Q. I see	1	A I would not say millions of dollars That
2	A The structure of the center was modeled	2	was the most substantial amount of funding that we
3	after NIH centers.	3	received
1	Q. I want to go back just quickly. We talked	4	Q. You don't know whether you got over a
i i	about all the ways, all the characteristics of your	5	million dollars from Janssen?
5	professional relationship with Janssen over the	6	MR PECK: Object to form
1	years. Do you have any idea how much money you've	7	A No.
3	gotten from Janssen either to you personally or to	8	Q. Do you have any idea Did Janssen,
) \	fund your research?	9	anybody from Janssen ever talk to you about the
) L	A The center was funded at \$500,000 a year and was funded for four years.	10 11	reasons they wanted to fund the study? Or fund the
2	Q. Do you have any idea how much money either	11 12	center. I'm sorry. A. Nobody discussed reasons. I sent a
}	you personally or the center has received from	13	proposal to Janssen to create such a center and it
,	Janssen over the course of your relationship?	14	was finally funded.
5	A I never totaled it.	15	Q. So you proposed the idea of the center to
5	Q. Is it just too much to count or you just	16	them?
7	don't know?	17	A Yes
}	MR. PECK: Object to form.	18	Q They didn't propose it to you?
9	A. No, I do not know.	19	A Absolutely not.
)	Q. Is it millions of dollars?	20	Q And this was around 2002?
L	A. From Janssen?	21	A. The center was funded in 2002.
2	Q Mm-hmm	22	Q How much money did they give you in 2002
3	A. Well, the center alone had 2 million	23	to fund the center? Janssen I mean
	Q Okay But all in, it's millions of	24	A The center budget was a half a million
1 5	dollars Pight?	25	dollars per year
	dollars Right? Stratos Legal Services	25	dollars per year Stratos Legal Services

Stratos Legal Services 800-971-1127

Stratos Legal Services 800-971-1127

			31 (Pages 121 to 124
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 121		Page 122
1	Q. And did that fund studies?	1	commercial entity could help the advancement of the
2	A No. The center was structured around	2	science of the diseases for which they could have
3	infrastructure support. As I mentioned before, we	3	effective treatments.
4	had five cores. One was neuroimaging. The neuro-	4	Q Janssen funded the study so they could
5	imaging core dealt with the development of software	5	make more money selling Risperdal Right?
6	that we can expedite the processing of MRI data from	6	MR PECK: Objection, foundation.
7	neuroimaging. The genetic core helped collect DNA	7	A Janssen funded the study to do the work
8	data on subjects that were going through our	8	that we proposed.
9	assessment The paradigm development core we	9	Q. Right Their goal was to advance their
10	evaluated and developed is driving simulation and	10	commercial interests. Right?
11	work simulation for ADHD.	11	MR SPIVACK: Objection, calls for
12	Q. What specifically did Janssen get for its	12	speculation
13	500,000 in 2002?	13	A. They funded us to do the studies that we
14	A Well, it was not specific. It was a very	14	proposed to advance science. What was there for
15	different type of funding than pharmaceuticals do,	15	them is for them to decide
16	that they fund a proposal very close to their	16	Q. Well, but you understand how this works
17	commercial interest This was advancing the science	17	I mean, Janssen is in the business to make money
18	of the diseases for which they have potential	18	Right?
19	treatments	19	A. Yes
20	Q You're saying Janssen's purpose in giving	20	Q. They sell Risperdal to make money. Right?
21	you that money was to advance science and not for	21	A (Witness nodded)
22	their commercial interest?	22	Q They're not a charity, are they?
23	A. To advance science. Our proposal was to	23	A. They are not.
24	advance science and not necessarily We thought	24	Q. Okay. The only reason that Janssen exists
25	about it as a win-win situation, that Janssen as a	25	is to make money for its partners and shareholders.
100	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009		February 26, 2009
1	February 26, 2009 Page 123	1	February 26, 2009
1 2	February 26, 2009	1 2	February 26, 2009 Page 124
1	February 26, 2009 Page 123 Right?		February 26, 2009 Page 124 opportunity for Janssen in its off-label promotion
2	February 26, 2009 Page 123 Right? MR. PECK: Objection, foundation	2	February 26, 2009 Page 124 opportunity for Janssen in its off-label promotion of Risperdal for kids?
23	February 26, 2009 Page 123 Right? MR PECK: Objection, foundation A. We conceptualize the study. The center	23	February 26, 2009 Page 124 opportunity for Janssen in its off-label promotion of Risperdal for kids? MR. SPIVACK: Objection, calls for
2 3 4	February 26, 2009 Page 123 Right? MR. PECK: Objection, foundation A. We conceptualize the study. The center has the moral responsibility of a pharmaceutical	2 3 4	February 26, 2009 Page 124 opportunity for Janssen in its off-label promotion of Risperdal for kids? MR. SPIVACK: Objection, calls for speculation.
2 3 4 5	February 26, 2009 Page 123 Right? MR. PECK: Objection, foundation A. We conceptualize the study. The center has the moral responsibility of a pharmaceutical company that has potentially helpful medicines to	2 3 4 5	February 26, 2009 Page 124 opportunity for Janssen in its off-label promotion of Risperdal for kids? MR. SPIVACK: Objection, calls for speculation. MR PECK: Objection, speculation.
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 125		Page 126
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1	though it was off-label? A. I have no influence or idea of that	1 2	 A. No. Q. You never heard it in the context of your
2 3	information. I publish scientific articles. I	3	Q. You never heard it in the context of your center?
4	describe data, results from studies, and this is	4	A. No. The center did science only.
5	what I publish in the literature. What is the	5	Q. Well, the truth is the center was just a
6	result of that is not for me to tell.	6	marketing device for Janssen Right?
7	Q Well, one of the results of your studies	7	MR SPIVACK: Objection
8	is to inform clinicians' practice. Right?	8	MR PECK: Objection, foundation.
9	A. The results of my studies are to share	9	MR SPIVACK: Argumentative
0	with clinicians and scientists results of a	10	A. The center was designed to advance the
1	systematic study that weighs efficacy and adverse	11	science of bipolar illness in children and ADHD
2	effects.	12	across a large spectrum This is what the center
3	Q. So they can take that into account when	13	did
4	they're treating kids Right?	14	Q Had nothing to do with making money
5	A. They can take into account when they treat	15	Right?
6	children, yes	16	A. No.
7	Q. Did anyone ever tell you from Janssen that	17	Q Okay There's Exhibit 6. I want you to
8	the purpose of funding your center was to generate	18	turn with me to the second page This is an e-mail
9	maximum revenue in 2002?	19	from Alex Gorsky You see this right here? Alex
0	MR. PECK: Object to form	20	Gorsky is the president of Janssen Pharmaceutical at
1	A. No.	21	that time. He is writing to a bunch of other people
2	Q. Nobody ever told you that?	22	at Janssen; he says "All," and the date is November
3	A. (Witness shook head.)	23	2, 2001, "All, As per some of my earlier
4	Q. Have you ever heard the phrase money on	24	discussions, please note the dates that Joe Scodari
5	the table?	25	has requested " Do you have any idea who loe
	Stratos Legal Services		Chrotop Ippsl Carrisoph
			Stratos Legal Services
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	800-971-1127 Joseph Biederman February 26, 2009 Page 127		800-971-1127 Joseph Biederman February 26, 2009 Page 128
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	Page 129		Page 130
1	of bipolar illness Aggression is a very common	1	for money on the table and then a response to that
2	problem in child psychiatry	2	statement saying this is an appropriate forum to
3	Q. Can you identify any of your papers that	3	discuss the J&J Center with Dr. Biederman, how can
4	can reasonably be interpreted to circumscribe the	4	you interpret that any other way than to mean that
5	use of Risperdal in kids?	5	Janssen was looking to you to help them develop this
6	A. My papers address the use of risperidone	6	off-label marketing campaign?
7	in the context of bipolar illness	7	MR. PECK: Objection form.
8	Q. But your papers try to expand the use of	8	MR. SPIVACK: Objection, asked and
9	Risperdal in this population. Right?	9	answered, argumentative, no foundation, calls for
10	A My papers described the efficacy and	10	speculation
11	safety of risperidone and other medicines for the	11	A. I have no idea what is in the mind of
12	management of children. It did not expand or	12	Janssen executives
13	retract or contract anything	13	Q Well, you just said what you thought was
14	Q Do you think Janssen paid you millions of	14	in the mind of Janssen.
15	dollars to limit the use of Risperdal in kids?	15	MR. SPIVACK: Objection, argumentative
16	MR. SPIVACK: Objection, calls for	16	A I'm sorry. I did not hear what you said.
17	speculation	17	Q You said the purpose of Janssen's funding
18	MR. PECK: Objection, foundation.	18	of the study was to promote science, didn't you?
19	A Janssen funded a center that was dedicated	19	A. The center The center's job and mission
20	to the advancement of the science of the conditions	20	was to promote science
21	for which they have effective treatments or	21	Q. That may have been your mission.
22	potentially effective treatments	22	Janssen's mission was to get the money on the table.
23	Q. And I understand that's your	23	Right?
24	interpretation of Janssen's intentions However,	24	MR. SPIVACK: Objection, argumentative,
25	having read this document that says we're looking	25	calls for speculation, no foundation.
	Stratos Legal Services	- -	Stratos Legal Services
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			34 (Pages 133 to 13
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 133		Page 13
1	been the case You need to keep in mind that at the	1	MR. SPIVACK: Object to form
2	time pediatric bipolar illness was not a well-known	2	A. I have no idea what you are referring to.
3	entity, so the notion is to understand what it is,	3	Q. Doctor, this is Exhibit 7. We're done
4	to define it in the best way possible, to understand	4	with 6. Oh, and, by the way, have you ever seen
5	its seriousness, and if the illness is serious	5	Number 6 before?
6	enough, may require treatment with serious	6	A I don't recall.
7	medicines. And they need to establish the benefits	7	Q. Have you ever seen Number 5?
8	by doing clinical trials, as they did. But it is a	8	A. I don't think so. I have seen it
9	step-by-step approach, it is not a one-to-one	9	Q. Except for when you might have read it.
10	correspondence	10	A. Yes
11	Q But taking that approach would ultimately	11	Q. You didn't review it with your lawyers?
12	advance the commercial interests of Johnson &	12	A I don't remember:
13	Johnson Right?	13	Q. Number 7 is called Annual Report 2002, The
] 4	MR PECK: Objection, foundation, form	14	Johnson & Johnson Center for Pediatric
15	BY MR TRAMMELL:	15	Psychopathology at the Massachusetts General
16	Q. Is that right?	16	Hospital This is your center Right?
17	A I believe that if the illness is prevalent	17	A. Yes
18	and morbid and severe and disabling and if	18	Q Have you ever seen this document?
19	risperidone proves to be safe and effective, that	19	A I have seen the document, yes.
20	they will benefit from that association between the	20	Q. You have seen it?
21	treatment and the disease.	21	A Yes, I have seen it.
22	Q. Well, even if Risperdal wasn't proven to	22	Q When did you see it?
23	be safe and effective, just having your name	23	A. Around the time it was written.
24	attached to its promotion would advance their	24	Q. So this is an internal Janssen document
25	commercial interests Isn't that right?	25	that was circulated to you. Right?
	Stratos Legal Services 800-971-1127		Stratos Legal Services 800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 135		
	rede too		Page 13
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1 2	MR. PECK: Objection, foundation A I don't know what it is	1	Right?
2	MR PECK: Objection, foundation A I don't know what it is		Right? A. We were talking to an interlocutor that
	MR. PECK: Objection, foundation A I don't know what it is Q. Well, you saw it. Right?	2	Right? A. We were talking to an interlocutor that was a commercial entity, so there has to be
2 3	MR. PECK: Objection, foundation A I don't know what it is Q. Well, you saw it. Right? A. Actually, I thought that this was	2 3	Right? A. We were talking to an interlocutor that was a commercial entity, so there has to be something for them So we saw that the intersect
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2 3 4 5	MR. PECK: Objection, foundation A I don't know what it is Q. Well, you saw it. Right? A. Actually, I thought that this was referring my report to them, not their internal	2 3 4 5	Right? A. We were talking to an interlocutor that was a commercial entity, so there has to be something for them So we saw that the intersect between advancing science is commercially viable.
2 3 4 5 6	MR. PECK: Objection, foundation A I don't know what it is Q. Well, you saw it. Right? A. Actually, I thought that this was referring my report to them, not their internal reporting. I have not seen internal documents of reporting I thought that this document is a document that I reported to them, not that they	2 3 4 5 6	Right? A. We were talking to an interlocutor that was a commercial entity, so there has to be something for them So we saw that the intersect between advancing science is commercially viable. This is what we alluded to.
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2 3 4 5 6 7 8 9 10 11 12	MR. PECK: Objection, foundation. A I don't know what it is. Q. Well, you saw it. Right? A. Actually, I thought that this was referring my report to them, not their internal reporting. I have not seen internal documents of reporting I thought that this document is a document that I reported to them, not that they reported internally. Q Okay. Having looked at it, do you know whether you've seen it? A. I don't think I've seen it.	2 3 4 5 6 7 8 9 10 11 12	Right? A. We were talking to an interlocutor that was a commercial entity, so there has to be something for them So we saw that the intersect between advancing science is commercially viable. This is what we alluded to. Q. Right Because they're not going to fund this kind of thing if they can't get anything out of it. Right? MR PECK: Object to form A This, they will not fund this if theoretically it will not have anything to do with
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2 3 4 5 6 7 8	MR. PECK: Objection, foundation. A I don't know what it is. Q. Well, you saw it. Right? A. Actually, I thought that this was referring my report to them, not their internal reporting. I have not seen internal documents of reporting I thought that this document is a document that I reported to them, not that they reported internally. Q Okay. Having looked at it, do you know whether you've seen it? A. I don't think I've seen it. Q. Okay If you go to the third page, which has a heading that says Executive Summary, go to the second paragraph; it says "An essential feature of the center is its ability to conduct research satisfying three criteria: A, it will lead to findings that improve the psychiatric care of children; B, it will meet high levels of scientific quality; and C, it will move forward the commercial goals of J&J." Did I read that right? A. Yes. Q. So there may have been multiple purposes	2345678901234567890123 11234567890122222	 A. We were talking to an interlocutor that was a commercial entity, so there has to be something for them So we saw that the intersect between advancing science is commercially viable. This is what we alluded to. Q. Right Because they're not going to fund this kind of thing if they can't get anything out of it. Right? MR. PECK: Object to form A This, they will not fund this if theoretically it will not have anything to do with their possibilities. So what I explained to you before, the statement's approach is starting the diseases for which they have effective treatments, is the beginning of that road, not the end where the road finishes Q The next sentence says "We strongly believe that the center's systematic scientific inquiry will enhance the clinical and research foundation of child psychiatry and lead to the safer, more appropriate and more widespread use of medications in general " Did I read that right?

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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 137		Page 138
1			
1 2	A Yes Q. Did I read that correctly?	1 2	the validity of disorders " Did I read that right? A Yes
3	A. Yes, that's correct.	3	Q What does that mean, the validity of
4	Q. So what they're saying here is that	4	disorders?
5	because of the work that you do at the center,	5	A. The meaning is not all temper tantrums are
6	there'll be more Risperdal used Right?	6	bipolar illness Not all lack of concentration is
7	MR. PECK: Object to form.	7	ADHD. So when we describe a condition, we need to
8	A. We believed that if the medicines if	8	do our best to make sure that this condition is
9	the disease is found to be morbid and disabling, if	9	valid
10	the medicines like risperidone are found to be safe	10	Q. So you and Janssen were inventing
11 12	and effective, clinicians will be more able to	11 12	disorders? MR. PECK: Objection, form.
13	deploy them for the right patients with better knowledge about the spectrum of effects and adverse	13	A. Absolutely not.
14	effects. This is what we meant	14	Q Is there something wrong with that,
15	Q. And the result will be that more people	15	inventing disorders?
16	will get Risperdal Right?	16	A Inventing disorders? Of course, the way
17	A The results will be that if this is a safe	17	that you say it and the choice of words has some
1.8	and effective treatment, our children will be	18	pejorative conspiratorial component
19	appropriately treated. And so if this is a	19	Q. You mean pejorative, you mean it has a bad
20	condition that affects a lot of children, then the	20	connotation?
21 22	consequence will be that more children will receive	21 22	 A. Yes Q Why is it bad to be creating diseases or
22	an effective treatment, an effective and safe treatment	22	creating disorders or creating categories of
24	Q The next paragraph, "Equally important to	24	disorders?
25	effective use of medications is the demonstration of	25	A. The diseases are not created The
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
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2	February 26, 2009 Page 139 conditions that we see in front of us are reconceptualized In other words, the child that	2	February 26, 2009 Page 140 MR SPIVACK: Objection, calls for speculation
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2 3 4 5 6	February 26, 2009 Page 139 conditions that we see in front of us are reconceptualized In other words, the child that was called before mentally retarded today may be called autism spectrum. So as we understand more these problems, we conceptualize in a different way Schizophrenia and bipolar illness were not	2 3 4 5 6	February 26, 2009 Page 140 MR SPIVACK: Objection, calls for speculation. A. I described that the children that were going under different names that were disturbed, some of these children may have a condition that is called bipolar illness. Not none of these children
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36 (Pages 141 to 144)

