

Joseph Biederman
February 27, 2009

Page 319

VOLUME 2 PAGES 319 - 613

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
L-6661-06

Johnson & Johnson Company, Janssen
Pharmaceutica Products, L.P., a/k/a
Janssen, L.P., et al.

Video Deposition of Joseph Biederman, M.D.
Friday, February 27, 2009
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600 Atlantic Avenue
Boston, Massachusetts 02210

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Registered Professional Reporter
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Joseph Biederman
February 27, 2009

Page 320

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Joseph Biederman
February 27, 2009

Page 321

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Joseph Biederman
February 27, 2009

Page 322

INDEX

DEPONENT	PAGE
Joseph Biederman, M.D by Mr Fibich	327
BIEDERMAN EXHIBITS FOR IDENTIFICATION PAGE	
17 CD labeled 02/26/09 Production Responsive to Avila Subpoena of 12/16/08	330
18 Printout Wednesday, February 25, 2009, from The Stanley Medical Research Institute website homepage (2 pages)	345
19 Dr. Biederman's response to 8/16/08 Libby Seaman e-mail (Bates B-E0002277 - 279) 20 Newspaper reprint from The Washington Post of Tuesday, February 15, 2005, titled Going to Extremes, Experts Question Rise in Pediatric Diagnosis of Bipolar Illness, a Serious Mood Disorder (8 pages)	394
21 Article entitled Risperidone for the Treatment of Affective Symptoms in Children with Disruptive Behavior Disorder: A Post Hoc Analysis of Data from a 6-Week, Multicenter, Randomized, Double-Blind, Parallel-Arm Study. Joseph Biederman, M.D., published in Clinical Therapeutics, Volume 28, November 5, 2006 (7 pages)	384

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Joseph Biederman
February 27, 2009

Page 323

1
2 BIEDERMAN EXHIBITS FOR IDENTIFICATION
3
4 22
5
6
7
8 23
9
10
11 24 Newspaper reprint from The Boston Globe 452
of January 30, 2009, titled Doctor
12 Scrutinized for Drug-Firm Ties Gets Kudos
From Bipolar Patients Kin (2 pages)
13
14 25 Page A18 from The New York Times 453
National of Tuesday, November 25, 2008
featuring article titled In Documents, Ties
15 Between Child Psychiatry Center and Drug
Maker
16
17 26 Cover E-mail sent Saturday, July 26, 469
2003, at 12:20 p.m. from Cahlan Pandina
subject: Pediatric Bipolar Notes, with
18 attached Protocol Outline: The Efficacy and
Safety of Flexible Dose Ranges of
19 Risperidone vs Placebo in The Treatment of
Manic or Mixed Episodes Associated with
20 Bipolar I Disorder in Adolescents
21 27 Planned letter to the editor of The New 478
York Times (Bates B-E0003321 - 326)
22
23 28 Multipage PowerPoint slides printout, 482
first slide headed Johnson & Johnson Center
for Pediatric Psychopathology Research
24 Director: Joseph Biederman, M.D.,
Administrative Coordinator Stephanie L. Van
25 Patten, M.A.

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Joseph Biederman
February 27, 2009

Page 324

1
2 BIEDERMAN EXHIBITS FOR IDENTIFICATION
3
4 29 Multipage PowerPoint slides printout, 495
first slide headed Johnson & Johnson Center
for Pediatric Psychopathology Research.
5 Director: Joseph Biederman M.D.,
6 Administrative Coordinator: Megan Almeida
7 30 Agenda headed the Johnson & Johnson 501
Center for Pediatric Psychopathology
8 Research at the Massachusetts General
Hospital, November 10, 2003 - 5:00 p.m. The
9 Four Seasons, Boston with attached slides
and administrative overview (B0000216 - 248)
10
11 31
12
13
14
15 32
16
17
18 33
19 34
20
21
22 35 Newspaper reprint from The Washington 531
Post, headed Comparison of Schizophrenia
Drugs Often Favors Firm Funding Study dated
23 April 12, 2006 (3 pages)
24 36 Article entitled Relationship Between 510
Drug Company Funding and Outcomes of
25 Clinical Psychiatric Research: Psychological