	Joseph Biederman		Joseph Biederman
	February 26, 2009 Page 141		February 26, 2009 Page 14
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1	Q. Do you know which disorders it's talking	1	but does have ADHD Risperdal is not a safe and
2	about, the validity of which disorders?	2	effective treatment. Right?
3	A. We were interested in bipolar illness and	3	A. No.
4	ADHD	4	Q And it's wrong to promote it for that
5	Q And were there multicenter placebo-	5	purpose, isn't it?
6	controlled randomized double-blind clinical trials	6	MR PECK: Objection, foundation
7	showing that Risperdal was safe and effective for	7	A. Yes
8	pediatric bipolar illness or ADHD at that time?	8	Q. Now, in order to demonstrate, what kinds
9	A. No. Risperidone is not a treatment for	9	of science would need to be generated to demonstrate
0	ADHD, by the way	10	the validity of pediatric bipolar disorder?
11	Q And you've never recommended it be used to	11	A. We conceptually thought to do neuroimaging
12	treat ADHD?	12	to see if the neuro-anatomy of the brain is
13	A. No.	13	different in people that have bipolar illness and
14	Q Would that be inappropriate?	14	ADHD using different imaging technologies. Our
15	A. Depending on circumstances.	15	genetic research was interested in trying to
Lб	Q. What circumstances would make Risperdal a	16	identify genes that are associated with one or the
L 7	safe and effective treatment for ADHD?	17	other.
L 8	A. There are children, 80 percent or so of	18	Q So the work you wanted to do to
19	children with bipolar disease with comorbid ADHD,	19	demonstrate the validity of pediatric bipolar
20	and the stimulus can make them worse. So sometimes	20	disorder was neuroimaging and genetic research?
21	just using one medicine can correct some of the	21	A And associated. We also were interested
22	symptoms of ADHD It's not to treat ADHD but to	22	in examining the course of the illness, to examine
23	help symptoms of ADHD in the context of bipolar	23	clinical correlates We examined familiality of
24	illness.	24	ADHD and bipolar illness These are things that we
25	Q. But if a kid doesn't have bipolar disorder	25	did
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Jacob Diederman		- 1 m 1 1
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
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	cage 145		rage 150
1	meant to be the gold standard It was never meant	1	speculation
2	to be the gold standard. That's kind of We think	2	A. I don't know how in what context my papers
3	about that as proof of concept. Is there any signal	3	were used My papers are data-driven and objective,
4	there in an open study to warrant a double-blind	4	so I only describe; I do not state or recommend
5	study? That's the way That's the reason that	5	All my papers had side effects listed in exhaustive
6	open studies are done.	6	detail. I do not make a sales speech of any type in
7	Q. It is hypothesis-generating. Right?	7	my papers. It's a description. How is this used?
8	A. It is a pilot. It's to see if there is	8	I have no idea
9	promise in their medicine.	9	MR TRAMMELL: I'll object as
10	Q. It is certainly not appropriate to take a	10	nonresponsive
11	hypothesis-generating study like an open label study	11	BY MR TRAMMELL:
12	and represent to people that that study is proof	12	Q. I understand you're not a Janssen
13	that Risperdal is safe and effective to treat the	13	salesman. But if a Janssen salesman took one of
14	disorder that was studied. Right?	14	your papers that you wrote about the use of
15		15	
15 16	A. My paper never had any statement in that	15	Risperdal in pediatric bipolar disorder and
	regard.	10	represented to a doctor or any other type of
17	MR. FIBICH: Objection, nonresponsive.		prescriber that Risperdal was safe and effective to
18	MR TRAMMELL: Yeah, objection,	18	treat pediatric bipolar disorder based entirely on
19	nonresponsive	19	your papers, would that be appropriate?
20	BY MR TRAMMELL:	20	MR SPIVACK: Objection, calls for
21	Q If someone took your paper and used it as	21	speculation
22	a basis for representing that Risperdal was safe and	22	MR. PECK: Objection, calls for
23	effective to treat pediatric bipolar disorder, any	23	speculation
24	of your papers, would that be appropriate?	24	A Probably is
25	MR SPIVACK: Objection, calls for	25	Q. What?
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		Joseph Biederman February 26, 2009
-	February 26, 2009 Page 151	-	February 26, 2009 Page 152
1	February 26, 2009 Page 151 A. Probably would be inappropriate	1	February 26, 2009 Page 152 MR SPIVACK: Shall we take a lunch break?
2	February 26, 2009 Page 151 A. Probably would be inappropriate Q. And, again, why is that?	2	February 26, 2009 Page 152 MR SPIVACK: Shall we take a lunch break? (Discussion off the record.)
2 3	February 26, 2009 Page 151 A. Probably would be inappropriate Q. And, again, why is that? A. Because it's a very small open study So	2 3	February 26, 2009 Page 152 MR SPIVACK: Shall we take a lunch break?
2 3 4	February 26, 2009 Page 151 A. Probably would be inappropriate Q. And, again, why is that? A. Because it's a very small open study So the efficacy data is limited to the sample size.	2 3 4	February 26, 2009 Page 152 MR SPIVACK: Shall we take a lunch break? (Discussion off the record.) (Luncheon recess at 12:15 p.m.)
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2 3 4 5 6 7 8	February 26, 2009 Page 151 A. Probably would be inappropriate Q. And, again, why is that? A. Because it's a very small open study So the efficacy data is limited to the sample size. That's the reason that we have large-scale studies. Q. Right It's a limitation of your type of study Right? A. Yes.	2 3 4 5 6 7 8	February 26, 2009 Page 152 MR SPIVACK: Shall we take a lunch break? (Discussion off the record.) (Luncheon recess at 12:15 p.m.) AFTERNOON SESSION 1:23 p.m. THE VIDEOGRAPHER: This is the beginning
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 153		Page 154
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1	speculation.	1	the use of medicines like risperidone for a small
2	MR PECK: Objection	2	subgroup of children that satisfied criteria for
3	A Not really.	3	bipolar illness
4	Q What is your impression of that statement?	4	Q. Got it. Your goal was to limit use of
5	A Disorders, the meaning in medicine of	5	Risperdal?
6	validity is the distinguishing a disorder from other	6	A No My goal was to argue that not all
7	disorders	7	children that have aggressive symptoms have bipolar
8	Q. Well, isn't it true and wasn't it your	8	disorder My goal was to try to separate the
9	understanding that what Janssen was trying to do	9	children that have aggressive symptoms in the
10	with the center and with your research was to look	10	context of bipolar illness from other children that
11	for markets for Risperdal any way they could and	11	may be just aggressive without bipolar illness.
12	create a market, if they needed to, by inventing	12	Q. And I'm sorry. I didn't mean to
13	disorders?	13	interrupt you. So your goal was to limit the use of
14	MR PECK: Objection, foundation	14	Risperdal to children who were probably in the
15	MR. SPIVACK: Objection, argumentative	15	extreme minority of the children that would be seen
16	BY MR TRAMMELL:	16	for this type of problem, to limit the use of
17	Q. Isn't that true?	17	Risperdal to the kids who were truly sick?
18	A. The center focused on the evaluation of	18	A. How clinicians use the medicine is not on
19	the correlates of biology and neuroimaging of	19	my hands. We were trying to describe a group of
20	pediatric bipolar illness and ADHD At the time	20	children that had a set of symptoms suggestive of
21	bipolar illness was not fully recognized in	21	bipolar illness, to try to distinguish those from
22	children, was going by different names like ADHD or	22	other forms of aggression that is not part of
23	conduct disorders or things of that type. So what	23	bipolar illness. And we argued that the potential
24	we were interested is to think about the possibility	24	antimanic effects of medicines like risperidone, not
25	that children have bipolar illness and try to limit	25	only risperidone, we evaluated all of them, should
	Stratos Legal Services 800-971-1127		Stratos Legal Services 800-971-1127
	000-571-1127	<u> </u>	000-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 155		Page 156
	-		-
1	be directed at those children, not just every child	1	I don't know. STEP, S-T-E-P program It's about
2	with aggression that this spectrum covers	2	four or five thousand adults with bipolar illness,
3	Q What percentage of kids have bipolar	3	in other words, systematically assessed and treated;
4	disorder?	4	and about close to 70 percent of those, a
5	A. We estimated based on other calculations	5	representative sample of bipolar adults in this
6 7	about 1 percent	6	country, had an onset in childhood or adolescence.
	Q. So the same percentage as in adults.	8	Q. Who conducted that study?
8 9	Right?	9	A. The study was funded by the National Institute of Mental Health
9 10	A. Adults it's more than 1 percent. It's about 2 to 3 percent.	10	Q. What percentage of the 1 percent of kids
10 11	Q. Okay So for some people bipolar disorder	10 11	that have bipolar disorder will respond to Risperdal
11 12		12	treatment?
12 13	manifests in childhood and for some people it	13	
13	manifests later on in life. Right? A. 70 percent of adults onset in childhood or	13 14	A. In our study, the open label study that we did was about 60, 65 percent.
14 15	A. 70 percent of adults onset in childhood or adolescence with bipolar illness.	14 15	
15 16	· · · · · · · · · · · · · · · · · · ·	16	Q. So 65 percent of that 1 percent are appropriate candidates for Risperdal. Right?
10 17	Q. So 70 percent of people who are adults who have bipolar disorder, that disorder onset when they	17 17	A. No. 65 percent of the 40 or so that we
18	were kids?	18	tested responded to risperidone.
19	A. Yes	19	Q. You weren't trying to make the point that
20	Q. And what is your basis for that statement?	20	60 percent of all kids that have bipolar disorder
20	A There's a very large study done by several	21	are appropriate candidates for Risperdal, are you?
22	centers in the country, a comparison somewhere on	22	A. No.
23	the order of 5,000 adults with bipolar illness.	23	
24	It's the largest study ever done on bipolar adults.	24	Q. Now, one of the ways Janssen wanted to use your research was to train doctors in these novel
	It's called the STEP study, Systematic Treatment	25	ways of screening kids to identify bipolar disorder
25	A S CARCO HE OTEN STOLY, SYSTEMATIC TRAINER **	ل يخ	ways or seconing kids to identify bipolal disorder
25		1	
25	Stratos Legal Services	1	Stratos Legal Services

			40 (Pages 157 to 160)
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 157		Page 158
1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 2 1 2 1 2 2 2 2 2 2 2 2 2 2 2 2 2	 Right? MR. SPIVACK: Objection, calls for speculation, argumentative MR. PECK: Objection, foundation. A. I have no idea what are you talking about. Q. Okay. Did you ever publish any articles or give any speeches the subject of which was discussing the diagnostic criteria for pediatric bipolar disorder? A. In all my talks on pediatric bipolar I describe what are the features that describe these children. Q. Right And the association of these features with bipolar disorder in these kids was a novel concept, wasn't it? A. It was not so novel. It was novel to the extent that we focus on severe irritability as a distinguishing feature Q. It certainly wasn't widely accepted that pediatric bipolar disorder was even a real disease, was it? A. It was considered to be a very infrequent. Q. It was considered to be a significant Stratos Legal Services 800-971-1127 	$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\0\\1\\1\\1\\1\\1\\1\\1\\1\\1\\1\\1\\1\\1\\1\\2\\2\\2\\2\\2$	 diagnostic criteria. Right? A. Irritability was always an important part of the diagnosis. This is the way that it is described in the DSM. Q. Was that your contribution to the diagnostic criteria, emphasizing the role of irritability in the onset of the disease? A. Our contribution in my mind was to point out that this is a common, much more common condition than was previously thought of. It was not rare. Q. Was the diagnosis of bipolar disorder and the use of medications to treat it in kids controversial when you began your research? A. No. I think that the entire idea of using medication to treat any psychiatric disorders in children is at the outset controversial, not only risperidone. So there is a school of thought that argues that children are angels and don't have any disorders, and that is not necessarily restricted to risperidone. Q. But you don't agree with that? A No, not only that I don't agree I think that the evidence that a sizeable number of children suffer from very serious emotional and behavioral Stratos Legal Services 800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 159		Page 160
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 disorders is not disputed. Q I suppose what is disputed is whether those disorders are a bipolar disorder and the proper manner for diagnosing what the disorder might be in the troubled kid. Right? A. Bipolar disorder is one of many conditions that afflict children. It's one of the least common Children about, about 5 to 10 percent of children have ADHD, about 2 to 3 percent have conduct disorder, 5 percent have major depression. So if you aggregate those numbers, somewhere in the order of magnitude of I would say 15 percent of children may have emotional or behavioral difficulties. Q What percentage of that 15 percent are appropriate candidates for Risperdal therapy? A. I would say that I recommended to consider 	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. Let me ask you this If Janssen promoted Risperdal to be used for non-bipolar kids, would that be appropriate in your mind? MR SPIVACK: Objection, calls for speculation. MR. PECK: Objection, foundation. A. I don't know if they do it You are finished? I do not know what they did or did not do. Q. If they did that, is that appropriate? A. Depending on MR. SPIVACK: Objection THE WITNESS: Sorry Are you finished? MR. TRAMMELL: Just wait for your lawyer and then you can answer. So you can answer now A. Depending on circumstances. You need to be more specific
1.8 1 0	risperidone only for bipolar illness.	18	Q Under what circumstances is off-label

23

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25

18 19 Q. So it's inappropriate to use Risperdal for 20 21 22 non-bipolar kids?

MR. PECK: Object to form. A There are in the clinical topography many 23 circumstances that physicians may make a decision to 24 use a particular compound outside the most 25 restricted use of the medicine. Stratos Legal Services

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promotion appropriate?

20 MR. SPIVACK: Objection, calls for a legal 21 conclusion. 22

A. Again, you are asking two separate questions Off-label use is legal, first of all.

Q. Right. I'm not asking about off-label ---

A. Very commonly used in medicine, and we owe Stratos Legal Services 800-971-1127

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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 161		Page 162
1234567890123456789012345 1123456789012345	 a lot of gratitude to discoveries because of off- label use. Whether the pharmaceutical company is promoting or not, I have no idea. MR TRAMMELL: I'll object as nonresponsive. BY MR. TRAMMELL: Q. Is it appropriate for Janssen to promote Risperdal for off-label uses in kids? MR PECK: Objection, foundation. MR SPIVACK: Objection A. I am not a lawyer. Q Well, as a clinician, do you think that's appropriate? Do you think it's appropriate for Janssen to be promoting a clinical practice that's not supported by the gold standard of scientific evidence? MR SPIVACK: Objection, calls for speculation, no foundation. MR PECK: Objection A. There is a lengthy process before the gold standard that you are alluding to, the randomized multi-site clinical trial, occurs; that I would say ten, fifteen years from the time of the first reports on potential use of a medicine until that standard is met 	1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 8 9 0 1 2 2 3 4 5 7 8 9 0 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	MR. TRAMMELL: I'll object again as nonresponsive. BY MR. TRAMMELL: Q And the reason the FDA requires rigorous testing is so that representations made about a drug are based on reasonably sound scientific evidence. Right? A. Right Q And so to promote the use of the drug in the absence of that evidence is inappropriate, isn't it? A. If the drug is promoted without evidence, yes Q. Well, if a drug is promoted without the gold standard, that's inappropriate Right? A. Yes. Q. Did anyone at Janssen ever tell you that one of the purposes of your center was to help Janssen target pediatricians to use Risperdal? A. No. Q. Did anyone ever tell you that one of the purposes of your center was to create research that would help Janssen target general psychiatrists so that they would use Risperdal in kids? A. My center focused on the clinical
25	standard is met Stratos Legal Services 800-971-1127	25	A My center focused on the clinical Stratos Legal Services 800-971-1127
and manufactor became	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 163		Page 164
1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 7 8 9 0 1 1 2 3 4 5 8 9 0 1 1 2 3 4 5 8 9 0 1 1 2 3 4 5 8 9 1 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 2 3 1 1 1 2 3 1 1 1 2 3 1 2 3 1 1 2 3 1 1 1 2 3 1 1 1 1	 conditions for which Janssen and McNeil have medicines. The center did not do clinical trials, so they did not promote anything. We started neuroimaging, genetics, paradigm development, we analyzed data on the illness itself, ADHD and bipolar illness Q. You don't consider yourself responsible for what Janssen did with your research, do you? A I don't. Q If Janssen Well, never mind. If you'd go to the next page of this document, it's the third bullet point I'm sorry under the heading Resolving Complex and Controversial Diagnostic Issues, the third bullet point says "Implementing training programs for screening tools in continuing medical education programs targeting pediatricians and general neychiatrists." Did I read that right? 	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MR PECK: Objection, foundation A What this means to me is that there is a scarcity of trained child psychiatrists with expertise in psychopharmacology for the population of affected children. So if the condition were to be found to be morbid and devastating and affect 1 percent of children, there is not enough resources in child psychiatry to treat all these children. So these children, there are several states that there is no child psychiatry to be found, so these children will require some kind of pharmacological support from their primary care physician or general psychiatrist Q By the way, do you know how much Risperdal is used in kids? A. No Q. You have no idea? A. No Bisperidone is used in adults as
19 20 21 22 23 24 25	psychiatrists." Did I read that right? A. Yes. Q. And so what they're saying is one of the specific goals of the research that you do, one of Janssen's specific goals of the research that you do will be to instruct doctors on how to diagnose bipolar disorder and use Risperdal to treat it. Is that what that means to you? Stratos Legal Services 800-971-1127	18 19 20 21 22 23 24 25	 A. No. Risperidone is used in adults as well, as you know. Q. Sure Would it surprise you that over 20 percent of all the Risperdal that's used is used in kids? A I have no idea how much risperidone is used in children. Q. Do you consider yourself in any way Stratos Legal Services 800-971-1127

			42 (Pages 165 to 168
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
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	Page 165		Page 166
1	responsible for that?	1	A. Now it's approved.
2	A. No.	2	Q. I understand In 2002 pediatricians
3	Q Is it appropriate in your mind for	3	treated people for whom the use of Risperdal was
4	Risperdal to target pediatricians to try to get them	4	off-label. Right?
5	to use Risperdal in their patients?	5	A. The use of risperidone for children in
6	MR PECK: Objection, form	6	2002 was off-label
7	MR SPIVACK: Objection, no foundation,	7	Q So in your opinion, and you've testified
8	calls for speculation.	8	to this already a few minutes ago, was it
9	A. As I mentioned to you before,	9	appropriate for Janssen to be doing this, to be
10	pediatricians are more abundant than child	10	targeting doctors who only treat patients for whom
11		11	
12	,	12	the use of Risperdal is off-label?
		13	MR. SPIVACK: Objection, asked and
13	, , , , , ,		answered, calls for speculation, no foundation.
14		14	MR. PECK: Objection
15		15	MR. TRAMMELL: You can answer
16		16	A. I would say yes.
17	Q. Let me ask you this This is 2002. Who	17	Q. It's appropriate?
18	do pediatricians treat, what age groups?	18	 A. It is not appropriate.
19		19	Q. It's not appropriate, is it?
20	18.	20	MR. SPIVACK: Objection, asked and
21	Q. Okay Pediatricians treat people for whom	21	answered
22		22	BY MR TRAMMELL:
23		23	Q So that I don't have to say gold standard
24		24	or placebo-controlled, I'm going to say clinical
25		25	trials to refer to clinical trials that would be
Γ.	Stratos Legal Services	<u> </u>	Stratos Legal Services
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	Joseph Biederman		Joseph Biederman
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Joseph Biederman		Joseph Biederman
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1.2	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication,	1 2	Joseph Biederman February 26, 2009
2	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical		Joseph Biederman February 26, 2009 Page 168 Q. Does it have an adolescent schizophrenia indication?
2 3	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical trials do you know of that have been conducted by	2 3	Joseph Biederman February 26, 2009 Page 168 Q. Does it have an adolescent schizophrenia indication? A. Yes, that's true. I forgot. Thank you.
2 3 4	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical trials do you know of that have been conducted by Janssen to support the use of Risperdal in kids?	2 3 4	Joseph Biederman February 26, 2009 Page 168 Q. Does it have an adolescent schizophrenia indication? A. Yes, that's true. I forgot. Thank you. Q. And so there was a clinical trial that was
2 3 4 5	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical trials do you know of that have been conducted by Janssen to support the use of Risperdal in kids? A. To my knowledge, there is a study that was	2 3 4 5	Joseph Biederman February 26, 2009 Page 168 Q. Does it have an adolescent schizophrenia indication? A. Yes, that's true. I forgot. Thank you. Q. And so there was a clinical trial that was done to support Obviously, there was a clinical
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2 3 4 5 6 7	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical trials do you know of that have been conducted by Janssen to support the use of Risperdal in kids? A. To my knowledge, there is a study that was not conducted by Janssen but included risperidone that was in autistic children with severe	2 3 4 5 6 7	Joseph Biederman February 26, 2009 Page 168 Q. Does it have an adolescent schizophrenia indication? A. Yes, that's true. I forgot. Thank you. Q. And so there was a clinical trial that was done to support Obviously, there was a clinical trial that was done to support the autism indication. Right?
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2 3 4 5 6 7 8 9 10 11	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical trials do you know of that have been conducted by Janssen to support the use of Risperdal in kids? A. To my knowledge, there is a study that was not conducted by Janssen but included risperidone that was in autistic children with severe aggression. That led to the approval of risperidone I believe in 2006 for severe aggression in autistic children. And the other study is the randomized clinical trial that led to the approval of	2 3 4 5 6 7 8 9 10 11	Joseph Biederman February 26, 2009 Page 168 Q. Does it have an adolescent schizophrenia indication? A. Yes, that's true. I forgot. Thank you. Q. And so there was a clinical trial that was done to support Obviously, there was a clinical trial that was done to support the autism indication Right? A. Yes Q. Did you participate in that? A. No. Q. You weren't a center?
2 3 4 5 6 7 8 9 10 11 12	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical trials do you know of that have been conducted by Janssen to support the use of Risperdal in kids? A. To my knowledge, there is a study that was not conducted by Janssen but included risperidone that was in autistic children with severe aggression. That led to the approval of risperidone I believe in 2006 for severe aggression in autistic children. And the other study is the randomized clinical trial that led to the approval of risperidone for pediatric bipolar illness	2 3 4 5 6 7 8 9 10 11 12	Joseph Biederman February 26, 2009 Page 168 Q. Does it have an adolescent schizophrenia indication? A. Yes, that's true. I forgot. Thank you. Q. And so there was a clinical trial that was done to support Obviously, there was a clinical trial that was done to support the autism indication Right? A. Yes Q. Did you participate in that? A. No. Q. You weren't a center? A. I was not.
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2 3 4 5 6 7 8 9 0 112 13 15 6 7 8 9 0 112 13 15 6 7 8 9 0 112 14 5 6 7 8 9 0 112 13 14 5 6 7 8 9 0 112 13 14 5 6 7 8 9 0 12 2 12 14 5 6 7 8 9 0 12 2 12 14 5 6 7 8 9 0 12 2 14 5 6 7 8 9 0 12 2 14 5 6 7 8 9 0 12 2 14 5 6 7 8 9 0 12 2 14 5 14 5 14 5 14 5 14 5 14 5 14 5	Joseph Biederman February 26, 2009 Page 167 appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical trials do you know of that have been conducted by Janssen to support the use of Risperdal in kids? A. To my knowledge, there is a study that was not conducted by Janssen but included risperidone that was in autistic children with severe aggression. That led to the approval of risperidone I believe in 2006 for severe aggression in autistic children. And the other study is the randomized clinical trial that led to the approval of risperidone for pediatric bipolar illness Q Are those Risperdal's only approved uses in kids? A. No Abilify has received approval and I believe Zyprexa may be receiving The clinical trials have been conducted with Zyprexa, Abilify, and risperidone, to my knowledge. Q. I'm sorry I was asking about Risperdal, so let me restate my question. Are the agitation associated with autism and the mania associated with pediatric bipolar disorder the only indications that Risperdal has for kids?	2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 2 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Joseph Biederman February 26, 2009 Page 168 Q. Does it have an adolescent schizophrenia indication? A. Yes, that's true. I forgot. Thank you. Q. And so there was a clinical trial that was done to support Obviously, there was a clinical trial that was done to support the autism indication Right? A. Yes Q. Did you participate in that? A. No. Q. You weren't a center? A. I was not. Q. Were you asked to participate in it? A. No Q. Did you ask to participate in it? A. No Q. Did you ask to participate in it? A. No. Q. And do you know the number of that trial? A. I do not, no. Q. And there was a clinical trial to support the use of Risperdal in kids with mania associated with bipolar disorder. Right? A. Correct. Q. Do you know the number of that trial? A. No.

			43 (Pages 169 to 172
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 169		Page 170
1	A. No	1	A. To my knowledge, the autism trial was
2	Q. You were asked but you weren't available.	2	conducted in an NIH-funded multi-site entity that is
3	Right?	3	called RUPP, R-U-P-P, research unit in
4	A. I don't remember exactly. I know I didn't	4	psychopharmacology. That is my understanding, that
5	participate I don't remember exactly the sequence	5	it was conducted in that setting But I am not
6	of events	6	totally sure
7	Q. I think you testified earlier they asked	7	Q At Ohio State?
8	you; you didn't have the capacity to do it at the	8	A. The RUPP included multiple sites, not one.
9	time	9	Q Who was the lead investigator at Ohio
10	A. Yeah, that's my recollection	10	State?
11	Q. Okay. And I suppose all the same Well,	11	A. I have no idea
12	for adolescent schizophrenia there was a clinical	12	Q. Do you know whether anyone associated with
13	trial that was done to support that application	13	RUPP has a relationship with Janssen?
14	Right?	14	A. I have no idea
15	A. Yes	15	Q Have you ever met anyone associated with
16	Q. Do you know the number of it?	16	RUPP?
17	A. No	17	A. Yes, of course
18	Q. And you didn't participate in it?	18	Q. Who?
19 20	A No. Q. And weren't asked and didn't ask them?	19 20	A. The person that oversees the RUPP at NIH is Benedetto Vitiello that is the head of the
21	A. No, schizophrenia is not a disorder that	21	extramural program in pediatric psychopharmacology
22	we have a lot of patients	22	for the NIMH
23	Q. Do you know of any other clinical trials	23	Q. Have you ever heard of Trial 93?
24	that have Oh, you said earlier that Janssen	24	A. No.
25	didn't conduct the autism trial	25	Q. Have you ever heard of Trial 97?
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
1	February 26, 2009 Page 171	1	February 26, 2009 Page 172
1	February 26, 2009 Page 171 A. No	1	February 26, 2009 Page 172 their interactions with regulatory authorities
2	February 26, 2009 Page 171 A. No Q. How about a Canadian trial called 19?	2	February 26, 2009 Page 172 their interactions with regulatory authorities Right?
2 3	February 26, 2009 Page 171 A. No Q. How about a Canadian trial called 19? A. I have no idea.	2 3	February 26, 2009 Page 172 their interactions with regulatory authorities Right? A. Nothing to do
2	February 26, 2009 Page 171 A. No Q. How about a Canadian trial called 19?	2	February 26, 2009 Page 172 their interactions with regulatory authorities Right? A. Nothing to do Q. So you don't perform clinical trials that
2 3 4	February 26, 2009 Page 171 A. No Q. How about a Canadian trial called 19? A. I have no idea. Q. How about a Canadian trial called 20?	2 3 4	February 26, 2009 Page 172 their interactions with regulatory authorities Right? A. Nothing to do
2 3 4 5	February 26, 2009 Page 171 A. No Q. How about a Canadian trial called 19? A. I have no idea. Q. How about a Canadian trial called 20? A. I have no idea Q. Have you ever heard of any clinical trials conducted involving Risperdal and children with	2 3 4 5	February 26, 2009 Page 172 their interactions with regulatory authorities Right? A. Nothing to do Q. So you don't perform clinical trials that are intended to be submitted to the regulatory authorities like the FDA. Is that right? A I do perform. My site participated in
2 3 4 5 6 7 8	February 26, 2009 Page 171 A. No Q. How about a Canadian trial called 19? A. I have no idea. Q. How about a Canadian trial called 20? A. I have no idea Q. Have you ever heard of any clinical trials conducted involving Risperdal and children with conduct disorders?	2345678	February 26, 2009 Page 172 their interactions with regulatory authorities Right? A. Nothing to do Q. So you don't perform clinical trials that are intended to be submitted to the regulatory authorities like the FDA. Is that right? A I do perform. My site participated in several registration studies. I did not participate
2 3 4 5 6 7 8 9	February 26, 2009 Page 171 A. No Q. How about a Canadian trial called 19? A. I have no idea. Q. How about a Canadian trial called 20? A. I have no idea Q. Have you ever heard of any clinical trials conducted involving Risperdal and children with conduct disorders? A. Yes.	2 3 4 5 6 7 8 9	February 26, 2009 Page 172 their interactions with regulatory authorities Right? A. Nothing to do Q. So you don't perform clinical trials that are intended to be submitted to the regulatory authorities like the FDA. Is that right? A I do perform. My site participated in several registration studies. I did not participate in the risperidone study.
2 3 4 5 6 7 8 9 10	February 26, 2009 Page 171 A. No Q. How about a Canadian trial called 19? A. I have no idea. Q. How about a Canadian trial called 20? A. I have no idea Q. Have you ever heard of any clinical trials conducted involving Risperdal and children with conduct disorders? A. Yes. Q. Which trials have you heard of?	2 3 4 5 6 7 8 9 10	February 26, 2009 Page 172 their interactions with regulatory authorities Right? A. Nothing to do Q. So you don't perform clinical trials that are intended to be submitted to the regulatory authorities like the FDA. Is that right? A I do perform. My site participated in several registration studies. I did not participate in the risperidone study. Q. Okay, that's what I'm asking about You
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	Joseph Biederman		Joseph Biederman
	February 26, 2009	ĺ	February 26, 2009
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	Page 173		Page 174
1	had a discussion with FDA that involved Risperdal?	1	any of your publications?
2	A No	2	A. Yes, we did an analysis of the Aman
3	Q. You're a consultant for Cephalon. Right?	3	result, a secondary analysis it's called, extracting
4	A. I consulted for Cephalon, yes	4	from the rating scale that they used symptoms of
5	Q Did you disclose that to the FDA when you	5	mania and depression. So we were able to publish a
6	were on the committee?	6	paper and documenting that, in addition to conduct
7	A. Absolutely	7	symptoms, risperidone also helped symptoms of
8	Q. Did anyone at Janssen ever tell you that	8	euphoria, agitation, and depression
9	they had submitted an application for approval of	9	Q. Do you know whether the data on which Aman
10	the use of Risperdal for conduct disorders in kids?	10	relied and I suppose indirectly you relied was ever
11	A. I don't remember.	11	submitted to a regulatory authority to try to get a
12	Q. You don't know whether anyone ever told	12	new indication for Risperdal?
<u>1</u> 3	you that?	13	A. I do not know.
14	A. I don't remember	14	Q. If that data was submitted and you were
15	Q Well, did anyone ever tell you that they	15	relying on it and the application under which that
16	had submitted that application but it had been	16	data was submitted was denied, would you have liked
17	denied by regulatory authorities?	17	to have known that?
18	A. I don't remember I receive	18	MR PECK: Objection
19	communications of all types all the time, so I don't	19	A. I am not sure, what are you asking? The
20	remember.	20	denial of an application has nothing to do with my
21	Q. Did you rely in any way on the Aman paper?	21	work. Application sometimes could be denied because
22	A. If what?	22	the FDA may not like the diagnosis Conduct order
23	Q The Aman paper	23	may be a diagnosis that FDA may not consider a good
24	A If I was involved in the Aman paper?	24	target for medicines But my work has nothing to do
25	Q No, no Did you rely on it in any way in	25	with the regulatory position on the application
	Stratos Legal Services 800-971-1127		Stratos Legal Services 800-971-1127
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	Joseph Biederman	-	Joseph Biederman
	Joseph Biederman February 26, 2009	-	Joseph Biederman February 26, 2009
	February 26, 2009		February 26, 2009
	February 26, 2009 Page 175		February 26, 2009 Page 176
1	February 26, 2009 Page 175 Q. And so I'm sure that's not a lucky guess,	1	February 26, 2009 Page 176 needs to show separation from placebo
2	February 26, 2009 Page 175 Q. And so I'm sure that's not a lucky guess, you know the FDA denied an indication for that,	2	February 26, 2009 Page 176 needs to show separation from placebo Q You mean the statistical power is a
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45 (Pages 177 to 180)

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	Joseph Biederman	-	Joseph Biederman
	February 26, 2009	!	February 26, 2009
	Page 177	1	Page 178
1	number of patients to show that separation But if	1	-
2	you have a relatively small number of patients and	2	
3	you have very robust separation from placebo, that	3	
4	means that the signal is very, very strong that the	4	
5	medicine is effective	5	Q But it was in your area of study, wasn't
6	Q This is Number 8	6	it?
7	A We're done with this?	7	A Not really In the most general sense.
8		8	I study children with emotional and behavioral
9		9	disorders, but I don't study conduct disorders
10		10	specifically And the category of disruptive
11 12		11	behavior disorder is a very broad category and
12		12 13	encompasses a huge number of disorders.
14		14	Q Right If I were to say to you, you know, how do you characterize a disruptive behavior
15		15	disorder, you would have no idea how to do that,
16		16	would you?
17		17	A No. There are three categories under that
18		18	rubric: ADHD, oppositional defiant disorder, and
19		19	conduct disorder. Together they may afflict
20		20	15 percent of children
21		21 22	Q But the phrase disruptive behavior
22			disorder is too vague to be used as a diagnostic
23		23	category?
24		24	A I am not the one to determine that
25		25	Disruptive behavior disorders is a category
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2 3 4	February 26, 2009 Page 179	23	February 26, 2009 Page 180 Q Did anyone at Janssen ever tell you there was a lot of concern among regulatory authorities about the high incidence of adverse events in kids with Risperdal?
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	Page 181		Page 182
1		1	A. Yes. We in fact published a paper
2		2	documenting or recommending or suggesting a
3		3	treatment for elevation of prolactin
4	Q. And why is that?	4	Q. And, by the way, what is prolactin?
5	A. Because it is less of a concern for	5	A. Prolactin is a hormone produced by the
6	efficacy than it is for safety, because for safety	6	hypophysis that as its name indicates it's released
7	if you have less common adverse events, you need	7	when the mother gives birth, to permit lactation.
8	more subjects to determine less common adverse	8	Pro means promoting, lact means lactation.
9	events. You can show efficacy on a smaller number	9	Q Does prolactin Does everyone's body
10	of subjects	10	produce prolactin?
11 12	Q. But for safety, this was an insufficient	11	A. Everybody produces prolactin at low
13	number of people in the trial. Right?	12 13	levels And what we are talking about here is elevated levels.
14	A. I would guess so Certainly the FDA	14	
15	considered it insufficient for regulatory purposes.	15	Q. Is there any danger in low levels of
16		16	prolactin in the body? A. Low levels? Not not I know of
17		17	Q Is there any danger of high levels of
18		18	prolactin in the body?
19		19	A. It's unclear. In postmenstruating,
20		20	postmenarchal women, elevated levels can produce
21		21	secretion of milk from the breast and can disrupt
22		22	the period
23		21 22 23	Q Is there any difference in the danger of
24		24	elevated prolactin levels in kids versus adults?
25	Q. Has that been your experience?	25	A. It's totally unknown. The children that
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
1	February 26, 2009 Page 183	1	February 26, 2009 Page 184
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
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	Page 185		Page 186
1	it is more likely to happen on risperidone than on	1	Q. You think that's something that would be
2	other drugs in the class.	2	important for doctors to know, that among the class
3	Q Have you ever reviewed Risperdal's package	3	of atypicals, Risperdal is the most likely or more
4	insert?	4	likely than the others to produce
5	A Yes, I did	5	hyperprolactinemia?
6	Q. Do you know whether it has any statement	6	MR. PECK: Object to form.
7	in the warning on prolactin that Risperdal poses a	7	A. I'm not sure that this is a clinical piece
		8	
8	greater risk of elevated prolactin levels than other	1	of information It's not that the elevation of
9	atypical antipsychotics?	9	prolactinemia is a lethal side effect. So I think
10	A. I don't remember	10	it's noted I don't know what to tell you
11	Q. You don't know whether it says that or	11	Q You think it's known?
12	not?	12	A It is known, yes
13	A I do not know that that exact phrase you	13	Q And it is not a lethal side effect so they
14	are asking me is in the package insert.	14	don't have to warn about it?
15	Q. Should the Risperdal label have	15	MR PECK: Object to form.
16	information in its warning, information in the	16	THE WITNESS: Can I respond?
17	prolactin warning that makes clear to doctors who	自7	A. The side effects are described in the
18	use it that it presents a unique risk for	18	package insert
19	hyperprolactinemia among the atypical class?	19	Q. Right.
20	MR. PECK: Object to form.	20	A. For physicians to read.
21	A. I believe that the package insert contains	21	Q I think you understand what I'm asking
22	the elevation of prolactin. I do not know whether	22	you.
23	they have to have some kind of additional details.	23	A No, I don't
24	But the elevation of prolactin is noted in the	24	Q Okay. You told me that Risperdal is
25	package insert.	25	unique among the atypicals in its elevated
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	Joseph Biederman		Joseph Biederman
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009 Page 187		February 26, 2009 Page 188
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 189		Page 190
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1	among drugs that they might choose	1	Q. We talked about the relative risk, the
2	MR SPIVACK: Objection, argumentative,	2	relative potential harm of prolactinemia in kids
3	misstates the witness's testimony	3	versus adults To your mind, is there a relative
4	BY MR. TRAMMELL:	4	difference in the potential harm for kids versus
5	Q. I mean, and perhaps we're not	5	adults of hyperprolactinemia?
6	communicating. I mean, can you explain to me why	6	A. The word "harm" may not be the best
7	you think that's not a risk worth warning about?	7	description of what we are discussing here. The
8	A. I think	8	impact of elevated levels of prolactin in children
9	MR. SPIVACK: Objection, misstates the	9	is not well-known. It's not well-understood
10	testimony	10	Q. How do you treat hyperprolactinemia?
11	A. I think that it is a risk worth mentioning	11	A. We published a paper in the late '90s
12	and it is listed in the PDR. You are asking me if	12	using a D2 agonist in children with high levels of
13		13	
	there should be some particular black box or a	F	prolactin These children were asymptomatic, did
14	particular warning, and I am not a regulator	14	not have any symptoms visible to us in physical
15	I think that the possibilities of	15	examination or clinical complaints; zero. But
16	prolactinemia are listed in the PDR.	16	because the levels of prolactin were high, I
17	Q. I'm asking you, should doctors know or be	17	preferred to try to bring it down. Another option
18	warned, regardless of how that warning looks on a	18	is to remove the medicine and change it to another
19	label, should doctors be warned of a relatively	19	one
20	greater risk among possible treatment alternatives?	20	Q Are you trying to say that because you've
21	MR. SPIVACK: Objection, asked and	21	never seen symptoms of hyperprolactinemia, that it
22	answered, calls for speculation	22	doesn't exist?
		1	
23	A I believe that the warning that they have	23	A. No.
24	about this possibility of hyperprolactinemia is	24	Q. Okay.
25	adequate.	25	A. I am saying that the scientific evidence
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1	February 26, 2009 Page 191 of what does it mean clinically in children is not	1	February 26, 2009 Page 192 It is not the side effect that is associated with
2	February 26, 2009 Page 191 of what does it mean clinically in children is not well-known	2	February 26, 2009 Page 192 It is not the side effect that is associated with visible problems in premenarche, prepuberty
2 3	February 26, 2009 Page 191 of what does it mean clinically in children is not well-known Q Despite the fact that it's not What did	2 3	February 26, 2009 Page 192 It is not the side effect that is associated with visible problems in premenarche, prepuberty children So it's not clear what symptoms people
2 3 4	February 26, 2009 Page 191 of what does it mean clinically in children is not well-known. Q Despite the fact that it's not What did you say?	2 3 4	February 26, 2009 Page 192 It is not the side effect that is associated with visible problems in premenarche, prepuberty children So it's not clear what symptoms people have
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	Joseph Biederman		Joseph Biederman
	February 26, 2009 Page 193		February 26, 2009 Page 194
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1	the reasons you don't think it's a serious risk or	1	Q. But you never did a study to determine
2	that it's unknown is because there's no clinical	2	whether Risperdal caused greater hyperprolactinemia
3	trial showing it Right?	3	than other atypicals?
4	A. I said that the clinical impact of	4	A We measured the levels of prolactin and
5	elevation of prolactin is not well-documented.	5	the percent of children that have elevations in
6	Q. Okay But it is based on the chemical	7	every one of the studies and we tested them all. O. 1 understand
8	compound Risperdal Right? A. Based what?	8	A. And we published in our papers the levels
9	Q The notion or Risperdal's effect on	9	of prolactin.
10	prolactin and understanding of that is based on	10	MR TRAMMELL: I object as nonresponsive.
11	Risperdal's chemical compound and its interaction	11	BY MR. TRAMMELL:
12	with neuroreceptors Right?	12	Q. I'm sure you know what I'm asking you.
13	A. Yes.	13	A No, I don't
14	Q And so because you can tell that Risperdal	14	Q Okay. Every study that you conduct has a
15	elevates, has the potential to elevate prolactin	15	purpose. Right?
16	levels simply based on its chemical compound, what	16	A. Yes
17	do you need a clinical trial for?	17	Q You're trying to prove or disprove a
18	A. You need to actually document that's the	18	hypothesis. Right?
19	case You need to show that it is in fact more than	19	A Right, yes, correct.
20	Zyprexa or Geodon or other medications on the class	20	Q Did you ever try to prove or disprove that
21	Q Did you ever do any research on the	21	Risperdal has a greater effect on prolactin levels
22	relative levels of prolactin in kids taking	22	than other atypical antipsychotics?
23	Risperdal versus other atypicals?	23	A. No
24	A. We measure prolactin in every study of an	24	Q. Did you ever propose to Janssen that that
25	atypical that we conduct.	25	kind of study be done?
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Joseph Biederman February 26, 2009 Page 195		Joseph Biederman February 26, 2009 Page 196
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 197		Page 198
1	completed in the past.	1	A The clinical and research program in
2	Q. And you published on all that work	2	pediatric psychopharmacology
3	Right?	3	Q. Which is different from the J&J Center?
4	A Yes O What is the basis or where was the work	5	A Yes And by the way the 18 Conter did it
6	Q. What is the basis or where was the work done that served as the basis for your studies, your	6	Q And, by the way, the J&J Center, did it have a physical address?
7	Risperdal studies?	7	A. No.
8	A. We had the contract to do an open label	8	Q It's just an entity. Right?
9	study of risperidone in children and adolescents	9	A It's a concept.
10	with pediatric bipolar illness	10	Q. Okay, it's a concept. There's no J&J
11	Q. You're making a distinction between your	11	building sign anywhere your building?
12	center and something else	12	A A building, no.
13	A. Yes The study that we did doing	13	Q. Can you tell me one more time, there's the
14	risperidone was done with a separate contract to do	14	J&J Center and what was the full title of it? Do
15	that study with Janssen It was not part of the	15	you remember?
16	center's focus	16	A The J&J Center for the Study of Pediatric
17 18	Q I understand. So Janssen gave you money every year to fund the center which had the cores	17 18	Psychopathology
19	which you keep talking about and then they would	19	Q And your program is called what?
20	separately give you money to fund studies?	20	A The clinical and research program in pediatric psychopharmacology
21	A. Yes	21	Q. Is that a concept too?
22	Q And where did those studies take place?	22	A. What do you mean, a concept?
23	A. The studies took place in my program at	23	Q Well, it's a way you characterize
24	Mass. General	24	different aspects of your business. Right?
25	Q What's the name of your program?	25	A I am a physician and not a businessman
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 199		Page 200
1	We see patients My program has about 3,000	1	A. Say that again?
2	children with severe mental illness that myself and	2	Q. You run it?
3	my colleagues care for The center carries a dozen	3	A. Yes
4	of scientists that explore the underlying scientific	4	Q. Do you get a salary from the program?
5	foundations of all disorders that afflict children.	5	A. Which program?
6	Q. Does the center have any employees?	6	 Q. The program you just described A. You have to be specific. J&J pays less
8	 A. No Q Does your program have any employees? 	8	A. You have to be specific. J&J pays less than 10 percent of my institutional salary
9	A. Yes.	9	Q. Okay. Did you write it down? Did you get
10	Q And who are they?	10	a salary from the J&J Center for pediatric
11	A You want me to name all of them?	11	psychopathology at MGH?
12	Q. Yes. How many are there?	12	A. Yes. That salary was about, it's less
13	A Depending on funding, there are as many as	13	than 10 percent of my total income. It's 5 or 7
14	one hundred.	14	thousand dollars a year.
15	Q. No, I don't want you to name them all.	15	Q And what is your total income?
16	All those people that work at your program, is that	16	A. My total income varies depending on
17 18	their only job?	17 18	sources of funding, but it's somewhere about 250
18 19	A. For some people that work part time, they have other jobs	18	Q What percentage of your income comes from Massachusetts General Hospital?
20	Q. Is there someone who works at your program	20	A. The entire income comes from Massachusetts
21	that's their only job?	21	General Hospital.
22	A. Yes	22	Q Are you paid for giving talks on behalf of
23	Q. And you employ up to a hundred people?	23	the pharmaceutical companies?
24	A. Yes	24	A Those are not salaries Those are outside
25	Q. And you run it?	25	activities
	Stratos Legal Services		Stratos Legal Services