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 325

1
2 BIEDERMAN EXHIBITS FOR IDENTIFICATION
3
4 37 Article entitled Cochrane Reviews 546
Compared With Industry-Supported Meta-
5 Analyses and Other Meta-Analyses of the Same
Drugs: Systematic Review published
6 6 October 2006 (5 pages)
7 38
8
9
10 39 Newspaper reprint headed Wall Street 557
Journal July 11, 2006, Financial Ties to
Industry Cloud Major Depression Study; At
11 Issue: Whether It's Safe for Pregnant Women
to Stay on Medication; JAMA Asks Authors to
12 Explain by David Armstrong (6 pages)
13 40
14
15
16 41
17
18
19 42
20
21 43
22
23 44 Two pages of handwritten notes (Bates 578
B0000190 and 191), with three attached
24 remittance advices (B0000192 - 194)
25

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Joseph Biederman
February 27, 2009

Page 326

1
2 BIEDERMAN EXHIBITS FOR IDENTIFICATION
3
4 45
5
6 46
7
8 47
9
10 48 Spreadsheet, untitled, with six columns: 596
PI Last Name; Fund; Last Mo Exp; Cash
Balance; Sponsor Name; Title (5 pages)
11
12 49 Cover letter dated February 25, 2009, 599
from Hogan & Hartson to Leslie LaMacchia,
13 re: Subpoena issued to Dr. Joseph Biederman
dated December 16, 2008, with attached
14 privilege log
15 50 Document headed Editorial, Conflict of 611
Interest, American Journal of Psychiatry,
16 April 2006, pages 571 through 573
17
18
19
20 (ORIGINAL EXHIBITS SENT TO ATTORNEY LAMACCHIA)
21
22
23
24
25

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Joseph Biederman
February 27, 2009

Page 327

1 -----
2 MORNING SESSION
3 9:03 a.m.
4 -----

5 (Biederman Deposition Exhibit 17 marked
6 for identification.)

7 THE VIDEOGRAPHER: We are back on the
8 record. This is day 2 in the videotaped deposition
9 of Dr. Joseph Biederman. Today's date is February
10 27, 2009, and the time is four minutes after 9:00.
11 You may continue.

12 JOSEPH BIEDERMAN, M.D.,
13 having been previously sworn on oath, was
14 examined and testified further as follows:

15 EXAMINATION

16 BY MR. FIBICH:

17 Q. Good morning, Dr. Biederman.

18 MR. PECK: Mr. Fibich, before you begin
19 I would just like to place my objection on the
20 record to your interrogation of Dr. Biederman today.

21 Mr. Trammell was admitted in the Avila
22 case and he spent all of yesterday deposing
23 Dr. Biederman. With regard to the Adams case, he
24 was also admitted and the order of admission
25 indicates that he had the consent of his adversary,
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Joseph Biederman
February 27, 2009

Page 328

1 which was me, and I did in fact consent to
2 Mr. Trammell's admission in the Adams case. And
3 that was for the purpose of deposing Janssen
4 corporate reps whose depositions have been ongoing
5 for the past several months.

6 I object to both you and Mr. Trammell
7 examining Dr. Biederman. You are both sponsored by
8 the same law firm, you are one party, and that is
9 the party for Avila. One attorney should be doing
10 the questioning and one attorney should be doing the
11 objecting, not two attorneys.

12 In addition, I have the right to cross-
13 examine Dr. Biederman. And the fact that two
14 counsel from the same sponsor, essentially for the
15 same client, are taking up time that would impede my
16 cross-examination, I object. I understand that
17 Mr. Smith also has some questions, which means that
18 if I get a chance at all, it will be very late in
19 the day, if at all. And for these reasons I object.

20 MR. SMITH: This is Ken Smith. As I said,
21 I told you I might have some questions. I didn't
22 say I would have some questions.