	Joseph Biederman		Joseph Biederman
	February 26, 2009 Page 201		February 26, 2009 Page 202
1	Q. I understand Do you know what income	1 cons	ultation in 2007.
2	means?	2 Q	
3	A If I know the word income? Yes		sultations in 2007?
4	Q Okay What is your income?		I don't remember exactly But it was
5	A Could you define what are you asking?		it, I would say, all around consultation I think
б	Q. How much money was paid to you in 2008?		170 or something like that
7	A. In 2008? The salary portion is about 250	7 Q	170? And how much did you make from your
8	or 260.		ate practice in '07?
9	Q Any other income that you have?	9 A	
10	A Yes I have some private practice and I		at 100,000
11	have consultation and talks that I give.	.1 Q	
12 13	Q. And what was the total of that		I think in 2007 may have been a little bit I think was maybe 230 or something like that
14	compensation? A In 2008 the consultation and talks were	.3 iess .4 Q	
15	about 50 or 60 thousand and the private practice,		panies is more than half of your income or it was
16	about 100,000		007 Right?
17	Q So about \$400,000 in 2008?		No I think that the income of outside
18	A. Roughly		vities is not only from drug companies, it's
19	Q That was your total income?		CME activities and other sources, not from drug
20	A. (Witness nodded.)		panies
21	Q. That's what you'll report to the	21 Q	
22	Government?	•	that?
23	A Yes.	23 A	
24	Q Was it more or less in 2007?	-	vities Some are other type of consultations
25	A. It was a little bit more. I did more	25 Q	,
	Stratos Legal Services 800-971-1127		Stratos Legal Services 800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
1	February 26, 2009 Page 203 to do with teaching at Harvard or seeing patients at	1 Q	February 26, 2009 Page 204
1 2	February 26, 2009 Page 203 to do with teaching at Harvard or seeing patients at MGH. Right?	2 A	February 26, 2009 Page 204 Thousands? No; dozens, dozens
2 3	February 26, 2009 Page 203 to do with teaching at Harvard or seeing patients at MGH. Right? A. Those are outside activities.	2 A 3 BY	February 26, 2009 Page 204 Thousands? No; dozens, dozens MR. TRAMMELL:
2 3 4	February 26, 2009 Page 203 to do with teaching at Harvard or seeing patients at MGH. Right? A. Those are outside activities. Q. More than half of your income is not	2 A 3 BY 4 Q	February 26, 2009 Page 204 Thousands? No; dozens, dozens MR. TRAMMELL: You don't know whether you made more money
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			52 (Pages 205 to 208)
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 205		Page 206
	-		-
1	Disorder - A Retrospective Chart Review. You're	1	review it?
2	listed as an author	23	A No, I actually typed in the words.
3	A. Yes. Q. Did you write this?	4	Q Did you have a consulting relationship with Janssen at this time?
5	A. Yes.	5	A. I am not aware that I had a consulting
6	Q. You wrote it?	6	relationship.
7	A. I wrote it with my colleagues.	7	Q Do you know of anybody else that's listed
8	Q. Did you actually put pen to paper and	8	as an author that had a relationship with Janssen at
9	write the words that are in this study?	9	the time?
10	A Yes	10	A. I am not aware of
11	Q Did you write the first draft of this	11	Q Do you know whether this study was funded
12	study?	12	by Janssen?
13	A. I don't remember who wrote the first	13	A. No, this study was not funded by anybody
14	draft, but the case series came from my patients in	14	Q Who funded it?
15	the clinic.	15	A. It was not funded by anybody. We just
16 17	MR SMITH: Objection as nonresponsive	16 17	collected data from our records, tabulated it and
18	MR TRAMMELL: Objection, nonresponsive BY MR TRAMMELL:	17 18	reported it
19	Q Do you know who wrote the first draft?	19	Q. Now, it says it was published August of 1999.
20	A. I believe that I did the first draft, but	20	A. Mm-hmm
21	I am not I cannot tell you with certainty.	21	Q. And the conclusion of this study is,
22	Q. And when you say you wrote the first	22	"Although limited by its retrospective nature, this
23	draft, does that mean you actually sat at a keyboard	23	study suggests that risperidone may be effective in
24	and generated a document or does that mean somebody	24	the treatment of manic young people and indicates
25	sent you the first draft and you were the first to	25	the need for controlled clinical trials of
	Stratos Legal Services		Stratos Legal Services
	800-971-1127	-[800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 207		Page 208
11	risperidone and other atypical neuroleptics in	1	treatment of manic young people, wouldn't it?
2	juvenile mania." Did I read that right?	2	A. It would not
3	A. Yes	3	MR. SPIVACK: Objection, calls for
4	Q. So it's saying that this study is limited	4	speculation, no foundation.
5	by its retrospective nature. What does that mean?	5	A. It would not be appropriate.
6	A This is a chart review in which	6	Q This is 10. 10 is a case report published
7	risperidone was added to other treatments, so the	7	in the Journal of Child and Adolescent
		10	
8	children were receiving other treatments, not only	8	Psychopharmacology, November 4, 2001. You and
9	risperidone And by being retrospective means that	9	Louise Glassner Cohen are the authors. Right?
9 10	risperidone. And by being retrospective means that a study that is more evaluative has to be		Louise Glassner Cohen are the authors. Right? A Correct
9	risperidone. And by being retrospective means that a study that is more evaluative has to be prospective, so you start You cannot say much	9 10	Louise Glassner Cohen are the authors. Right? A Correct Q What is a case report?
9 10 11	risperidone. And by being retrospective means that a study that is more evaluative has to be	9 10 11 12 13	Louise Glassner Cohen are the authors. Right? A Correct
9 10 11 12 13 14	risperidone. And by being retrospective means that a study that is more evaluative has to be prospective, so you start You cannot say much from a retrospective study; it's just a signal. The	9 10 11 12 13 14	Louise Glassner Cohen are the authors. Right? A Correct Q What is a case report? A. It's a group of children that have very elevated levels of prolactin that we treated with a selective D2 agonist called cabergoline.
9 10 11 12 13 14 15	risperidone. And by being retrospective means that a study that is more evaluative has to be prospective, so you start You cannot say much from a retrospective study; it's just a signal. The process starts with clinical observation. This was a clinical observation with our patients, my patients	9 10 11 12 13 14 15	Louise Glassner Cohen are the authors. Right? A Correct Q What is a case report? A. It's a group of children that have very elevated levels of prolactin that we treated with a selective D2 agonist called cabergoline Q. Why were you studying this? Why did you
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			54 (Pages 215 CO 210
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 213		Page 214
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1	So even though these are just case series,	1	were perfectly happy to make a safety distinction
2	doctors know epilepsy affects at least 1 to 2	2	when you're saying Risperdal is not associated with
3	percent of the population, so doctors are likely to	3	a risk but you disavow any obligation by Janssen to
4	meet an epileptic child that has psychiatric	4	make a distinction when Risperdal is associated with
5	illnesses that require psychiatric treatment So	5	a risk And is the reason that you do that because
6	having some idea that the drug is not exacerbating	6	they've paid you so much money?
7	seizure is an important piece of information, not	7	MR. SPIVACK: Objection, compound,
8	definitive or divine, but at least gives some kind	8	misstates the testimony, argumentative
9	of information in the absence of nothing	9	A. The paper on prolactin Sorry.
10	Q. Knowledge is better than nothing and it's	10	MR. SPIVACK: Go ahead
11	important for doctors to have this knowledge in	11	A The paper on prolactin described the
12	their risk/benefit analysis Right?	12	prolactinemia as associated with risperidone and
13	A. Yes	13	I tried to treat it by using a medicine. This paper
14	Q. And knowing is better than ignorance,	14	discusses the fact that children that require
15	except when it comes to relatively greater levels of	15	psychiatric intervention, in this case with
16	hyperprolactinemia. Right?	16	risperidone, their seizures did not exacerbate
17	MR. SPIVACK: Objection, argumentative	17	Both are important issues.
18	MR PECK: Objection	18	Q. Right While you're being paid by
19	A. I have no idea what you want from me, but	19	Janssen, you are minimalizing side effects
20	I am discussing that prolactinemia was an issue	20	associated with Risperdal Right?
21	I was always very concerned about prolactinemia	21	MR PECK: Object to form
22	I treated prolactinemia I don't know what is the	22	MR SPIVACK: Objection, no foundation
23	basis for your attack.	23	A I am not minimalizing anything
24	Q. It's not an attack 1 mean, I want to	24	Q. Did Janssen There's a Janssen author on
25	understand the distinction you make I mean, you	25	that paper Right?
	Stratos Legal Services 800-971-1127	1	Stratos Legal Services 800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 215		Page 216
1	A. Yes.	1	A. On occasion.
2	MR TRAMMELL: We've got to change tapes.	2	Q. And what did you talk about?
3	THE VIDEOGRAPHER: This is the end of tape	3	A. I only talk about the diseases for which a
4	number 3 The time is 2:39 We're off the record	4	condition I talk on pediatric bipolar illness or
5	(Short recess taken)	5	ADHD
6	THE VIDEOGRAPHER: We're back on the	6	Q. Do you talk about the use of Risperdal to
7	record This is the beginning of tape number 4	7	treat those conditions?
8	The time is 2:55	8	A. I talk on the disease and I would say
9	BY MR TRAMMELL:	9	90 percent of my talk on pediatric bipolar is on the
10	Q Doctor, we're back on the record. You	10	disease, its clinical manifestations, and I mention
11	understand you're still under oath. Right?	11	among the treatments available our results of
12	A. Yes	12	risperidone
13	Q. Okay Now, when you would go give these	13	Q So you talk about Risperdal, even if it's
14	talks that Janssen hired you to give, what kinds of	14	just for a small part of the time You talk about
15	things would you talk about?	15	Risperdal when you give your talks about the
16	A. First of all, Janssen did not hire me to	16	diseases. Right?
17	give talks	17	A. I talk about the disease and I talk about
18	Q. Okay Does that mean that you never were	18	treatments, and one of the treatments is
19	paid by Janssen to speak to anybody?	19	risperidone
20	A No That means the talks that I give is	20	Q Right And the disease is pediatric
21	on the diseases and some may or may not be funded by	21	bipolar disorder. Right?
22	Janssen Not always I know who funds a particular	22	A. Yes.
23	program	23	Q. And ADHD with comorbid pediatric bipolar
24	Q. Well, maybe you misunderstood me Janssen	24	disorder?
25	paid you to give talks Right?	25	A. I talk on ADHD separately from bipolar
25	Stratos Legal Services	25	Stratos Legal Services
25		25	

	Joseph Biederman February 26, 2009	1	Joseph Biederman February 26, 2009
	- Page 217		Page 21
1	illness. When I talk on bipolar illness, I describe	1	A. I talk about the disease, I talk about the
2	a sizeable number of children with bipolar illness	2	treatments, and I describe what we know about the
3	have comorbid ADHD	3	different treatments.
4		4	
5	Q. When you're speaking at CME events, do you	5	Q. But you don't talk about side effects
	talk about Risperdal?		generally?
6	A I talk about pediatric bipolar disease,	6	A. I talk about side effects if somebody asks
7	and when I talk about treatments I describe the	7	me
8	treatments available to treat pediatric bipolar	8	Q. But it's not part of your slide deck.
9	illness based on the evidence available to me at	9	Right?
0	that time, and that includes risperidone.	10	A. Not necessarily. Depending on time
1	Q. Sure Do you talk about the side effects	11	available, I describe in some of the talks the
.2	of Risperdal at those talks?	12	weight gain being associated with atypical
.3	A. The talks have a finite amount of time, so	13	neuroleptics.
. 4	I can only spend a few seconds per slide. Out of a	14	 Q You mean you tell everybody that Zyprexa
. 5	slide set of about 100 slides, I may have one or two	15	is the worst offender for weight gain and that the
. 6	slides for risperidone	16	others are not as bad?
. 7	Q In your risperidone slides, are you	17	A. No I tell that the average weight gain
8	discussing side effects?	18	in our studies with Zyprexa were 5 kilos over eigh
19	A. The risperidone slides are mainly	19	weeks and risperidone was 2-1/2 kilos over eight
20	reporting on the efficacy part	20	weeks.
21	Q. So you're talking about the disease and	21	Q. Why do you tell people about weight gain?
22	then you say "This is my understanding of the	22	A Because weight gain is one of the most
23	treatments available This is Risperdal. I have	23	significant liabilities of the atypical
24	studied it and found it to be effective in treating	24	neuroleptics
25	this disease"?	25	Q. Because it can lead to diabetes and a
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 219		Page 22
1	-		and I frequently do not know who pays for the talk
1 2	number of other health complications. Right?	1	in the form of grand rounds or a scientific
	A Weight gain is a problem in medicine, not	6	
		-	
3	only for diabetes It's a problem in its own right.	3	symposia I never talk on risperidone.
3 4	Q. But it is a problem for diabetes. Right?	4	symposia. I never talk on risperidone. Q. You don't know who pays for those talks?
3 4 5	Q. But it is a problem for diabetes. Right?A. Weight gain is one of the risk factors for	4 5	symposia. I never talk on risperidone. Q. You don't know who pays for those talks? A. Pardon?
3 4 5 6	 Q. But it is a problem for diabetes. Right? A. Weight gain is one of the risk factors for diabetes. 	4 5 6	 symposia. I never talk on risperidone. Q. You don't know who pays for those talks? A. Pardon? Q. You don't know who pays for those talks?
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3 4 5 6 7 8	 Q. But it is a problem for diabetes. Right? A. Weight gain is one of the risk factors for diabetes. Q. And so when you're talking about weight gain and Risperdal, it is to say that in your 	4 5 6 7 8	 symposia I never talk on risperidone. Q. You don't know who pays for those talks? A. Pardon? Q. You don't know who pays for those talks? A. Not always I know who pays for the talk I get an invitation to speak at an academic
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			56 (Pages 221 to 224
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
			-
	Page 221		Page 222
1	talks that you give for them?	1	A. Sorry. Define that for me.
2	A No.	2	Q Well, the way you characterized pediatric
3	Q. Why don't you let them do that?	3	bipolar disorder, your contribution is
4	A. Because it's my talk	4	characterizing something that used to be thought of
5	Q. You don't want any idea that they're	5	as something else as pediatric bipolar disorder.
6	influencing the content of your talk. Right?	6	Right?
7	A. Absolutely not	7	A. I define the set of symptoms that
8	Q. Do you think it would be inappropriate for	8	characterize the disorder as fulfilling all
9	Janssen Never mind.	9	structured diagnostic interviews criteria for
10	Is childhood mania or was it ever a	10	bipolar disorder So instead of calling an animal
11		11	with four legs and a tail an animal with four legs
12	disease about which the clinical community was	12	
$12 \\ 13$	skeptical?	13	and a tail, I said maybe this should be called a
	A. Yes.		dog.
14	Q. And why?	14	Q What are affective storms?
15	A It was considered a very uncommon disease	15	A. The term "affective storms" allude to a
16	Q. And because of that, there was a	16	very severe agitated, aggressive state
17	reluctance to treat it Right?	17	Q. Is there a scientific definition for it?
18	A. No. I think children went under different	18	A What do you mean?
19	names and they were treated the same way So does	19	Q Well, is it a subjective phrase or is
20	not matter what you call it, so some clinicians felt	20	there some sort of objective criteria for affective
21	more comfortable with the label of conduct disorder	21	storms?
22	or severe ADHD or oppositional-defiant disorder.	22	A. An affective storm is subjective All our
23	The treatment may be the same.	23	nosology is subjective, is based on signs and
24	Q. But it was never thought of as potentially	24	symptoms "Affective storms" is a term that was
25	a psychotic disorder Right?	25	used I believe by Dr Davis many years ago before my
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
1	February 26, 2009 Page 223		February 26, 2009 Page 224
1 2	February 26, 2009 Page 223 time to describe a prolonged state of temper	1 2	February 26, 2009 Page 224 suspicion that somebody may be suffering from
2	February 26, 2009 Page 223 time to describe a prolonged state of temper outbursts.	1 2	February 26, 2009 Page 224 suspicion that somebody may be suffering from Q. Okay. Does pediatric bipolar disorder
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 225		Page 226
1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 6 7 8 9 0 1 1 2 3 4 5 1 1 2 3 4 5 1 1 2 3 4 5 1 1 2 3 4 5 1 2 3 4 5 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 2 3 1 2 3 1 1 2 3 1 2 3 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 2 1 1 2 2 1 2 1	 that can be either euphoric or irritable, associated with additional symptoms such as distractibility, hypersexuality, agitation, difficulties in concentration, difficulties in functioning. Q. Those are not the criteria for kids, though? A. The same criteria are used for kids as are used for adults. Q. Are those criteria useful for kids? A. Yes. Q. Does someone have to satisfy those criteria to be accurately diagnosed as bipolar? A. Yes. Q. Okay, this is 12 Doctor, is this a set of slides from a talk you gave? A I think so. Q. Do you know when? A. No. Q. You can't tell just from looking at it? 	12345678901234567890 112345678901234567890	Janssen-sponsored event or an event sponsored by some other drug company? A. Could be anywhere. Q Well, it would be one of those two. Right? A. I participate in congresses, so it's not Maybe more than two or three. Q It would have been a talk to other doctors, though, probably Right? A. Most likely.
21 22 23 24 25	 A. No Q. Do you know what kind of audience you would have given this talk to? A. No Q. It would either have been at a CME or a Stratos Legal Services 800-971-1127 	21 22 23 24 25	 Q. Why was it important to you to make those your first two bullet points? A Because the issue of not diagnosing and choosing another name may be an important error in Stratos Legal Services 800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 227		Page 228
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	clinical judgment, so the problem of controversy leads to funding agencies not funding the necessary research to establish It's a vicious circle that if I send a paper on pediatric mania, the paper is likely to be rejected because pediatric mania does not exist because there are no papers on the subject, something like that. Q. And did you say earlier, did you testify that kids have an atypical expression of bipolar disorder compared to adults? A. Atypical only in the developmental variability of the clinical picture, not in the items that define it. Q. Okay	1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 4 5 6 7 1 2 3 1 2 3 1 2 5 1 2 3 1 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 3 1 1 2 1 2	 A. Yes. The abnormal mood has two components, either euphoria or irritability, or both. Q. You certainly can't diagnose pediatric bipolar disorder just based on irritability. Right? A. No. I said that irritability is not enough; has to be severe, persistent, and it has to be accompanied by additional symptoms.
17 18 19 20 21 22 23 24 25	Q Irritability is one of the criteria Right? Stratos Legal Services 800-971-1127	17 18 20 22 23 24 25	 Q. Does this mean fighting with your brothers and sisters? A. No. This includes things like taking a baseball bat and attempting to murder your sibling. Q It has to be that kind of action Right? A. It has to be very severe, yes. Q. Why didn't you explain that in this slide? A. Because the irritability that we see in manic children is not fighting with your sibling Stratos Legal Services 800-971-1127

			58 (Pages 229 to 232
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 229		Page 230
$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\0\\1\\1\\2\\3\\4\\5\\6\\7\\8\\9\\0\\1\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2$	 reason; opening the door of the car, a moving car on the highway, and attempting to jump. Okay? Q Do you tell doctors when you talk on this that the type of irritability that is necessary to diagnose pediatric bipolar disorder is the type that involves some sort of excessively violent attack like trying to kill a parent or family member? A. No. I say that the type of irritability that we see in children is extremely severe. Not all are murderous. Q. What types of activity in between fighting with your brothers and sisters and trying to kill your parent satisfy the criteria for irritability? A Well, for example, spending five hours Stratos Legal Services 	$1 \\ 2 \\ 3 \\ 4 \\ 5 \\ 6 \\ 7 \\ 8 \\ 9 \\ 0 \\ 1 \\ 1 \\ 2 \\ 1 \\ 3 \\ 4 \\ 1 \\ 5 \\ 6 \\ 7 \\ 8 \\ 9 \\ 0 \\ 1 \\ 1 \\ 2 \\ 2 \\ 2 \\ 2 \\ 2 \\ 2 \\ 2 \\ 2$	 demolishing your room after you were not allowed to watch your TV show; taking a baseball bat and demolishing every furniture in the house. Q It has to be that extreme? A. It has to be way out there in the decibels of aggression. Q What is the scientific criteria for evaluating whether irritability rises to a level sufficient to be indicative of bipolar disorder? A We don't have an aggressometer. It is a subjective judgment. We wrote an article describing that there are different levels of irritability like there are different levels of fever or different levels of seizures Q And that's why it's vague, right, because it's a subjective judgment and A. It's not vague at all Q. Okay. Can you tell me exactly what kinds of behaviors are included and are not included in your definition of irritability necessary to be diagnosed with bipolar disorder? A Yes It is a protracted state of very severe agitation, explosiveness and dyscontrol lasting totally different than normal human experience. And that's something that physicians Stratos Legal Services
	Joseph Biederman	-	Joseph Biederman
	February 26, 2009 Page 231		February 26, 2009 Page 232
	-		-
1 2	are trained to understand and diagnose If you were to have one of those children in your household, you	1 2	that these children did not exist, they were just under different names
3	would have no difficulty recognizing that the	3	Q. How long does the irritability have to
4	behavior is totally abnormal These are the	4	protract? How long does it have to last?
5	children that the police needs to be called in	5	A Usually more often than not for at least a
6	okay? or the ambulance to take the child to the	6	week to qualify.
7	emergency room This is the kind of behaviors I'm	7	Q Is that included in your explanation here?
8	talking about	8	Or do you give that explanation when you talk to
9 10	Q. I think that's the point, that I'm not	9 10	doctors about it?
11	qualified to diagnose bipolar disorder. I might agree with you that a child is a terror and is not	11	A Yes, I do. I think that there's a limited amount of material that I can hit in a talk. It's
12	much fun to have around, but that doesn't mean that	12	not necessarily that I'm covering every niche of the
13	that child is bipolar.	13	disorder, so I'm trying to hit on the highlights.
14	A No.	14	And the irritability part, the same question that
15	Q So the problem with these criteria are	15	you are asking me about, as you say, fighting with
16	that they are completely vague, that doctors who are	16	your siblings is not part of it
17	not trained at diagnosing bipolar disorder or	17	Q. So in order to be irritability And I'm
18	doctors who have not studied this population are	18	just trying to understand this, because it's not
19	unable to evaluate whether kids who're just angry or	19	clear to me. In order to qualify as irritability
20	kids who are just acting out actually have a	20	that can substantiate a diagnosis of bipolar
21	psychotic illness Isn't that right?	21	disorder, a child has to be in a murderous rage
22	A. No I think that the kind of behaviors	22	persistently for a week?
23	that I am describing are very, very severe These	23	A. I did not say murderous That's not a
24	children have been called in the past conduct	24	requirement for diagnosis It has to be severe,
25	disorder, oppositional-defiant disorder It's not	25	persistent, incapacitating, for a period of a week
1	Stratos Legal Services	1	Stratos Legal Services

21 22 23 A. No I think that the kind of behaviors that I am describing are very, very severe These requirement for diagnosis It has to be severe, persistent, incapacitating, for a period of a week Stratos Legal Services 800-971-1127 24 children have been called in the past conduct disorder, oppositional-defiant disorder. It's not Stratos Legal Services 800-971-1127 25

		59 (Pages 233 to 236)
	Joseph Biederman	Joseph Biederman
	February 26, 2009	February 26, 2009
	Page 233	Page 234
	-	
12	A child goes to sleep at night Q. What if a child is just irritable for a	 parents to use Risperdal where they probably shouldn't?
3	week?	3 MR. PECK: Object to form, foundation
4	A. That may not be enough. The irritability	4 BY MR. TRAMMELL:
5	that we see in children that have oppositional-	5 Q. Did anybody ever tell you that?
6	defiant disorder is a mild problem. It's kind of	6 A No.
7	like a bad hair day. The irritability that we see	7 Q. Anybody ever say that to you, "That's our
8	in depression does not rise to the irritability of	8 plan here with Risperdal"?
9 10	extreme proportions that we see in mania. So being	9 A. Not at all.
11		10 Q. And, again, what's the scientific 11 definition of irritable?
12		12 A. I think that you are using the wrong
13		13 words. The scientific definition, irritability is a
14		14 clinical symptom. Clinical symptoms are
15	0	15 descriptive, not scientific What is the scientific
16	······································	16 definition of a headache? There's no scientific.
17	0	17 You have a headache
18 19		18 Q. Is it as easy to diagnose pediatric 19 bipolar disorder as a headache?
20		20 A. No. But in the headaches, the way that
21		21 the headache is afflicting the patient alerts the
22		2.2 physician as to whether you have a tumor, you have
23	it's so hard to understand what would qualify as	23 migraine headaches, or tension headaches. So the
24		2.4 clinical topography of the symptom tells the trained
25	,	25 clinician what could be the underlying cause of the
	Stratos Legal Services 800-971-1127	Stratos Legal Services 800-971-1127
-	000-971-1127	000-971-1127
	Joseph Biederman February 26, 2009	Joseph Biederman February 26, 2009
1	February 26, 2009 Page 235	February 26, 2009 Page 236
1 2	February 26, 2009	February 26, 2009 Page 236 1 offensive that you will think that I would not know 2 the difference between a temper tantrum and this
2 3	February 26, 2009 Page 235 problem So headaches are very different and there are very many reasons in medicine to have a headache.	February 26, 2009 Page 236 offensive that you will think that I would not know the difference between a temper tantrum and this condition
2 3 4	February 26, 2009 Page 235 problem So headaches are very different and there are very many reasons in medicine to have a headache. Q. How do you tell whether someone who has	February 26, 2009 Page 236 offensive that you will think that I would not know the difference between a temper tantrum and this condition Q. But maybe you can educate me and the jury
2 3 4 5	February 26, 2009 Page 235 problem So headaches are very different and there are very many reasons in medicine to have a headache. Q. How do you tell whether someone who has mania according to your criteria doesn't actually	February 26, 2009 Page 236 offensive that you will think that I would not know the difference between a temper tantrum and this condition Q. But maybe you can educate me and the jury A. I would be happy to
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2 3 4 5 6 7	February 26, 2009 Page 235 problem So headaches are very different and there are very many reasons in medicine to have a headache. Q. How do you tell whether someone who has mania according to your criteria doesn't actually have ADHD? A My definition of mania is based on the	February 26, 2009 Page 236 offensive that you will think that I would not know the difference between a temper tantrum and this condition Q. But maybe you can educate me and the jury A. I would be happy to Q. Were you around when the kids would cry for no reason?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 20 21	February 26, 2009 Page 235 problem So headaches are very different and there are very many reasons in medicine to have a headache. Q. How do you tell whether someone who has mania according to your criteria doesn't actually have ADHD? A My definition of mania is based on the Diagnostic and Statistical Manual of Mental Disorders, not on my inspiration. Q Isn't it consistent with children's normal conduct to be irritable? A No. Q It isn't? A. No. Q Do you have any children? A. Yes. Q Were you around when they were young? A. Where do you think I was? Q. I don't know. A Okay Of course I was around. Q Were you around? A Yes. Q Were you ever in the house when they would	February 26, 2009Page 2361offensive that you will think that I would not know2the difference between a temper tantrum and this3condition4Q. But maybe you can educate me and the jury5A. I would be happy to6Q. Were you around when the kids would cry7for no reason?8A. Yes9Q. Were you around when they would yell and10scream at each other?11A. This is not what I am talking here.12Q. Were you around when that stuff happened?13A. Yeah.14Q. And which antipsychotic drug did you treat15them with?16A. The problems that families consult with me17are extraordinarily debilitating, severe and18devastating. Many of these children require19institutionalization or placement outside the home.20I am not talking about normal occurrence of everyday21living.22Q. So, in other words, when your kids were23irritable or crying, they weren't antipsychotic, but
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[1	60 (Pages 257 to 240)
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 237	[Page 238
1	A. The problems	1	pediatrics that is called behavioral pediatrics that
2	MR SPIVACK: Objection, argumentative,	2	you have a reasonable amount of mental health
3	misstates the testimony.	3	training And as I explained to you before, there
4	A The problems that I consult on and treat	4	is a capacity problem in our field that there are
5	are orders of magnitude different than normal	5	not enough trained child psychiatrists to evaluate
6	childhood experiences.	6	and treat all the children that require assessment
7	Q. But the differences in magnitude and	7	and treatment.
8	judging those differences is entirely subjective,	8	Q. Does that mean that children should get
9	isn't it?	9	substandard care just because there aren't enough
10	 All psychiatric diagnoses are subjective 	10	doctors?
11	in children and in adults	11	A. No. I am only stating the reality, that
12	Q. And doesn't that create a tremendous	12	there are not enough child psychiatrists in the
13	amount of danger of misdiagnosis?	13	world, in this country, to attend to the many
14	A I think that subjectivity requires more	14	children that require care It's not something that
15	clinical training than when you have objective	15	I developed; it's a reality of our society.
16 17	parameters that anybody can determine. So there is	16 17	Q. And so children get substandard care?
18	training to be able to secure that the diagnosis is actually accurate, and that is what doctors are	18	MR SPIVACK: Objection, argumentative, misstates the testimony, asked and answered
19	trained to do for many years	19	MR TRAMMELL: What about speculation?
20	Q. Right Psychiatrists?	20	MR SPIVACK: Are you objecting to your
21	A. Psychiatrists, yes	21	own question?
22	Q. So the dangers of misdiagnosis are less in	22	BY MR. TRAMMELL:
23	psychiatrists than they are in nonpsychiatrists?	23	Q. Doctor, if you'll go to Bates range,
24	A. Not only psychiatrists, depending on what	24	you'll see on the bottom or the side of your exhibit
25	we are talking about There is a discipline within	25	there's a JJRE stamp? You see that?
	Stratos Legal Services		Stratos Legal Services
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	Topoph Diodormon		locoph Wiederman
	Joseph Biederman February 26, 2009		Joseph Biederman Februarv 26, 2009
	February 26, 2009		February 26, 2009
1	February 26, 2009 Page 239 A. Yes.	1	February 26, 2009 Page 240 or pressured speech." And you've created an acronym
2	February 26, 2009 Page 239	2	February 26, 2009 Page 240 or pressured speech." And you've created an acronym or you've listed an acronym that says Dig Fast
2 3	February 26, 2009 Page 239 A. Yes. Q. It's right here on the side of the document.	2 3	February 26, 2009 Page 240 or pressured speech." And you've created an acronym or you've listed an acronym that says Dig Fast A. It was not created by me.
2 3 4	February 26, 2009 Page 239 A. Yes. Q. It's right here on the side of the document. A. Mm-hmm.	2 3 4	February 26, 2009 Page 240 or pressured speech." And you've created an acronym or you've listed an acronym that says Dig Fast A. It was not created by me. Q. Okay. But the acronym exists and you used
2 3 4 5	February 26, 2009 Page 239 A. Yes. Q. It's right here on the side of the document. A. Mm-hmm. Q. If you'll go to JJRE, the last three	2 3 4 5	February 26, 2009 Page 240 or pressured speech." And you've created an acronym or you've listed an acronym that says Dig Fast A. It was not created by me. Q. Okay. But the acronym exists and you used it?
2 3 4 5 6	February 26, 2009 Page 239 A. Yes. Q. It's right here on the side of the document. A. Mm-hmm. Q. If you'll go to JJRE, the last three numbers are 891, the DSM Criteria. I think this is	2 3 4 5 6	February 26, 2009 Page 240 or pressured speech." And you've created an acronym or you've listed an acronym that says Dig Fast A. It was not created by me. Q. Okay. But the acronym exists and you used it? A. Yes
2 3 4 5 6 7	February 26, 2009 Page 239 A. Yes. Q. It's right here on the side of the document. A. Mm-hmm. Q. If you'll go to JJRE, the last three numbers are 891, the DSM Criteria. I think this is for bipolar disorder Is that right?	2 3 4 5 6 7	February 26, 2009 Page 240 or pressured speech." And you've created an acronym or you've listed an acronym that says Dig Fast A. It was not created by me. Q. Okay. But the acronym exists and you used it? A. Yes Q. Did I read those right?
2 3 4 5 6 7 8	February 26, 2009 Page 239 A. Yes. Q. It's right here on the side of the document. A. Mm-hmm. Q. If you'll go to JJRE, the last three numbers are 891, the DSM Criteria. I think this is for bipolar disorder Is that right? A. Yes	2 3 4 5 6 7 8	February 26, 2009 Page 240 or pressured speech." And you've created an acronym or you've listed an acronym that says Dig Fast A. It was not created by me. Q. Okay. But the acronym exists and you used it? A. Yes Q. Did I read those right? A Yes
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		1	
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 241		Page 242
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	clean their room and they stop cleaning their room	1	A. In the context of any. Distractibility is
2	and start playing with their toys?	2	one item; it occurs in other conditions. If you
3	A. No. Distractibility refers to the	3	have an attack of asthma, you also will be
4	inability to stay on task. So usually for children,	4	distractible. If you are febrile with influenza,
5	the inability to stay on task is around schoolwork.	5	you may not be able to concentrate. So
6	Q. I'm giving you examples of not staying on	6	distractibility is one. That's the reason that
7	task and you're telling me that those are not	7	there are many symptoms, not just one.
8	criteria for bipolar disorder How is anybody supposed to know that from the word distractibility?	8	Q. Right But it is the most common symptom?
10	A That's the reason that you have training	10	 A No, it's not the most common Q. Okay, we'll get to that in a minute. And
11	and you go to medical school and you go to residency	11	just so we're all clear, this is the type of talk
12		12	you would give when you were hired by Janssen to
13	you understand the difference. If I ask you to	13	give talks. Right?
14		14	A. This is the type of talk
15		15	MR PECK: Object to form
16		16	A that I give when I talk on pediatric
17	Q That's certainly true.	17	bipolar illness.
18	MR SPIVACK: So stipulated.	18	Q. Including when Janssen hires you Right?
19	BY MR TRAMMELL:	19	A. This is a talk that I give when I talk
20	Q. So if a doctor goes to medical school,	20	about pediatric bipolar illness; I define the
21		21	illness By the way, these are not my definitions;
22		22	this is something that is accepted in our nosology
23	A. Yes	23	for children and adults
24	• •	24	Q. But you talk about this subject matter
25	disorder?	25	when you give talks that Janssen has paid you to
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Tocoph Riodorman
	February 26, 2009		Joseph Biederman February 26, 2009
	Page 243		-
	rage 240		Page 244
1	-	1	-
1	give Right?	1	"persistent" mean?
2	give Right? A This is the talk that I give when I talk	1 2 3	"persistent" mean? A. Well, persistent is more often than not;
	give Right? A This is the talk that I give when I talk about pediatric mania with or without Janssen.	2	"persistent" mean? A. Well, persistent is more often than not; it's lasting weeks, not minutes
2 3	give Right? A This is the talk that I give when I talk	2 3	"persistent" mean? A. Well, persistent is more often than not;
2 3 4	give Right? A This is the talk that I give when I talk about pediatric mania with or without Janssen. Q. Okay, but with Janssen Right?	2 3 4	"persistent" mean? A. Well, persistent is more often than not; it's lasting weeks, not minutes Q. Number 2, "I, increased activity or
2 3 4 5	 give Right? A This is the talk that I give when I talk about pediatric mania with or without Janssen. Q. Okay, but with Janssen Right? A. Sometimes with Janssen. Q. Now, can you give me an example of distractibility that would satisfy the criteria for 	2 3 4 5	"persistent" mean? A. Well, persistent is more often than not; it's lasting weeks, not minutes Q. Number 2, "I, increased activity or psychomotor agitation," is that the same thing as hyperactivity? A. No. Psychomotor agitation is a state of
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			62 (Pages 245 to 248
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
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	Page 245		Page 246
1	play videogames or just wants to play the piano?	1	example.
2	Has he met two criteria?	2	Q. Okay. So if
3	A. No, because the psychomotor agitation is a	3	A. But not doing your homework would be
4		4	somebody that is just oppositional or unable to do
	very severe state that the person cannot stop moving		
5	and it's a frantic state of going from door to door	5	the homework. Distractibility is a clinical
6	or room to room or wall to wall. It has the	6	phenomenon in which a person can't attend to task
7	feeling, as I said before, of a caged animal.	7	and looks to other areas for interest
8	Q. I understand And you're trying to evade	8	Q How do you tell the difference?
9	me, but there's an "or" there	9	A. This is the reason that you go to school
10	MR. SPIVACK: Objection, argumentative	10	Q So it's just doctors in their subjective
11	BY MR. TRAMMELL:	11	judgment are supposed to decide?
12	Q. It says "increased activity or psychomotor	12	A. Yes
13	agitation."	13	Q. "Grandiosity or inflated self-esteem," is
1.4	A. Yeah I did not invent the criteria.	14	that like little girls that say they're princesses?
15	Q I understand. So increased activity is	15	Is that what that means?
16	Well, we've talked about that	16	A. No.
17	So a kid that doesn't do his homework for	17	Q What does that mean?
18	a semester and that just wants to play the piano all	18	A. It means like thinking that you are
19	the time or draw pictures, has he met two criteria?	19	Superman and you can fly, so you go to the window
20	A Not doing the homework No. I'm not	20	and trying to fly.
21	sure where you're going with this But not being	21	Q. So a little boy who puts on his Superman
22	able to attend to task or being distractible is	22	costume and runs around the house is grandiose?
23		23	A No A little boy that puts the costume
2.4	different than refusing to do your homework.	24	
	Q Well, that was the example you gave.	25	on, opens a window and try to jump is
25	A You asked me for an example, I gave an	z 5	Q. So it has to be some sort of suicidal
	Stratos Legal Services		Stratos Legal Services
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	Joseph Biederman	ĺ	Joseph Biederman
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009	-	February 26, 2009
1	February 26, 2009 Page 247 action?	1	February 26, 2009 Page 248 line or
1 2	February 26, 2009 Page 247		February 26, 2009 Page 248 line or A. Not for me or even for you.
	February 26, 2009 Page 247 action? A. No, has to be something out of the ordinary	1	February 26, 2009 Page 248 line or A. Not for me or even for you. Q. Well, why don't you tell me how you draw
2	February 26, 2009 Page 247 action? A. No, has to be something out of the	1 2 3 4	February 26, 2009 Page 248 line or A. Not for me or even for you.
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Joseph Biederman Joseph Biederman February 26, 2009 February 26, 2009 Page 250 Page 249 1 BY MR TRAMMELL: 1 MR. SPIVACK: Objection, no foundation. 2 Q. It is a perfectly appropriate answer for 2 I do not know what doctors understand. 3 you to say "I can't draw the line, I have no idea." 3 But the kind of things that I am talking about, a 4 4 Α. No, that's not true. I have an idea doctor hearing of the behaviors that I am describing 5 5 0 Okay. Well, tell me where you draw the will not see that as normative behavior б line. 6 "Flight of ideas or racing thoughts," what Q, 7 A. The idea is if the symptoms are disabling, 7 does that mean? 8 8 persistent, associated with distress and disability, A. That the thoughts are flooding your head; 9 9 those symptoms are abnormal that the child has ideas that are changing very 10 Q. Give me an explicit example of where you 10 rapidly in his or her head. 11 can draw the line in all cases. 11 Q. How about, can you give me an example of 12 12 A. You never draw the line in all cases; you that? draw the line in individual cases. So if somebody 13 13 Well, ideas, I don't know what example to A 14 engages in an activity that is totally out of their 14 give A person that is talking about three or four 15 15 purview, they want to do something that they have no subjects at a rapid clip. The patients sometimes 16 skills of any kind and they think that they have and 16 complain that the head is flooded with thoughts and 17 they actually engage in those activities So those 17 ideas and they cannot stop it 18 are things that are not necessarily just regular 18 Q So the patient, the kid, has to come in 19 play of children. 19 and say "My head is flooded with racing thoughts"? 20 Q. Do you understand that doctors hearing 20 A No The children will say "I have ideas 21 21 this who aren't trained in psychiatry might get the that I cannot stop" and "My brain is racing" is what 22 misimpression that that means things that don't rise 22 children say The parents complain that the child 23 23 to the level of psychotic grandiosity or bipolar talks about five subjects at the same time. 24 24 grandiosity? Do you understand that they might get So when a kid talks about multiple 0 25 25 that misimpression? subjects at the same time, they meet one of the Stratos Legal Services Stratos Legal Services 800-971-1127 800-971-1127 Joseph Biederman Joseph Biederman February 26, 2009 February 26, 2009 Page 251 Page 252 1 criteria for bipolar disorder? 1 if he's a boy. 2 A If it's disabling and severe and does not 2 Q. That's what activities with painful 3 3 make any sense, yes. consequences mean? 4 4 Q Next is "Activities with painful A. These are the childhood -- You asked me 5 consequences " Now, isn't that so vague that it's 5 about the childhood equivalent. In adults is б absurd? I mean, that is a useless criteria, isn't 6 hypersexuality, is buying sprees, is inappropriate 7 it? Because kids hurt themselves all the time. 7 behavior. These are not just little things that 8 8 MR. SPIVACK: Objection, argumentative people do 9 9 A I think that you should write a letter to O. Aren't there things that kids do that 10 American Psychiatric Association. I did not invent 10 would be extraordinary for adults but are just part 11 11 these criteria This usually reflects things like of normal childhood behavior? h 2 12 buying sprees, reflects things like engaging in A. No. 13 13 extramarital affairs Those are the things So 0 No? 14 14 going on drinking binges beyond recognition or A. I think that the children that engage in 15 traveling across the world without having money to 15 these activities do things that other children of 16 travel across the world These are the things that 16 the same age don't. 17 this is alluding to 17 Q. Children are just little adults and they 18 18 Q How would this manifest in a kid? act the exact same way? 19 19 A In kids it will manifest as doing like I A. No They have equivalent abnormal 20 told you before A patient of mine, for example, 20 behaviors A child may not have a credit card but 21 went through the ducts of the air-conditioning to 21 may be insisting on buying things all the time, for 22 watch, a seven-year-old, to watch his mother undress 22 example. 23 23 in the shower, for example. Or downloading Q. But it is extraordinary for an adult to 24 pornography or touching the genitalia of a 24 cry for no reason It's not extraordinary for a 25 classmate, or touching the breast of their teacher 25 kid, is it? Stratos Legal Services Stratos Legal Services 800-971-1127 800-971-1127