23 MR. FIBICH: Mr. Peck, how long do you
24 feel you'd need to have for your cross of
25 Dr. Biederman?

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Joseph Biederman
February 27, 2009

Page 329

1 MR. PECK: I would suspect that I need at
2 least two hours.

3 BY MR. FIBICH:

4 Q. Dr. Biederman, we have not formally been
5 introduced, have we?

6 A. No.

7 Q. Once again, my name is Tommy Fibich and
8 I'm here on behalf of people that have brought a
9 lawsuit against Janssen Pharmaceuticals. Do you
10 understand that?

11 A. I understand that.

12 Q. Do you understand the nature of the
13 lawsuit that we have brought against Janssen?

14 A. No.

15 Q. You don't understand what the allegations
16 are?

17 A. I do not know anything about a lawsuit.

18 Q. You have been subpoenaed here today. Is
19 that correct?

20 A. Yes.

21 Q. And in response to the subpoena to come
22 here today, you produced certain documents to your
23 lawyers and they have turned those over to us in
24 response to that subpoena. Is that your
25 understanding?

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Joseph Biederman
February 27, 2009

Page 330

1 A. That's correct.

2 MR. FIBICH: Mr. Spivack, we have labeled
3 as Biederman Exhibit Number 17 the production that
4 we had, what you have represented to be responsive
5 to that subpoena. We have some questions about it,
6 so I want to make this part of the record. That's
7 the disc that was produced to us.

8 MR. SPIVACK: Sorry. My eyes are going,
9 so....

10 MR. FIBICH: I understand.

11 MR. SPIVACK: All right. Thank you, sir.

12 BY MR. FIBICH:

13 Q. You understand you're under oath?

14 A. Yes.

15 Q. Do you understand the obligations that
16 that oath imposes upon you?

17 A. Yes, I understand.

18 Q. And what are those, sir?

19 A. That I have to say the truth and
20 everything but the truth.

21 Q. That's right, everything that there is
22 with respect to the truth. You can't hold anything
23 back. You understand that, do you not?

24 A. Yes, I do.

25 Q. And you understand that there could be

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Joseph Biederman
February 27, 2009

Page 331

1 penalties applied against you should there be a
2 violation of that oath?
3 A. I understand.
4 Q. You understand that. Correct?
5 A. Correct.
6 Q. Dr. Biederman, have you ever given a
7 deposition before we started yesterday?
8 A. Yes.
9 Q. And on how many occasions have you been
10 deposed?
11 A. To my knowledge, once.
12 Q. And would you tell me the nature of that
13 deposition? What type matter was that involved?
14 A. It was a patent litigation between Lilly
15 and some genetic companies.
16 Q. And did I understand you to say patent?
17 A. (Witness nodded.)
18 Q. You've got to say "yes." You can't shake
19 your head.
20 A. Patent, yes, patent.
21 Q. And for which party did you testify?
22 A. I don't know which party. There was no
23 party; they were just lawyers questioning. There
24 was a challenge to the patent and I was asked to be
25 deposed.

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Joseph Biederman
February 27, 2009

Page 332

1 Q. And were you seeking to help protect that
2 patent or were you seeking to try to have that
3 patent voided?
4 A. I was not seeking anything. In fact,
5 I did not want to be deposed at all, but...
6 Q. Was your testimony in support of the
7 patent or against the patent?
8 A. Neither.
9 Q. Who asked you to testify?
10 A. The genetic companies that were
11 challenging Lilly for the patent on Strattera.
12 Q. And when was this?
13 A. It was about two months ago.
14 Q. And where did this take place?
15 A. In Boston.
16 Q. And do you recall the names of the lawyers
17 that were involved in that?
18 A. I only -- No. I only recall the lawyer
19 from Mass. General that went with me. His name is,
20 hmmm -- I don't remember -- Paul Cushing.
21 Q. And did that litigation involve a
22 pharmaceutical product?
23 A. Yes.
24 Q. And what was the product?
25 A. The product was Strattera.

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Joseph Biederman
February 27, 2009

Page 333

1 Q. Can you spell that for our court reporter?
2 A. Yes, S-t-r-a-t-t-e-r-a.
3 Q. Now, I apologize for going over some
4 things we talked about yesterday but I'm somewhat
5 unclear and it's probably my fault. But as I
6 understand things, you are a member of Harvard
7 Medical School?
8 A. Correct.
9 Q. And at Harvard Medical School, you hold a
10 position of full professorship. Is that correct?
11 A. That's correct.
12 Q. And as a result of being a professor at
13 Harvard Medical School, do you draw a salary from
14 Harvard?
15 A. No.
16 Q. Do you derive any income whatsoever as a
17 result of your association with Harvard Medical
18 School?
19 A. None. Harvard does not pay me a cent.
20 Q. Do you receive a stipend? Do you
21 receive --
22 A. No.
23 Q. Do you receive an office there?
24 A. No; nothing.
25 Q. So what do you do -- What you do at

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Joseph Biederman
February 27, 2009

Page 334

1 Harvard Medical School you basically do for free?
2 A. Everything that I do for Harvard Medical
3 School is for me because they don't pay me a cent
4 for anything. I am employed by Mass. General and I
5 teach residents. That's who I teach.
6 Q. At Mass. -- Excuse me. I didn't mean to
7 cut you off. You teach residents. Is that correct?
8 A. Yes.
9 Q. And Mass. General Hospital, that is the
10 teaching hospital for Harvard Medical School?
11 A. Yes. It's one of a dozen hospitals that
12 are affiliated with Harvard.
13 Q. Is it the most prominent hospital that is
14 affiliated with Harvard?
15 A. I don't know. I think that it's one of
16 the most prominent.
17 Q. What is the reputation of Massachusetts
18 General Hospital?
19 A. It's a very reputable institution.
20 Q. And is that the only hospital where you
21 treat patients?
22 A. Yes.
23 Q. And do you receive a salary from
24 Massachusetts General Hospital?
25 A. That's correct.

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Joseph Biederman
February 27, 2009

Page 335

- 1 Q. And what is your salary that you receive
2 from Massachusetts General Hospital?
3 A. Could you repeat the question?
4 Q. What is your salary that you draw from
5 Massachusetts General Hospital?
6 A. It's about 260,000, fifty -- sixty
7 thousand dollars.
8 Q. And in addition to that salary, do you
9 also receive income from patients that you treat at
10 Massachusetts General Hospital?
11 A. No. The patients that I -- I have a small
12 private practice that I have after hours, but the
13 patients that I see through the clinics at
14 Mass. General, they pay the hospital, not me.
15 Q. And the small practice that you have after
16 hours, do you derive income from that practice?
17 A. Yes, I do
18 Q. And what is the income that you derive
19 from that practice?
20 A. Modest. It's about, I would say, between
21 80 and a hundred thousand dollars a year.
22 Q. And what is the name of the practice? Is
23 it Joe Biederman, psychiatrist?
24 A. No, it's -- Yes.
25 Q. When you send a bill to a patient that you
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Joseph Biederman
February 27, 2009

Page 336

- 1 see in your private practice, what is the bill --
2 who is the bill from?
3 A. The bill is from me.
4 Q. "Me," do you mean some entity or --
5 A. No.
6 Q. -- do you mean yourself?
7 A. Myself.
8 Q. Now, what is your relationship or
9 association with the Yawkey Clinic for Outpatient
10 Care?
11 A. The Yawkey Clinic is one of the buildings
12 of Mass. General funded by the Yawkey family where
13 outpatient clinics are located; and on the sixth
14 floor, suite A is child psychiatry.
15 Q. Are you associated with that clinic?
16 A. I am associated with Mass. General. The
17 physical place that I work is at the Yawkey Center.
18 Q. Do you derive any income or moneys
19 whatsoever from the Yawkey Clinic?
20 A. No. The salary is from Mass. General.
21 Q. Now, yesterday we talked about the Johnson
22 & Johnson Center for Pediatric Psychotherapy. Do
23 you recall that?
24 A. Psychopathology.
25 Q. Psychopathology, excuse me. And that is
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Joseph Biederman
February 27, 2009