	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 253		Page 254
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1	A Children cry for reasons	1	may not be different but they have developmental
2	Q Well, to cry for nonapparent reasons.	2	variability because they are children. And as I
3	A No, children cry for a reason: when they	3	said before, a child may not have a credit card but
4	are frustrated, when they're sad, when they're	4	has other manifestation of excessive buying
5	reprimanded. Adults with depression sometimes cry	5	Q. If you'll go to, the last three numbers
6	continuously	6	are 895.
7	Q. Okay, well, how about this? And this	7	A. Say again?
8	doesn't seem to be a controversial point and I can't	8	Q. The last three numbers on the side are
9	imagine why you're disputing it But my son wears a	9	895
10		10	
	Superman costume sometimes and he's four. That	1	
11	would be an extraordinary thing for me to do,	11	Q Says Frequency of Bipolar Symptoms It
12	wouldn't it?	12	references a Wozniak and Biederman study, which I
13	A. No, you can dress as Superman on	13	assume is you? You're Biederman?
14	Halloween	14	A. Yes, I'm Biederman
15	Q And this may be funny to you but it's not	15	Q. It says 97 percent of Well, I assume
16	funny to me. And just so we're clear, you're saying	16	what this means, and you can tell me if I'm wrong,
17	that there are no distinctions between the types of	17	is that in the kids who met the diagnostic criteria
18	extraordinary behavior that kids engage in versus	18	for a pediatric bipolar disorder, 97 of them
19	adults, and so I just want the jury to understand	19	satisfied the D criteria?
20	exactly what you're telling doctors are the	20	A. 97 percent had distractibility, yes.
21	diagnostic criteria for treating these kids for	21	Q. 97 percent, okay. Was that the most
22	bipolar disorder.	22	common characteristic?
23	MR. SPIVACK: Objection, misstates the	23	A. One of the most common ones, yes
24	testimony, argumentative.	24	Q And, again, it's tied with increased
25	A. The symptoms that children have in content	25	activity. Right?
_	Stratos Legal Services		Stratos Legal Services
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	Joseph Biederman		Joseph Biederman
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009		February 26, 2009
-	February 26, 2009 Page 255		February 26, 2009 Page 256
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2	February 26, 2009 Page 255 A. 97 percent also had increased activity. Q. And those are the two highest, aren't	1 2	February 26, 2009 Page 256 criteria A. Yes
2 3	February 26, 2009 Page 255 A. 97 percent also had increased activity. Q. And those are the two highest, aren't they?	1 2 3	February 26, 2009 Page 256 criteria A. Yes Q and it's three if it's elevated or
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 257		Page 258
1	bipolar or did they have both?	1.	A. The criteria are the criteria They are
2	A They had both	2	equally
3	Q But you're sure they had both?	3	Q What are they for ADHD? I'm sorry
4	A Yes	4	A The criteria for ADHD, depending on the
5	Q Is it possible that you have imprecise	5	nosology at the time, today the Diagnostic and
6	diagnostic criteria and you're calling kids that	6	Statistical Manual of Mental Disorders - Fourth
7	have one or the other the same?	7	Edition requires you to have six out of nine
8	A The diagnosis of bipolar illness requires	8	symptoms of either distractibility either
9	an abnormal mood and additional symptoms There is	9	inattention or hyperactivity and passivity When we
10	nothing in the defining features of ADHD that speaks	10	did this study, the criteria required eight out of
11	to abnormal mood	11	fourteen symptoms of inattention, distractibility,
12	Q I want to go through these individually,	12	and hyperactivity.
13	the criteria If you go to 903, these are What	13	Q. Was one of the points of your talk, talks
14	I think this is is the percentage of kids who hit	1.4	like this that you gave, to get doctors who were
15	distractibility as one of their criteria, how that	15	comfortable with ADHD to see those patients as
16	manifests in the kid Right?	16	bipolar?
17	A No This is a different module and the	17	A. No My point was to highlight the fact
18	module on ADHD asks the symptoms that define ADHD	18	that children with bipolar disorder frequently also
19 20	Q This is only ADHD?	19	have ADHD.
	A Yes In order to qualify for ADHD, you have to have a certain number of symptoms, a	20	Q Which DSM was it you quoted from a second
21 22	particular age of onset and associated impairment	21 22	ago? A. The DSM-III-R
23	and disability	23	Q. What is the average age of onset of
24	Q Are the criteria for ADHD more or less	24	bipolar disorder in kids?
25	rigid than bipolar disorder for kids?	25	A. In our study it was around five
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009		February 26, 2009
	February 26, 2009 Page 259		February 26, 2009 Page 260
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2	February 26, 2009 Page 259 Q. If you go to page 914, it says 4 55 A Yeah, around five. Where do you want me	2	February 26, 2009 Page 260 that we conducted the analysis. We looked at children that met criteria in structured diagnostic
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Joseph Biederman February 26, 2009	Joseph Biederman February 26, 2009
Page 261	Page 262
1Q. And so there are these five psychological2disorders here on page 914 and all of them onset3under the age of five in your study?4A. Yes.5Q. Was that an extraordinary finding to you?6A. No.7Q. Why not?8A. Because conditions that afflict children9very often emerge in the preschool years.10Q. And what do you base that on, by the way?11A. On the structured diagnostic interviews12that we conducted.13Q. This study and your experience. Right?14A. This is information from a study, not from15experience16Q. Now, was one of the reasons you were17talking to doctors about early onset of bipolar18disorder to validate the disorder?19A. The purpose of talking about a condition20or any talk is to educate, not to validate21Validate is a statistical psychometric approach22The purpose of a talk is to educate.23Q. The purpose was to convince doctors that24bipolar disorder in kids is real and it can be25diagnosed Right?	1 A The purpose is to describe what we had 2 found in our research. 3 Q. Which is that bipolar disorder in kids is 4 real and it can be diagnosed. Right? 5 A Yes 6 Q But moreover, it's real, it can be 7 diagnosed, and it can be treated. Right? 8 A. The diagnosis If the diagnosis is 9 correct, it can be treated, yes. 10 Q. And one of those treatments is Risperdal 11 Right? 12 A. Right 13 Q. Is the structured diagnostic interview 14 K-SADS? A. 15 A. The one that we used is the K, for child 16 It is a structured interview that has modules for 17 all psychiatric conditions that afflict children. 18 Q. Did you modify the criteria in any way? 19 A. We only modified to accommodate to the 20 DSM-IV from the DSM-III-R MR 21 MR TRAMMELL: Let's take a break. 22 <
Stratos Legal Services 800-971-1127	Stratos Legal Services 800-971-1127
Joseph Biederman February 26, 2009	Joseph Biederman February 26, 2009
Page 263	Page 264
 1 This is the beginning of tape number 5. The time is 2 4:09. 3 BY MR. TRAMMELL: 4 Q. Now, Doctor, we just finished talking 5 about the substance of the kind of talk that you 6 would give when you would talk about bipolar 7 disorder, including the times when you would talk on 8 Janssen's behalf. Do you remember that discussion? 9 A. (Witness nodded.) 10 Q Now, your role, your role or your 11 relationship with Janssen was based on you helping 12 them sell Risperdal or market Risperdal. Right? 13 MR. PECK: Objection, foundation. 14 A That was not my role 15 Q Well, certainly you knew the reason they 16 had any association with you at all was that you 17 would help in their sales and marketing efforts for 18 Risperdal Right? 19 A. I never helped them on the marketing or 20 sales effort. 10 Q Did they ever tell you "Doctor, this 21 research you're doing, this work that you're doing, 22 is very helpful for us in our effort to make a lot 24 of money selling Risperdal"? 25 A No. 26 Stratos Legal Services 800-971-1127 	 Q. And as far as you know, you weren't part of the sales and marketing operation at Janssen for Risperdal. Right? A. I was not. Q. Certainly nobody ever told you that? A. No Q. You would have objected had they told you that. Right? A. Yes. Q. You would have said "I don't sell drugs, I talk to doctors about science, I'm a doctor, I talk about patients." Right? A. Right. Q. Something like that? A. Mm-hmm. Q. This is Biederman 13. It says Key Points From 2003 Child & Adolescent Business Planning Session 2, dated June 12, 2002. Then it says Sales & Marketing Do you see that? A. Yes Q. If you go down below Current Projects, it says key: "Need to train KOLs" which I think means key opinion leaders "to handle the media; need a proactive media plan." The first bullet point, "J&J Center for the Study of Pediatric Stratos Legal Services 800-971-1127