Page 337

- 1 just a name, is it? There isn't a building or a
2 wing?
3 A. No.
4 Q. Is that correct?
5 A. That's correct.
6 Q. Now, you are a director of that center.
7 Correct?
8 A. I was.
9 Q. You were. You are no longer?
10 A. The center ceased to exist in 2005.
11 Q. And as a director for that center, you
12 received what you indicated yesterday was a
13 relatively small amount of money?
14 A. That's correct.
15 Q. Did you derive any other income from this
16 center during its existence?
17 A. No.
18 Q. Now, I also saw some terms, a Center for
19 Child and Adolescent Psychiatric Research. Is that
20 another center there at Massachusetts General?
21 A. I am not sure, what are you referring to?
22 Q. I'm sorry?
23 A. Where did you get that?
24 Q. That was just in some papers. Do you know
25 what that means, where it comes from?
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Joseph Biederman
February 27, 2009

Page 338

- 1 A. I don't know. You have to be more
2 specific.
3 Q. Well, I'm just asking you, is there a
4 Center for Child and Adolescent Psychiatric Research
5 at Massachusetts General, to your knowledge?
6 A. No.
7 Q. Is there a Massachusetts General Hospital
8 Center for Pediatric Mania?
9 A. We have a clinic for pediatric mania,
10 program for pediatric mania. It's not a center.
11 Q. Well, I'm seeing the term Center for
12 Pediatric Mania. Is there a center?
13 A. No. We call it clinical and research
14 program in pediatric bipolar illness.
15 Q. Do you derive any income from any of these
16 entities that we've been discussing other than the
17 income from Johnson & Johnson?
18 A. The salary at Mass. General is composed of
19 components, clinical care, research, foundations.
20 It is a composite of different sources of
21 activities.
22 Q. Now, when you go out and publish papers,
23 you list your affiliation with Harvard Medical
24 School, do you not?
25 A. Yes.
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Joseph Biederman
February 27, 2009

Page 339

1 Q. And you list your affiliation with
2 Massachusetts General. Is that correct?
3 A. That's correct.
4 Q. And why do you do that, sir?
5 A. Because those are my affiliations.
6 Q. And what's the purpose of listing those?
7 A. Because this is my affiliations. Like
8 I put my last name and my first name and my degree.
9 Q. Well, you put those on there, quite
10 frankly, because it gives credence to you, does it
11 not?
12 A. No. This is the truth and this is my
13 affiliation. I work at Mass. General and I hold an
14 appointment. The standard in academia and
15 scientific intercourse, the people that publish and
16 present list their affiliation. It's nothing unique
17 to me.
18 Q. And I understand. I'm not saying it's
19 unique to you. I'm asking you, do you believe that
20 your association with Harvard and your association
21 with Mass. General give you additional credibility
22 as a spokesman for whatever views you may hold?
23 A. I don't think so. I think that they
24 derive credibility because of my scientific
25 activities, not the other way around. There are
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Joseph Biederman
February 27, 2009

Page 340

1 many people, Mass. General employs 10,000 people
2 that are not prestigious. I am prestigious because
3 of the quality of my work, not because I work there.
4 Q. Well, we're going to get to your prestige
5 in a little while. But as a practical matter, when
6 you're here today, you're not speaking the views of
7 Harvard Medical School, are you?
8 A. No.
9 Q. You're not speaking the views of
10 Mass. General Hospital, are you?
11 A. No.
12 Q. The views that you're expressing here
13 today are the views of Joseph Biederman. Correct?
14 A. That's correct.
15 Q. And the views that you express in your
16 scientific papers likewise are not the views of
17 Harvard. Correct?
18 A. That's correct.
19 Q. And the views that you express in your
20 scientific papers and presentations and lectures,
21 those are not the views of Harvard or of
22 Mass. General but rather the views of Joe Biederman.
23 Correct?
24 A. Let me clarify. My papers are scientific
25 papers. I describe data. I conduct statistical
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Joseph Biederman
February 27, 2009

Page 341

1 analysis. So it's not -- I don't proselytize or
2 evangelize; I state the facts. This is science, not
3 advertising or proselytical type of activities. So
4 I express -- The results of a study are mine, but
5 the views as you describe it may be perceived as
6 some kind of philosophical views on a subject.
7 Q. Doctor, I must not have asked my question
8 very well because I don't think you were responsive,
9 and I object.
10 A. Maybe.
11 Q. The views that you express in lectures,
12 seminars, scientific papers or in the newspaper,
13 whatever views of yours that are out there, those
14 are your views? You're not speaking on behalf of
15 Mass. General and you're not speaking on behalf of
16 Harvard, are you?
17 A. That's correct.
18 Q. Now, yesterday when we were talking about
19 the Center for Child and Adolescent Pediatric
20 Psychopathology, you indicated that it was
21 structured along NIH cores. Is that correct?
22 A. That's correct.
23 Q. And NIH stands for National Institutes of
24 Health. Correct?
25 A. That's correct.
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Joseph Biederman
February 27, 2009

Page 342

1 Q. But the National Institutes of Health has
2 nothing to do with this particular center, does it?
3 A. No.
4 Q. You were just using that to describe the
5 manner in which this center was structured.
6 Correct?
7 A. That's correct.
8 Q. Now, what is the Stanley Medical Research
9 Institute?
10 A. The Stanley family has a foundation that
11 is called now the Stanley Medical Institute that
12 funded us for a few years to conduct the
13 psychopharmacological research on pediatric bipolar
14 illness.
15 Q. The Stanley Medical Research Institute you
16 said was created by one family, the Stanley family?
17 A. To my understanding, yes.
18 Q. Do you know the Stanley family?
19 A. No.
20 Q. Who is the director of the Stanley Medical
21 Research Institute?
22 A. I don't remember.
23 Q. Do you know any of the people that are
24 associated with that particular institute?
25 A. I knew them. I just don't remember their
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Joseph Biederman
February 27, 2009

Page 343

1 names.
2 Q. Where is the Stanley Medical Research
3 Institute located?
4 A. I do not know.
5 Q. Have you ever been to that particular
6 institute?
7 A. No.
8 Q. What have you had to do with the Stanley
9 Medical Research Institute?
10 A. We put an application for conducting this
11 type of research that I described and they funded
12 us.
13 Q. And what is the Treatment Advocacy Center?
14 A. Treatment Advocacy Center? I have no
15 idea.
16 Q. You've never seen that term used with
17 respect to the Stanley Medical Research Institute?
18 A. No.
19 Q. How many studies has the Stanley Medical
20 Research Institute funded of yours?
21 A. They funded a center, so there was a group
22 of studies, studies that involved neuroleptics and
23 studies that followed up, but mostly a study that
24 involved treatment.
25 Q. What center did they fund?
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Joseph Biederman
February 27, 2009

Page 344

1 A. They funded the center for the treatment
2 of pediatric mania, so we conducted studies
3 examining Zyprexa, Seroquel, risperidone. We did a
4 study of preschoolers, these type of things.
5 Q. So the Center for Pediatric Mania has been
6 funded exclusively by the Stanley Medical Research
7 Institute?
8 A. Yes. It's the center for the treatment of
9 pediatric mania. That's probably correct.
10 Q. Okay. And what is your relationship to
11 that center?
12 A. I was the director of the center.
13 Q. You said you were. Are you currently?
14 A. No. The center ceased to exist in the
15 early 2000.
16 Q. Why did it cease to exist?
17 A. Because they run out of funds. Many of
18 these activities are time-limited; they are not
19 lifetime.
20 Q. Was the Stanley Medical Research Institute
21 set up to your knowledge for the purposes of funding
22 your research?
23 A. I am not understanding your question.
24 Q. Was the Stanley Medical Research Institute
25 set up solely for the purposes of funding your
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Joseph Biederman
February 27, 2009