	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 265		Page 266
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1	Psychopathology "Which is your center, right?	1	Q Do you have any reaction other than that?
2	A Yes	2	A. I am not a marketing, I never did any
3	Q "Joint effort by Janssen, OMP, and McNeil	3	marketing; I produce data
4	Consumer, in Boston with Joe Biederman " Do you see	4	Q. Does it bother you that one of their
5	that?	5	motivations was to exploit your work for sales
6	A Yes	6	purposes?
7	Q And that's you Right?	7	MR. SPIVACK: Objection
8	A. Yes	8	MR. PECK: Objection, foundation.
9	Q So the truth is, whether they ever told	9	MR SPIVACK: And assumes facts not in
10	you or not, Janssen thought of you as kind of like a	10	evidence
11	paid spokesman, somebody that could help them sell	11	A. I do not know what their intention is, but
12	Risperdal Right?	12	I know my work My work never had any advertising
13	MR. PECK: Objection to form, foundation	13	in it. The vast majority of my work had to do with
14	MR. SPIVACK: And calls for speculation	14	the disease, not with the treatment There are many
15	BY MR TRAMMELL:	15	more papers on risperidone than my papers.
16	Q Do you know?	16	Q. Well, and you weren't the only KOL, were
17	A No I consider my role as a scientist,	17	you?
18	and the intersect between my science and my research	18	A. No.
19	and the business partner is that it should be	19	Q. And so whatever your intentions were, you
20	something for them as well But it's predicated on	20	had no idea or did you know that one of your
21	the idea that the science is the primary concern as	21	purposes to Janssen was to facilitate sales and
22	far as I was concerned	22	marketing efforts?
23	Q What is your reaction to seeing reference	23	MR. PECK: Objection, foundation.
24	to you on a sales and marketing planning document?	24	A. I saw an intersect between a commercial
25	A I had no idea that I was in this document	25	entity like J&J and the science that we produced
~~~~	Stratos Legal Services	2.5	Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 267		
	Page 207		
	-		Page 268
1	that at the end, if the illness is a serious	1.	Q. Right. You did several and what you got
2	that at the end, if the illness is a serious illness, if the treatments that they have available	2	Q. Right. You did several and what you got out of those studies is you got the opportunity to
2 3	that at the end, if the illness is a serious illness, if the treatments that they have available are safe and effective, then they could benefit from	2 3	Q. Right. You did several and what you got out of those studies is you got the opportunity to study the use of Risperdal in diseases you were
2	that at the end, if the illness is a serious illness, if the treatments that they have available are safe and effective, then they could benefit from their product, not before	2 3 4	Q. Right. You did several and what you got out of those studies is you got the opportunity to study the use of Risperdal in diseases you were curious about or were the subject of your practice.
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2 3 4 5 6	that at the end, if the illness is a serious illness, if the treatments that they have available are safe and effective, then they could benefit from their product, not before Q. So just so we understand what everybody was getting out of the deal, you got to do research	2 3 4	Q. Right. You did several and what you got out of those studies is you got the opportunity to study the use of Risperdal in diseases you were curious about or were the subject of your practice. What Janssen got out of it is the ability to expand the use of Risperdal and make more money because of
2 3 4 5	that at the end, if the illness is a serious illness, if the treatments that they have available are safe and effective, then they could benefit from their product, not before. Q. So just so we understand what everybody	2 3 4 5	Q. Right. You did several and what you got out of those studies is you got the opportunity to study the use of Risperdal in diseases you were curious about or were the subject of your practice. What Janssen got out of it is the ability to expand the use of Risperdal and make more money because of your findings. Right?
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			68 (Pages 269 to 272)
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	30		-
	Page 269		Page 270
1	A. I don't know	1	marketing people were at your meeting about the
2	Q. Did you ever have any meetings with	2	research and science?
3	Janssen marketing people?	3	MR. PECK: Objection, foundation
4	A. I met with marketing people on occasion	4	A. I am not sure that I knew their positions
5	Q. At Janssen?	5	in the company.
6	A The meetings that we have twice a year,	6	Q. Did you or did you not know that they were
7	one of those meetings occurred at Janssen and I'm	7	not scientists, they were from the marketing
8	not sure exactly. There are people from Janssen and	8	department?
9	people from McNeil in which we produced a kind of	9	A. My primary relationship with Janssen and
10	report of what has transpired with the center in the	10	McNeil were the scientists, not other executives
11	previous year	11	Q. I understand. And I'll object as
12	Q. So y'all would have a meeting about the	12	nonresponsive. Despite the fact that your primary
13	center twice a year with Janssen, you and people	13	relationship was with the medical affairs people and
14	from the center and people from Janssen?	14	
15	A. Yes	15	the science people, at some of these meetings there
			were marketing people present Right?
16 17	Q. And among those people that would be at	16	A. Right.
	the meeting on Janssen's behalf were the marketing	17	Q. Did you ever wonder why they were there?
18	people. Right?	18	A I did not ask why they were there
19	A. I am not sure who was there, but there	19	Q. Did it occur to you at that time, well,
20	were people from Janssen and McNeil	20	wait a minute, they're just getting me to do this
21	Q. Did you ever say why are the marketing	21	research so they can sell more Risperdal?
22	people here?	22	A I always assume that there is an
23	A I think that they have the choice of	23	intersect. I saw it as a win-win situation between
24	bringing whoever they see fit.	24	me advancing science and the commercial entity
25	Q. Well, did you think it was odd that the	25	having some benefit They are not a philanthropical
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
			-
	Page 271		Page 272
1	organization	1	illness, could intersect
	O. I wish I could have said it that well.	2	O. Well, their interest was in selling more
2	Q. I wish I could have said it that well. That's exactly my point You understood that what	2	Q. Well, their interest was in selling more drugs. Right?
2	That's exactly my point You understood that what	3	drugs Right?
2 3 4	That's exactly my point You understood that what Janssen was getting out of it was advancing their	3 4	drugs Right? MR SPIVACK: Objection, calls for
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2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 7 8 9 0 1 2 3 4 5 8 9 0 1 2 2 3 4 5 7 8 9 0 1 2 2 3 4 5 7 8 9 0 1 2 2 3 4 5 7 8 9 0 1 2 2 3 4 5 1 2 2 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	<ul> <li>That's exactly my point You understood that what Janssen was getting out of it was advancing their commercial interest in selling more Risperdal Right?</li> <li>A. The way that I understood it is like I would understand a venture capitalist that is investing in a venture. The success of the venture is predicated on several components and forces that are unforeseen So the process of expanding or using or whatever words you choose to use is predicated on the understanding of the disease and establishing that the treatment is safe and effective. Those conditions have to be met for risperidone to be more widely used.</li> <li>Q. So they were making an investment in the center and in you in the hopes that research would come out of the center that would expand the use of Risperdal and pay off for them in the form of more Risperdal sales and more money Right?</li> <li>MR PECK: Object to form.</li> <li>A. I always thought that my interest was to advance science and their interest, if they have an effective and safe compound to treat a serious</li> </ul>	3456789012345678901234 1123456789012234	<ul> <li>drugs. Right? MR. SPIVACK: Objection, calls for speculation. MR. PECK: Objection.</li> <li>A. Their interest in selling more drugs is predicated on the idea that the disease is a serious disease and the drug is safe and effective. Those things have to be met for the drug to be better used.</li> <li>Q Right. And so if your research proved that the disease was a serious disease and that Risperdal was effective to treat it, they could make more money. Right?</li> <li>A. They have still to do the critical trial that they did, the randomized FDA type of registration study to show safety and efficacy. Only then the medicine will be considered safe and effective.</li> <li>Q. And I think you said this earlier; I just want to make sure. You're not naive enough to testify that Janssen was funding your research because it didn't care about making money Right?</li> </ul>

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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 273		Page 274
1	an intersect between science and a commercial	1	studies?
2	entity. In fact, they were funding activities that	2	A. (Witness nodded.)
3	were not directly related to their commercial	3	Q. In any of those nine papers, did you
4	interest.	4	determine that Risperdal wasn't safe or effective to
5	Q. Let me ask you this: How many studies did	5	treat the disease you were studying?
6	Janssen pay you to do on Risperdal?	6	A. In the papers I described what I saw. I
7	MR SPIVACK: Objection, form,	7	reported in detail what were the rate of response
8	argumentative.	8	and I detailed all the side effects that we noted
9	A. To my recollection, we did two studies	9	Q. In all of those studies Risperdal was
10	One was an open label study of risperidone and we	10	effective at treating whatever you were studying
11	did an imaging study using a technology that is	11	Right?
12	called spectroscopy that is based on MRI to examine	12	A. Was effective in about 60 to 70 percent of
13	the effect of risperidone on the brain.	13	the children that received treatment with
14	Q How many papers have you written since you	14	risperidone
15	began your consulting relationship with Janssen	15	Q In any study where you compared Risperdal
16	about Risperdal?	16	to another drug, Risperdal was more effective
17	A I have written papers before any	17	Right?
18	consulting relationship with Janssen. I believe	18	A No Abilify was more effective than
19	that I have written somewhere like nine papers of	19	risperidone
20	the fifty or sixty that have been written on	20	Q. When was that? When did that paper come
21	risperidone in children	21	out?
22	Q So nine papers plus the two studies that	22	A. I think 2007 or
23	you did?	23	Q. After the center closed?
24	A No, that includes the studies.	24	A The center closed in 2005 Abilify came
25	Q Okay, includes the results of those	25	around that time, so I think it's an issue. I
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
1	February 26, 2009		February 26, 2009
	Page 275		Page 276
1	cannot study medicines that are not available to me,	1	Q. Have you ever done a study where the
2	so I tried to study each of the atypical	2	sponsor's drug wasn't better?
3	neuroleptics as they came to market.	3	A Many We did a study for one of the
4	Q. And in 2007 when you wrote the paper where	4	companies of Johnson & Johnson examining galantamine
5	Abilify beat Risperdal, did you have a consulting	5	that is a cholinergic drug showing that it has no
6	relationship with Bristol-Myers Squibb, who makes	6	efficacy in ADHD We did two studies on Depakote
7	Abilify?	7	also by Abbott that showed it had very limited
8	A I had funding, relatively modest funding	8	applicability in pediatric bipolar illness We did
9	from Bristol-Myers Squibb Parenthetically I not	9	a study with carbamazine funded by Shire showing it
10	only studied the atypical neuroleptics, I studied	10	has very modest effect, an effect the response was
11	carbamazine as well.	11	about 30 percent. The response of Zyprexa, for
12	Q. So in the study Bristol-Myers Squibb	12	example, was much more modest, and funded by Lilly,
13	funded, their drug beat Risperdal Right?	13	was much more modest than the response to
14	A It was not a head-to-head comparison	14	risperidone and Abilify.
15	Using the same protocol that we used to treat	15	Q Were these studies all published?
16	children with risperidone, we noted that the rate of	16	A Yes
17	response was about 80 or 90 percent compared with 60	17	Q Did you ever do a Risperdal study that was
18	to 70 percent We did not do a head-to-head	18	funded by Janssen that was not positive for
19	comparison.	19	Risperdal?
20 21	Q. But the rate of response for Abilify was	20 21	A. I did only one study on risperidone I did a study that was funded by Japasan I did
21	higher than for Risperdal Right? A. Yes	21 22	did a study that was funded by Janssen. I did
22	Q And that was a study that was funded by	22 23	another study in preschoolers that was funded by the Stanley Foundation in children four to six that we
23 24	Abilify's manufacturer. Right?	23 24	compared risperidone and Zyprexa The studies that
24	A. Correct.	24 25	we did, say, with Geodon showed modest funded by
1 m J		20	
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	Stratos Legal Services 800-971-1127		Stratos Legal Services 800-971-1127

	10 (rages 277 to 200)
Joseph Biederman February 26, 2009	Joseph Biederman February 26, 2009
Page 277	_
<ul> <li>Pfizer showed modest effects</li> <li>So the fact that we received funding does</li> <li>not mean that the results are positive And I would</li> <li>like to state for the record that our modest results</li> <li>with open label technology were fully replicated ten</li> <li>years later with a randomized clinical trial that is</li> <li>the gold standard of the industry.</li> <li>MR TRAMMELL: I'll object as</li> <li>nonresponsive.</li> <li>BY MR. TRAMMELL:</li> <li>Q That's Exhibit 14 in front of you Have</li> <li>you ever seen that document before?</li> <li>A Not that I know.</li> <li>Q Have you ever seen 13 before, the sales</li> <li>and marketing document?</li> <li>A. No</li> <li>Q 14 is a set of slides It says on the</li> <li>front page New Initiative, exclamation point, J&amp;J</li> <li>Pediatric Research Center at Mass. General Hospital,</li> <li>authored by Gahan J. Pandina, Ph.D., who works at</li> <li>Janssen Right?</li> <li>Q. Go to the second page, please.</li> </ul>	<ul> <li>Children and Adolescents. It says "Pharmacologic treatment of children and adolescent psychiatric disorders is widespread" and it says "Most use is off-label with limited data to guide treatment." Do you see that?</li> <li>A. Yes</li> <li>Q. At the bottom bullet point says "Strong needs for expert collaboration to inform pediatric initiatives " Do you see that?</li> <li>A. Yes.</li> <li>Q. And when they say expert collaboration, they're talking about you and the center Right? MR SPIVACK: Objection, calls for speculation, no foundation</li> <li>BY MR. TRAMMELL:</li> <li>Q. Well, it's in the document entitled J&amp;J</li> <li>Pediatric Research Center at Mass General. MR SPIVACK: Same objection.</li> <li>A. This is a general statement, not only with me. I am not the only pediatric psychiatrist interested in pediatric bipolar illness and psychopharmacology</li> <li>Q. One of the reasons they collaborated with</li> </ul>
2.4 A Second?	24 you was to inform their pediatric marketing
25 Q. Yes, sir, Pharmacologic Treatment of Stratos Legal Services 800-971-1127	25 campaign Right? Stratos Legal Services 800-971-1127
Joseph Biederman February 26, 2009	Joseph Biederman February 26, 2009
Page 279	Page 280
1MR SPIVACK: Objection, calls for2speculation, no foundation.3A. I think a serious responsible4pharmaceutical company that knows that their drug is5used off-label without any knowledge should support6the expansion of the knowledge base about what to7treat, who to treat, and how safe and effective is8the treatment9Q. What should they do?10A. They should do studies to11Q. Clinical trials?12A They should examine the disease as they13were doing with me and they should conduct clinical14trials as they did.15Q16kids, they should have conducted clinical trials.17Right?18MR. SPIVACK: Objection, misstates the19testimony.20A. Risperidone was used very widely without21clear boundaries for indications22Knowledge is at the heart of my discussions with23Janssen. I argue that the responsible	1for which doctors are using their drugs. So2knowledge about the disease and about the safety and3efficacy of the treatment is very critical.4Q. And it's important when they study the5drug to tell doctors the truth about what they find.6Right?7A. Studies are descriptive and objective.8This is what was done, this is what the results9were. They are not philosophical data papers10Things that I wrote are descriptive and factual11Q. When you say they're not philosophical,12are you trying to say there's no objective truth?13A. We can have this discussion14MR PECK: Object to form.15A at another time in another place16Q. Well, what this means, "Strong need for17expert collaboration to inform pediatric18initiatives," what that means is they needed the19credibility of someone like you who writes high-20impact papers and who, according to you, is a leader21in diagnosing and treating bipolar disorder to help22them get the word out about this off-label use.
<ul> <li>pharmaceutical company has the ethical, moral,</li> <li>scientific responsibility to understand the diseases</li> </ul>	<ul> <li>23 Right?</li> <li>24 MR PECK: Objection to form, foundation</li> <li>25 MR SPIVACK: Objection, argumentative,</li> </ul>

			71 (rages 201 to 204
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 281		Page 282
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1	calls for speculation	1	percent of our market is kids" to you?
2	BY MR. TRAMMELL: Q. Isn't that how you understand that?	2 3	A Not specifically I knew that it was widely used.
4	A. I don't understand it the way you	4	Q. But you didn't know it was that high?
5	understand it It's your interpretation of a	5	A. I did not know it was 21 or 22 or 18
6	sentence. My understanding is that they need more	6	percent.
7	information, that the fact that the drug is used is	7	Q. Certainly because it's that high, it
8	not enough; that they need to know more about when	8	increases the need for a responsible pharmaceutical
9	to use it, how to use it, and how safe and effective	9	company to fully understand the possible efficacy
10	it is	10	and the possible risks associated with treatment of
11	Q Well, whether or not you and I understand	11	that population Right?
12	it, we're going to see how Janssen understood it	12	A. Correct
13	here in a second But if you go to the next page,	13	Q. The fourth bullet point says "Treatment
14	Risperidone Treatment in Children and Adolescents,	14	with Risperdal in this population continues despite
15	"Risperdal is widely used to treat psychiatric	15	lack of well-controlled clinical research. Limited
16	disorders in children and adolescents" and "Children	16	available data results in potential for medical
17 18	and adolescents approximate 21 percent of the	17 18	misuse "Do you see that? A. Yes.
18	Risperdal market " Do you see that? A Yes	18 19	<ul> <li>A. Yes.</li> <li>Q. I think this is more of what you were</li> </ul>
20	Q. Did you know the number was that high?	20	talking about. The reason you have to get the true
21	A No.	21	information out there about a condition for which
22	MR. SPIVACK: Objection, calls for	22	your drug is widely used is to prevent misuse
23	speculation, no foundation	23	Right?
24	BY MR. TRAMMELL:	24	A. In the absence of information, there is
25	Q Did anybody at Janssen ever say "21	25	danger of inappropriate use. So the fact that this
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 283		Page 284
1	is the reality on the ground, that clinicians are	1	A. I agree with that.
2	using this medication widely, is a strong impetus	2	Q. You are a global expert, people around the
3	for a responsible pharmaceutical company to	3	world know that you are an expert in diagnosis and
4	understand the enemy a little bit better. The	4	treatment of bipolar disorder and ADHD?
5	enemy: the disease.	5	A 37
~	O Is the improvement that working matters as	~	A. Yes.
6	Q. Is the impression that you've gotten so	6	Q. "Dr. Biederman has a large research team,
7	far from this document that Dr Pandina is saying	6 7	Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean
7 8	far from this document that Dr Pandina is saying the drug is widely used in this population but its	6 7 8	Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean Hospital, and Harvard University This group was
7 8 9	far from this document that Dr Pandina is saying the drug is widely used in this population but its use is poorly understood? Is that the impression	6 7 8 9	Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean Hospital, and Harvard University. This group was identified as one of the most important
7 8 9 10	far from this document that Dr Pandina is saying the drug is widely used in this population but its use is poorly understood? Is that the impression you've gotten so far?	6 7 8 9 10	Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean Hospital, and Harvard University. This group was identified as one of the most important international scientific research centers by JPI "
7 8 9 10 11	far from this document that Dr Pandina is saying the drug is widely used in this population but its use is poorly understood? Is that the impression you've gotten so far? A The way that I read this document is that	6 7 8 9 10 11	Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean Hospital, and Harvard University. This group was identified as one of the most important international scientific research centers by JPI " Did I read that right?
7 8 9 10 11 12	far from this document that Dr Pandina is saying the drug is widely used in this population but its use is poorly understood? Is that the impression you've gotten so far? A The way that I read this document is that he's saying that there is very important need to do	6 7 9 10 11 12	<ul> <li>Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean Hospital, and Harvard University. This group was identified as one of the most important international scientific research centers by JPI "</li> <li>Did I read that right?</li> <li>A. Yes, you read it correctly.</li> </ul>
7 8 9 10 11 12 13	far from this document that Dr Pandina is saying the drug is widely used in this population but its use is poorly understood? Is that the impression you've gotten so far? A The way that I read this document is that he's saying that there is very important need to do more research on the subject.	6 7 8 9 10 11 12 13	<ul> <li>Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean Hospital, and Harvard University. This group was identified as one of the most important international scientific research centers by JPI "</li> <li>Did I read that right?</li> <li>A. Yes, you read it correctly.</li> <li>Q What is JPI?</li> </ul>
7 8 9 10 11 12 13 14	far from this document that Dr Pandina is saying the drug is widely used in this population but its use is poorly understood? Is that the impression you've gotten so far? A The way that I read this document is that he's saying that there is very important need to do more research on the subject. Q. Right, and collaborate with experts to	6 7 9 10 11 12 13 14	<ul> <li>Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean Hospital, and Harvard University. This group was identified as one of the most important international scientific research centers by JPI "</li> <li>Did I read that right?</li> <li>A. Yes, you read it correctly.</li> <li>Q. What is JPI?</li> <li>A. JPI I think is Johnson-something I don't</li> </ul>
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			72 (Pages 265 CO 200)
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 285	Ì	Page 286
1	creating information that doctors could rely on to	1	marketing Risperdal?
2	prescribe more Risperdal and treat kids who	2	MR PECK: Objection, foundation
3	otherwise wouldn't be diagnosed as bipolar Right? MR PECK: Objection to form, foundation.	3	A. The purpose of the center was to advance science in childhood psychopathology, to illuminate
5	A. That's absolutely not my reading of this	5	some of the conditions that clinicians are using
6	document. This document says that we have a	6	risperidone for So I think that the issue of
7	scarcity of information on an important subject;	7	funding for marketing is not necessarily synonymous
8	that our medicine is widely used; that we need more	8	with marketing efforts
9	research on where to use it, when to use it, for	9	If you look at the second bullet,
10 11	whom to use it, and how safe and effective it is. This is what I read here What you are telling me	10 11	"reviewing specific scientific questions," what we wanted to do with the center was to advance
12	is a free interpretation of the same sentence.	12	knowledge.
13	Q And maybe I'm wrong But it's got nothing	13	Q. I understand And then if you keep
14	to do with marketing Right?	14	reading that, it says "related to key business
15	A. This is not a marketing statement.	15	areas " Do you see that?
16	Q. Okay, go to the next page. First bullet	16 17	A My understanding, I'm not a corporate
17 18	point, "With marketing, held initial discussions with MGH to discuss collaboration re specific	18	lawyer, but my understanding is that pediatric bipolar illness is a target for a company like
19	extramural research with risperidone." Did I read	19	Janssen to launch a clinical trial So the
20	that right?	20	eventuality that they actually did the clinical
21	A. Yes.	21	trial many years later was the conclusion of
22	Q. Do you remember that meeting?	22	research that was done before documenting that this
23 24	<ul> <li>A. No.</li> <li>Q. Does that refresh your recollection that</li> </ul>	23 24	is a serious illness, that risperidone may have a role to play; therefore they should conduct a
25	the purpose of creating the center was to help	25	randomized clinical trial, as they did, that led to
ř. J	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009 Page 287 approval of the drug.	1	February 26, 2009 Page 288 Q I'm sorry. The second-to-last page of the
2	February 26, 2009 Page 287 approval of the drug. Q I understand	1 2	February 26, 2009 Page 288 Q I'm sorry. The second-to-last page of the document.
2 3	February 26, 2009 Page 287 approval of the drug. Q I understand. A. So this is a marketing. If that happens,	1	February 26, 2009 Page 288 Q I'm sorry. The second-to-last page of the document. MR. SPIVACK: What's the Bates number?
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			73 (Pages 289 to 292)
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 289		Page 290
1	key contributors" the first one is Kent Bockes. Do	1	A. No.
2	you know who Mr. Bockes is?	2	Q. Kind of makes me feel like I chose the
3	A. No.	3	wrong document. This is an e-mail from Gahan
4	Q. Do you know what his job was at this time?	4	Pandina, March 22, 2002, to several people within
5	A No.	5	Janssen; the subject is "Feedback regarding MGH
6	Q Would it surprise you that he was the	6	pediatric seminar." And an MGH pediatric seminar
7	national sales director for Risperdal? A. I don't know who he is	78	would have been a pediatric seminar for doctors that you held at MGH. Right?
9	Q Well, at any rate, he's a key contributor	9	A. This is a postgraduate course that we run
10	in the formation of your center and he's the	10	every other year.
1.1	national sales director. Does that surprise you?	11	Q And the audience is doctors. Right?
12	MR. PECK: Objection, form, foundation	12	A. Not only doctors There are social
13	A I do not know how Janssen planned to fund	13	workers and educators in attendance as well.
14 15	<ul> <li>my center I know what the center proposed to do.</li> <li>Q. Does this help illuminate for you that</li> </ul>	14 15	Q. But they are people who might use Risperdal in the course of their practice?
16	Janssen's purpose in creating and funding your	15	A. Yes.
17	center was to help it sell more Risperdal?	17	Q. It says "Christine, Ramy and Carmen:
18	MR SPIVACK: Objection, calls for	18	Georges and I wanted to share some information as a
19	speculation	19	follow-up to the meeting with Dr. Biederman This
20	MR. PECK: Objection, form and foundation	20	feedback came from an attendee of the large three-
21 22	A It illuminates only that different pharmaceutical companies use different pots of money	21 22	day educational seminar, over 1,000 physicians, \$700 CME course, in child psychopharmacology and
23	to fund certain activities.	23	pediatric bipolar disorder that Dr. Biederman and
24	Q. This is Biederman 15. And, again, you've	24	his group conducted. This meeting began the day"
25	never seen that slide set before, have you?	25	First of all, did I read that first sentence right,
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 291		Page 292
1	or these first two sentences right? Did I read them	1	It says "This meeting began the day immediately