Page 345

1 research?
2 A. Not at all. They funded a huge number of
3 centers of different types, in adult and pediatric
4 psychiatry.
5 Q. Why does the Stanley family have an
6 interest in bipolar mania and schizophrenia, if you
7 know?
8 A. I do not know. Usually this interest can
9 derive from personal issues, so I do not know.
10 MR. FIBICH: Let's mark this as the next
11 exhibit.
12 (Biederman Deposition Exhibit 18 marked
13 for identification.)
14 BY MR. FIBICH:
15 Q. Doctor, this is an exhibit that's been
16 marked as Exhibit 18.
17 A. Mm-hmm.
18 Q. It was taken off the Web page for the
19 Stanley Medical Research Institute. Do you see
20 that?
21 A. Mm-hmm.
22 Q. And then on the next page, if you'd go to
23 the second page, it lists some studies that they
24 funded. Do you see those?
25 A. Mm-hmm.
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 346

1 MR. SPIVACK: Mr. Fibich, just if I could
2 ask, on the first page there is some type at the
3 bottom that says "List of funded studies, see
4 Biederman's name."
5 MR. FIBICH: Right.
6 MR. SPIVACK: Is that on the original Web
7 page?
8 MR. FIBICH: I do not know the answer to
9 that. I did not pull this off myself and I will not
10 make the representation that it is.
11 MR. SPIVACK: Okay.
12 MR. FIBICH: It may be that someone typed
13 that on there to call it to my attention; it may be
14 on there. I don't know.
15 MR. SPIVACK: Okay.
16 MR. FIBICH: It looks unusual to be on a
17 website, let me say.
18 MR. SPIVACK: Right. That's why I asked.
19 Okay.
20 BY MR. FIBICH:
21 Q. Dr. Biederman, if you would go to the top
22 of page 2 of this particular exhibit, you see that
23 there are four studies that are funded?
24 A. Yes.
25 Q. And you were the principal investigator on
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 347

1 all four. Is that correct?
2 A. That's correct.
3 Q. They were all four studies with respect to
4 bipolar disorder?
5 A. Yes, pediatric bipolar disorder, yes.
6 Q. And the first one was discontinued. Do
7 you see that?
8 A. Mm-hmm.
9 Q. You've got to say "yes." You can't --
10 A. Yes. Sorry. I apologize.
11 Q. Okay. Why was this study discontinued?
12 A. Because patients were improved enough when
13 we treated them. The study was sequenced to treat
14 the mania first. Bipolar illness has two phases,
15 mania and depression. And the issue whether
16 antidepressants can be deployed in the treatment of
17 the manic phase is an area of great clinical
18 interest, so the patients that were supposed to be
19 in the paroxetine arm were offered.
20 So what was happening, we had two options,
21 to use bupropion, or Wellbutrin, or paroxetine, or
22 Paxil, and patients were not sufficiently severely
23 depressed to enter the depressed part. So they
24 improved enough with the anti-manic treatments that
25 we did not recruit for the depressive part.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 348

1 Q. Did you publish the results of that?
2 A. Were too small number of patients to
3 publish. It was five or six.
4 Q. So the answer is no?
5 A. No.
6 Q. So you had a small number of patients to
7 begin with. Is that correct?
8 A. No. The patients were large. Small
9 number of patients that were severely affected with
10 depression to be in the other arms.
11 Q. Well, I thought I understood you to say
12 that this particular drug worked so well that you
13 didn't have enough severely depressed people to go
14 forward with the study. Is that correct?
15 A. The treatment with the atypical
16 antipsychotic provided sufficient relief of
17 depressive symptoms that many children were no
18 longer severely depressed after we treated them.
19 Q. So you got a good result with respect to
20 the treatment that was afforded the people in this
21 study. Correct?
22 A. That's correct.
23 Q. And you did not publish that. Correct?
24 A. No, I published the results of the
25 treatment with the atypical antipsychotics. Our