2	right?	2	after our meeting with him," meaning you,
4	A. Yes Q Correctly?	4	Dr. Biederman, "at Janssen last week. Dr Biederman was very well-received by the group. The validity
5	A. The only incorrect statement here is that	5	of his diagnosis of pediatric mania was completely
6	the postgraduate course was on child	6	accepted and his diagnostic techniques deemed to be
7	psychopharmacology. One of dozens of talks was on	7	excellent. He was very balanced in his approaches
8	pediatric bipolar disorder.	8	to treatment and not perceived to be aligned with
9 10	Q So Gahan is wrong but I read it right? MR. PECK: Objection	9 10	any company in particular Evidently, he made quite a point regarding the metabolic issues related to
11	A You read it right, yes	11	olanzapine, to the extent of stating that this drug
12	Q. You did a lot of these seminars. Right?	12	should not be used in the treatment of children and
13	A. No. This seminar on pediatric	13	adolescents, highlighting the issues with published
14	psychopharmacology is given as a three-day	14	data." Did I read that correctly?
15	postgraduate course and that is by subscription	15	A. The reading is correct. One more time I
16 17	People pay fees to attend; it's not funded by anybody.	16 17	want to emphasize that the talk on pediatric mania was given by Dr Wozniak and not by me as one of
18	Q. But this isn't the only one you ever spoke	18	thirty talks that we deliver over a long weekend.
19	at?	19	Q But she was talking about your or your and
20	A. No, no, no. This talk on pediatric	20	her work on diagnosing pediatric mania Right?
21	bipolar illness was not my talk, it was	21	A. Correct.
22 23	Dr. Wozniak's talk that he's alluding to The	22 23	Q. But they're attributing the diagnostic
23	course is given every other year, our postgraduate course.	23 24	techniques to you Is that inappropriate? A. No, because I am the more senior I am
25	Q. Well, well, maybe Dr. Pandina is mistaken	25	the director of the course and my work on pediatric
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 293		Page 294
$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\0\\1\\1\\2\\3\\4\\5\\6\\7\\8\\9\\0\\1\\2\\2\\3\\4\\2\\2\\2\\3\\4\\2\\5\end{array}$	<ul> <li>mania is well-known. But this particular talk, we're talking about our joint work.</li> <li>Q. And they point out that you're not perceived to be aligned with any company in particular. Either that's because you work with almost every company or that they think it's an advantage that doctors don't see you as a salesman, they see you as Dr Biederman, the best pediatric psychiatrist in the world. Right?</li> <li>MR. SPIVACK: Objection, foundation, calls for speculation</li> <li>A. I am not aligned with any pharmaceutical company When I describe treatments, I describe all treatments as the data show</li> <li>Q. And that perceived objectivity is what makes you so credible. Right?</li> <li>A. It's not a perceived objectivity; it is an objectivity When I talk on the subject, the slide that you showed, I talk about all treatments available, not just one</li> <li>Q. In talking about all the treatments, you made sure to make a point the day after your meeting with Janssen talking about Risperdal how their chief competitor, olanzapine, should not be used in the population you were hired by Janssen to promote for. Stratos Legal Services 800-971-1127</li> </ul>	1 2 3 4 5 6 7 8 9 10 11 12 13 14 5 6 7 8 9 10 11 12 13 14 5 16 7 12 22 22 22 22 22 22 22 22 22	<ul> <li>Right?</li> <li>A I was never hired MR. PECK: Objection to form MR. SPIVACK: Objection, calls for</li> <li>speculation, misstates the testimony, argumentative.</li> <li>A. I was never hired by Janssen to promote</li> <li>risperidone. That's absolutely not true. The</li> <li>meeting, we met with them twice a year. The meeting</li> <li>happened by chance to have been in the week</li> <li>preceding our course, not by design.</li> <li>Q So it's a complete coincidence that the</li> <li>day after you meet with Janssen, you were telling a</li> <li>thousand doctors to not use their chief competitor</li> <li>in the population that you're studying for</li> <li>Risperdal?</li> <li>MR. PECK: Objection, form.</li> <li>MR. SPIVACK: Objection, argumentative.</li> <li>BY MR TRAMMELL:</li> <li>Q. Is that a coincidence, Doctor?</li> <li>MR. SPIVACK: Objection, argumentative.</li> <li>A. We met with Janssen on a regular basis</li> <li>throughout the duration of the J&amp;J Center at times</li> <li>that were convenient to them and us, yes, not</li> <li>related to our course. Second, I did not remember</li> <li>that we made any strong recommendations. What we</li> <li>Stratos Legal Services</li> <li>800-971-1127</li> </ul>
un <b>P</b> alanan an An	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 295		Page 296
1 2 3 4 5 6 7	may have done, what Dr Wozniak may have described is what I said before: that the weight gain associated with olanzapine was twice as large as the weight associated with risperidone. But we included in that information the fact that risperidone still produced a substantial weight gain of 2-1/2 kilos over eight weaks. That is not minor. So we never	1 2 3 4 5 6 7	same type of study that we did for each of the neuroleptics and anticonvulsants that we tested. Each one of those, we measure weight So we said olanzapine produced a 5-kilo weight gain, risperidone produced a 2-1/2-kilo weight over eight weeks. This is what we said The conclusions of what to do in your rick (honefit analysic is in the

over eight weeks That is not minor. So we never
said use or do not use that. This is the
interpretation of the writer, not my interpretation
I never said to use or not to use this or that drug
Q. I understand that Risperdal also causes

dangerous weight gain in kids. But are you saying
that when they say "Evidently he made quite a point
regarding the metabolic issues related to
olanzapine," that they are confusing you for

16 Dr. Wozniak?

MR PECK: Object to the form and the
 foundation and the editorializing
 A I am not responsible for an internal

e-mail and interpretation of the writer. I can only
tell you that we never say do or do not do We
describe -- I do not know, because I may not have

been in the room when Dr Wozniak delivered thetalk. The only information that we deliver for

25 clinicians to consider is the weight gain in the

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7 what to do in your risk/benefit analysis is in the 8 hands of the practitioners, not that we proscribe 9 the use of olanzapine because it was a competitor to 10 Janssen. 11 O. And this was at the outset of your 12 activities with Janssen and the center Right? 13 This was at the beginning? 14 A. I believe that the center may not have 15 been even operational at that time because we 16 started in early 2002. We assembled the personnel, 17 we thought about our projects, et cetera, et cetera. 18 So at that time we did not have anything going. 19 Q. Had they paid you the 500,000 by this 20 point? 21 A They paid an advancement. I think the 22 500,000 was for the year, not necessarily at the 23 outset. I do not know when the money came, but we 24 were planning to do the activities. We had a 25 budget, we had a proposal, we had activities that we Stratos Legal Services

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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 297		Page 298
1	were planning to do But March is very early 2002	1	Q. Is that an insignificant amount of money
2	when we started	2	to you?
3	Q Can you say with any certainty whether	3	A. No. It's a small amount relative to half
4	they paid you the 500,000 the day before you gave	4	a million budget and directing multiple scientific
5	the talk telling doctors not to use their biggest	5	activities
6	competitor?	6	Q. Well, the next paragraph says "I think
7	A I did not tell doctors not to use their biggest competitor and I do not remember any	7	this is a clear example of the utility of partnering with a group such as MGH, who has the potential of
9	exchange of moneys in the meeting with Janssen The	9	reaching and having a significant impact on the
10	moneys came to Mass General, not to me This is	10	field of child and adolescent psychiatry with these
11	not personal money And the moneys may have come, I	11	types of professional activities in non-sponsored
12	do not remember when the moneys arrived, the day	12	venues " Did I read that correctly?
13	they arrived, and I do not know what amount arrived	13	<ol> <li>You are a very good reader.</li> </ol>
14	first either	14	Q Okay, thank you.
15	Q. Well, the money came to Mass General to	15	And so my understanding of this, and you
16 17	pay for the concept that was the center from which you drew a salary. Right?	16 17	tell me how you interpret it, but my understanding
18	A I drew a small salary as the director of	18 18	is what they're saying is using Dr Biederman and his group who have this perceived objectivity will
19	the center, yes	19	help us convince doctors who treat kids to use
20	Q And how small was that salary?	20	Risperdal and the benefit is enhanced because he
21	A The salary was about 5 or 7 thousand	21	speaks at so many of these venues that aren't
22	dollars a year	22	sponsored by us.
23	Q And is that an insignificant amount of	23	MR PECK: Objection to form, foundation
24	money to you?	24	BY MR. TRAMMELL:
25	A It's 5 or 7 thousand dollars a year. Stratos Legal Services	25	Q Is that how you interpret that? Stratos Legal Services
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009		February 26, 2009
1	February 26, 2009 Page 299		February 26, 2009 Page 300
1	February 26, 2009 Page 299 A. No	1	February 26, 2009 Page 300 your Risperdal pitch will be that much more credible
2	February 26, 2009 Page 299 A. No. Q Okay. I'm curious to hear how you could	1 2	February 26, 2009 Page 300 your Risperdal pitch will be that much more credible when you deliver it to doctors who treat the
	February 26, 2009 Page 299 A. No. Q Okay. I'm curious to hear how you could possibly interpret it any other way.	1	February 26, 2009 Page 300 your Risperdal pitch will be that much more credible when you deliver it to doctors who treat the patients in the market they are trying to target
2 3	February 26, 2009 Page 299 A. No. Q Okay. I'm curious to hear how you could	1 2 3	February 26, 2009 Page 300 your Risperdal pitch will be that much more credible when you deliver it to doctors who treat the
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	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 301		Page 302
1	attend these advisory boards?	1	Q. What's the earliest that bipolar disorder
2	A I guess that they do	2	can present in a person?
3	Q Why?	3	A. Some parents describe their children as
4	A I don't know why	4	never having been well from infancy. Not that this
5	Q Is it so that they can use whatever	5	means we diagnose it in infants. But when asked a
6	information you give them to help them sell	6	
7	Risperdal better?	7	question when things started, they say they were never well
8	MR SPIVACK: Objection, argumentative,	8	Q You would never suggest to a doctor that
9	asked and answered, calls for speculation	9	they could diagnose bipolar disorder in an infant,
10	BY MR TRAMMELL:	10	would you?
11	Q If you don't know, you don't know	11	A. No
12	A I do not know	12	Q. And it's impossible because you can't tell
13	Q Okay	13	whether it's onset as an infant. Right?
14	Now, we talked earlier about whether mania	14	MR PECK: Objection
15	in children presents different from adults and you	15	A. No, I did not say that. I said that the
16	said it doesn't Right?	16	description that parents provide us is that a child
17	A I did not say that	17	was dysregulated affectively since birth, cried all
18	Q Okay Can you clarify that for me?	18	the time, was difficult to soothe, was a horrendous
19	A I said that the items are the same We	19	toddler, had massive temper tantrums, et cetera,
20	use the same criteria as we use in adults, but we	20	et cetera
21	have developmental understanding of how the symptom	21	Q I just want to make this really clear for
22	can manifest itself in children I gave you the	22	the jury. Dr Biederman, as the global authority,
23	example of buying with credit cards Since children	23	according to you, on diagnosing bipolar disorder,
24	don't have credit cards, they cannot go on buying	24	can you diagnose bipolar disorder in an infant?
25	binges	25	<ul> <li>You probably would have a lot of</li> </ul>
	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman		Joseph Biederman
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009 Page 303	1	February 26, 2009 Page 304
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2 3	February 26, 2009 Page 303 difficulties making the diagnosis in an infant. What I was alluding to was the fact that many of these children, as many as 30 percent in our	2	February 26, 2009 Page 304 under the right circumstances that was brought to you as bipolar? MR. SPIVACK: Same objection.
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1	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	Page 305		Page 306
1	need?	1	whether bipolar disorder has onset in an infant.
2	A Well, if there are biomarkers, for	2	Right?
3	example. If our imaging technology or our genetic	3	A. What we are determining is that the onset
4	technology will alert us to a particular mutation	4	of symptoms, not of the diagnosis, were early
5	that aggregates in children with bipolar illness, so	5	enough. Not the diagnosis per se but the symptoms.
6	a child that is expressing very abnormal behaviors	6	The parents were not able to tell us that the child
7	in infancy with that mutation, the suspicion would	7	has ever been mood-well
8	be higher.	8	Q. Does the condition onset in infancy?
9	Q. So if you were able to use the techniques	9	
10	you just mentioned, could you diagnose an infant	10	A. The condition can onset in infancy Q. It can?
11	with bipolar disorder?	11	A. Yes
12	•	12	
13	A. Again, it's a totally speculative. What		•
14	I am telling you, when the imaging technology,	13	A. It could
	biomarkers, genetic research will be advanced, the	14	Q. So it's possible that people, that babies
15	field will be able to make younger and younger	15	still in the womb could be diagnosed with bipolar
16	diagnosis You will be able to know that you are	16	disorder. Right?
17		17	A. I cannot do that today Nobody is
18	can say today that Huntington's disease is going to	18	suggesting that I'm not sure what is your purpose.
19	affect you when you are 50 at birth	19	But, for example, descriptions of children with
20 21		20 21	ADHD, there's a very famous paper published in
22	possible to diagnose an infant with bipolar		Science by a researcher by the name of Gabrielle
	disorder?	22	Weiss from Canada She described that mothers of
23 24	A. Today we have No, we don't have	23 24	ADHD children described very hyperactive fetuses
24		24 25	in utero. So the children were kicking all the
23	- · ·	25	time, they're moving all the time, things of that
	Stratos Legal Services 800-971-1127		Stratos Legal Services 800-971-1127
	000-971-127		000-971-1127
	Joseph Biederman		Joseph Biederman
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2	February 26, 2009 Page 307 type. That does not mean that we make a	2	February 26, 2009
2 3	February 26, 2009 Page 307 type. That does not mean that we make a diagnosis in utero But those are historical	2 3	February 26, 2009
2 3 4	February 26, 2009 Page 307 type. That does not mean that we make a diagnosis in utero But those are historical accounts to stress the point that some of these	2 3 4	February 26, 2009
2 3 4 5	February 26, 2009 Page 307 type. That does not mean that we make a diagnosis in utero But those are historical accounts to stress the point that some of these conditions emerge at the beginning of life; and of	2 3 4 5	February 26, 2009
2 3 4 5 6	February 26, 2009 Page 307 type. That does not mean that we make a diagnosis in utero But those are historical accounts to stress the point that some of these conditions emerge at the beginning of life; and of course people have life before they are born, as you	2 3 4 5 6	February 26, 2009
2 3 4 5 6 7	February 26, 2009 Page 307 type. That does not mean that we make a diagnosis in utero But those are historical accounts to stress the point that some of these conditions emerge at the beginning of life; and of course people have life before they are born, as you know.	2 3 4 5 6 7	February 26, 2009
2 3 4 5 6 7 8	February 26, 2009 Page 307 type. That does not mean that we make a diagnosis in utero But those are historical accounts to stress the point that some of these conditions emerge at the beginning of life; and of course people have life before they are born, as you know. Q. Does bipolar disorder onset in utero?	2 3 4 5 6 7 8	February 26, 2009
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	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 309		Page 310
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1		1	MR. PECK: No, we're on the record
2		2	MR. SPIVACK: Yes. Before we go off the
3		3	record, what time are we starting tomorrow?
4	A file-la la seconda con a	4	MR FIBICH: 9:00
5	A. I don't know where you are reading.	5	MR. SPIVACK: And who is questioning
7	<ul><li>Q The last paragraph.</li><li>A The last paragraph on the page?</li></ul>	7	tomorrow? MR. FIBICH: I am.
8	A The last paragraph on the page:	8	MR. SPIVACK: And who do you represent?
9		9	MR. FIBICH: Avila
10		10	MR. SPIVACK: The same party as
11	A. Just a second I want to make sure that I	11	Mr. Trammell?
12	know where you are reading. Will you show me?	12	MR TRAMMELL: No
13	Q Right there	13	MS LaMACCHIA: Mr Fibich has been pro
14	A. Okay	14	hac'd in and paid his fees in the In re Risperdal/
15		15	Seroquel/Zyprexa.
1.6		16	MR PECK: Mr. Trammell was pro hac'd in
17		17	to do depositions in the Avila case and corporate
18		18	representatives of Janssen That's what he was pro
19		19	hac'd in for That's what you asked my consent for
20 21	MD TDAMO (THE Hard Strate day	20 21	and that's what I consented to MS LaMACCHIA: The fact that Mr. Trammell
22	MR TRAMMELL: I'm done for the day.	21	
23	Thank you, Doctor. THE VIDEOGRAPHER: This is the end of tape	22	was pro hac'd in to the Mabel Adams matter in In re Risperdal/Seroquel/Zyprexa means that he is entitled
24	number 5 and the deposition for today. The time is	24	to take a deposition of a corporate or a nonparty
25	5:06 We're off the record	25	witness
1	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	Joseph Biederman February 26, 2009		Joseph Biederman February 26, 2009
	February 26, 2009	1	February 26, 2009
1 2	February 26, 2009 Page 311	1 2	February 26, 2009 Page 312
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}	Joseph Biederman February 26, 2009		Joseph Biederman February 26 2009
	Page 313		February 26, 2009 Page 314
1	MR PECK: Counsel for Dr Biederman has	1	understand what your position is Your position
2	raised the point and he's raised a valid point	2	MR SPIVACK: Well, I'm telling you my
3	Mr. Trammell I have no objection to asking questions	3	position
4	because he is here representing the Avila plaintiffs	4	MR FIBICH: Do you object? That's all
5	sponsored by Bailey Perrin; he can continue the	5	I want to know
6	questions	6	MR. SPIVACK: Well, it may be all you want
7	MR. FIBICH: My question to you is	7	to know, but let me go ahead and tell you why I'm
8	MR. PECK: But I would have an objection	8	objecting
9	to you and to Ms LaMacchia, for example, because	9	MR FIBICH: Tell you what Let me take a
10	she's from Bailey Perrin	10	short break, unless you object, and then we can come
11	MR. FIBICH: I'm not asking you for your	11	back on the record
12	reasons. I'm asking you, do you object to me asking	12	MR SPIVACK: No, I don't object if you
13	questions tomorrow?	13	think it might help us settle this
14 15	MR PECK: I object to you asking	14	MR FIBICH: Well, it might/it might not.
15	questions for the same reason you objected to the	15 16	Let's take a short break
16	fact that	16 17	MR PECK: Before we take a short break,
18	MR. FIBICH: No, no, I'm not asking for your reason; I'm just trying to understand what	17 18	because you're going to want to talk about this, a reminder to all present that you are bound by the
19	you'r eason; I'm just trying to understand what	18 19	stipulated protective order that was entered in the
20	Mr. Spivack, are you going to object to me	20	New Jersey litigation and the Foti litigation,
20	asking questions tomorrow?	21	anybody here that's involved in other litigations,
22	MR. SPIVACK: I am if the pro hac motion,	22	in the sense that you cannot disseminate Janssen
23	the order is limited to Avila I mean, the way	23	documents that were produced during discovery in New
24	I understand it	24	Jersey.
25	MR. FIBICH: No, let me just first	2.5	I noticed that a number of the exhibits
<b>–</b> –	Stratos Legal Services		Stratos Legal Services
	800-971-1127		800-971-1127
	MA WAANA AR IN THE INTERNATIONAL STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN THE STRATEGY IN T		
	Joseph Biederman		Joseph Biederman
	February 26, 2009		February 26, 2009
	Page 315		Page 316
1	have Janssen Bates numbers on them. A few of the	1	not done that, tell me
2	documents were declassified; most of them were not	2	MR PECK: Ms LaMacchia, do you degree?
3	And those documents which were not declassified are	3	MS. LaMACCHIA: I have always agreed
4	subject to the protection of the protective order.	1.	
		4	MR. PECK: Ms. Ho?
5	If anybody disagrees, please state it on	4 5	MR. FIBICH: Do you agree to not
6	If anybody disagrees, please state it on the record		MR. FIBICH: Do you agree to not disseminate these documents as your co-counsel
6 7	If anybody disagrees, please state it on the record MR. SMITH: No, we agree subject to the	5	MR. FIBICH: Do you agree to not disseminate these documents as your co-counsel agreed? Are you going to obey court orders? I can
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Joseph Biederman February 26, 2009 Page 317 1 COURT REPORTER'S CERTIFICATE 1, J Edward Varallo 3 Professional Reporter and Notary Public in the Commonwealth of Massachusetts (my commission expires 5 12/24/2015), hereby certify that the deposition of 6 Joseph Biederman, M D [Volume 1] 2 DATE: February 26, 2009 3 IN RE: Risperdal/Scroquel/Zyprexa Li ligation, Case Code 274; Alma Avila, as next fired 6 Johnson & Johnson Company, Janssen 7 in the matter of 1 ne: Risperdal/Scroquel/Zyprexa Li ligation, 7 in the matter of 1 ne: Risperdal/Scroquel/Zyprexa 8 Lifigation, Case Code 274; Alma Avila, as next fired 9 JOhnson & Johnson Company, Janssen 9 DisTRIBUTION TO COUNSEL The original signature 10 page from the deposition of 13 second by me, the deponent provided striftsfictory 14 evidence of identification as required by Executive 15 Order 453 (03-13) of the Governor 16 rocriffy that the doposition transcript 17 produced by me is true and accurate to the best of 18 my ability. 19 Tectriffy that the doposition transcript 10 attorney, or relative of any party lifigant, and 21 text or other rousies, in the 22 outcome of this suit 23 24 25 DATED: 3/6/2009 J Edward Varallo 25 DATED: 3/6/2009 J Edward Varallo 26 Stratos Legal Services 27 BOD-971-1127 20 Stratos Legal Services 28 BOD-971-1127				00 (12962 01) 00 010	-
Page 317Page 3181COURT REPORTER'S CERTIFICATE I, J Edward Varallo, RMR, CRR, Registered Commonwealth of Massachusetts (my commission expires 5 12/24/2015), hereby certify that the deposition of 6 Joseph Biederman, M D taken on February 26, 2009, in the matter of In re: Risperdal/Seroquel/Zyprexa 8 Litigation, Case Code 274; Alma Avila, as next 6 friend of Amber N Avila, an individual case v 6 Johnson & Johnson Company, Janssen Pharmaceutical 1 Products, L-P, et al1WITNESS: Joseph Biederman, M D (Volume 1]210Johnson & Johnson Company, Janssen Pharmaceutical 1 Products, L-P, et al5of Amber N Avila, an individual case v 911Products, L-P, et al 1 senographically and transcribed; that before being 13 sworn by me, the deponent provided satisfactory 14 evidence of identification as required by Executive 15 Order 455 (03-13) of the Governor 16 I certify further that I am not counsel, 17 produced by me is true and accurate to the best of 17 my ability.10DISTRIBUTION STRUCTIONS After reading the transcript 16 17 with the deposition transcript 16 17 produced by me is true and accurate to the best of 17 my ability.10WITNESS INSTRUCTIONS After reading the transcript 16 17 certify further that I am not counsel, 18 and void and the reason for it on the errata 202023SIGN AND DATE THE ERRATA SHEET and return it, along 24232423SIGN AND DATE THE ERRATA SHEET and return it, along 24242423					
1       COURT REPORTER'S CERTIFICATE       1       WITNESS: Joseph Biederman, M D       [Volume 1]         2       I, J Edward Varallo, RMR, CRR, Registered       1       WITNESS: Joseph Biederman, M D       [Volume 1]         3       Professional Reporter and Notary Public in the       1       Commonwealth of Massachusetts (my commission expires       1       DATE: February 26, 2009         5       12/24/2015), hereby certify that the deposition of       5       of Amber N Avila, as next friend       5         6       Joseph Biederman, M D taken on February 26, 2009,       6       Johnson & Johnson Company, Janssen       1         9       friend of Amber N Avila, an individual case v       7       Pharmaceutical Products, L P a//a         9       friend of Amber N Avila, an individual case v       9         10       Johnson & Johnson Company, Janssen Pharmaceutical       10       DISTRIBUTION TO COUNSEL The original signature         1       page/errata sheet was sent to Peter S Spivack,       12       Esq. to obtain signature from the deponent When         13       sworn by me, the deponent provided satisfactory       13       signed, please send original to Leslie LaMacchia,         14       evidence of identification as required by Executive       14       Esq. to obtain signature from the deposition         15       Order 455 (03-13) of the Governor </td <td></td> <td></td> <td></td> <td>-</td> <td></td>				-	
2I, J Edward Varallo, RMR, CRR, Registered2DATE: February 26, 20093Professional Reporter and Notary Public in the3IN RE: Risperdal/Seroquel/Zyprexa Litigation,4Commonwealth of Massachusetts (my commission expires512/24/2015), hereby certify that the deposition of5512/24/2015), hereby certify that the deposition of6of Amber N Avila, as next friend56Joseph Biederman, M D Laken on February 26, 2009,7Johnson & Johnson Company, Janssen7in the matter of In re: Risperdal/Seroquel/Zyprexa7Pharmaceutical Products, L P a/k/a8Litigation, Case Code 274; Alma Avila, as next8Janssen. L P, et al9friend of Amber N Avila, an individual case v910Johnson & Johnson Company, Janssen Pharmaceutical10DISTRIBUTION TO COUNSEL The original signature17products, L P, et al was recorded by me11page/errata sheet was sent to Peter S Spivack,12stenographically and transcribed; that before being12Esq, to obtain signature from the deponent When13sworn by me, the deponent provided satisfactory13signed, please send original to Leslie LaMacchia,14evidence of identification as required by Executive14Esq, two will supply a copy of the signed errata15order 455 (03-13) of the Governor15sheet to other counsel present at the deposition16I certify further that I am not counsel,19of your deposition, please note any change or17my ability.18of		Page 317	İ	Page 318	a . too a she
z	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	February 26, 2009 Page 317 COURT REPORTER'S CERTIFICATE I, J Edward Varallo, RMR, CRR, Registered Professional Reporter and Notary Public in the Commonwealth of Massachusetts (my commission expires 12/24/2015), hereby certify that the deposition of Joseph Biederman, M D. taken on February 26, 2009, in the matter of In re: Risperdal/Seroquel/Zyprexa Litigation, Case Code 274; Alma Avila, as next friend of Amber N Avila, an individual case v Johnson & Johnson Company, Janssen Pharmaceutical Products, L. P, et al was recorded by me stenographically and transcribed; that before being sworn by me, the deponent provided satisfactory evidence of identification as required by Executive Order 455 (03-13) of the Governor I certify that the deposition transcript produced by me is true and accurate to the best of my ability. I certify further that I am not counsel, attorney, or relative of any party litigant, and have no interest, financial or otherwise, in the outcome of this suit	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Joseph Biederman February 26, 2009 Page 318 WITNESS: Joseph Biederman, MD [Volume 1] DATE: February 26, 2009 IN RE: Risperdal/Seroquel/Zyprexa Litigation, Case Code 274; Alma Avila, as next friend of Amber N Avila, an individual case v Johnson & Johnson Company, Janssen Pharmaceutical Products, L P a/k/a Janssen. L P, et al DISTRIBUTION TO COUNSEL The original signature page/errata sheet was sent to Peter S Spivack, Esq, to obtain signature from the deponent When signed, please send original to Leslie LaMacchia, Esq, who will supply a copy of the signed errata sheet to other counsel present at the deposition WITNESS INSTRUCTIONS After reading the transcript of your deposition, please note any change or correction and the reason for it on the errata sheet DO NOT make any notations on the transcript itself. Use additional sheets if necessary SIGN AND DATE THE ERRATA SHEET and return it, along with the transcript, to your counsel Stratos Legal Services	And a strength of