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 349

1 study was we publish the impact on bipolar symptoms
2 and depressive symptoms.
3 Q. Then you had another bipolar study using
4 risperidone and it says olanzapine. Was that a
5 comparative study, the second one that's referenced
6 there?
7 A. The second study was a study in
8 preschoolers.
9 Q. And did that result in publication?
10 A. Yes.
11 Q. And what's the name of that paper?
12 A. Risperidone and Olanzapine in the
13 Treatment of Bipolar Illness in Preschoolers.
14 Q. And when was that published?
15 A. I don't remember, but you can find it in
16 PubMed. It's one of the papers listed in my C.V.
17 Q. And then there was another one,
18 risperidone and olanzapine, quetiapine, that was
19 completed. Do you see that?

20 A. Yes.
21 Q. And was that published?
22 A. We submit to be published. We have it in
23 last stages of the review process.
24 Q. When you say "we," who is we?
25 A. Myself; and I don't work alone. Myself
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 350

1 and my colleagues.
2 Q. And who are the colleagues that are
3 working on that with you?
4 A. The statisticians, other colleagues that
5 work in the assessment of the subjects and so on and
6 so forth.
7 Q. Do they have names?
8 A. Dr. Wozniak, Dr. Mick.
9 Q. And who is the principal author on that
10 paper?
11 A. I think that may be me. I don't remember.
12 Q. You may be the principal author but you
13 don't know?
14 A. I am not sure. I think that I am the CD,
15 the lead author of this paper, yes.
16 Q. Who is doing the first draft of that
17 paper?
18 A. Me.
19 Q. Do you have a draft of that paper?
20 A. The paper is in review in a scientific
21 journal.
22 Q. Which scientific journal has it been
23 submitted to?
24 A. I think it's called Bipolar Disorders. I
25 don't remember on top of my head, but I can find out
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 351

1 for you if you want.
2 Q. I'm asking you what the name of the
3 publication is that the paper has been submitted to.
4 Can you tell me?
5 A. I cannot remember. I can find out if you
6 are curious to know. But it's a scientific journal
7 that the paper is being currently considered for
8 publication.
9 Q. I'm not asking you what type of journal
10 I presume it's a scientific journal. Okay?
11 A. I don't remember the journal. How many
12 times you want me to tell you? I don't remember the
13 journal. I will be able to find out if you want to
14 know. I don't have it in my active memory.
15 Q. Is your active memory good today?
16 A. It's very good. What about yours?
17 Q. We'll find out.
18 A. Okay.
19 Q. Actually, it's a little slow today
20 A. Good.
21 Q. Then the Concerta-Aterol study that
22 Stanley Center for Psychiatric Research funded, that
23 was discontinued. Correct?
24 A. That's correct.
25 Q. When was that discontinued?
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 352

1 A. In the early 2000
2 Q. Why was it discontinued?
3 A. For the same reasons. The children that
4 were treated with atypical neuroleptics had
5 indicated enough improvement in their ADHD symptoms
6 that the parents were not interested to add
7 Concerta
8 Q. And did you publish the results of your
9 findings with respect to that study?
10 A. No. Those findings, we reported that in
11 the study of risperidone and olanzapine and other
12 studies that we did what is the improvement on ADHD
13 symptoms. But this study had minimal amount of
14 patients to be a valuable study, so that's the
15 reason that we discontinued it.
16 Q. And a limited number of patients
17 oftentimes will mean that you cannot draw general
18 conclusions from the findings of that study.
19 Correct?
20 A. That's correct.
21 Q. Now, I want to make sure I understood what
22 you told me. Did you tell me that the study that
23 was discontinued that was a study of pediatric
24 bipolar disorder in relationship to Concerta use and
25 Aterol use, that the findings were contained in
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 353

1 another paper?
2 A. The study had two stages. Children were
3 treated with risperidone, olanzapine and
4 neuroleptics first for their manic symptoms and they
5 were only eligible to enter the stimulant part --
6 Eighty percent of children with pediatric mania have
7 ADHD comorbidly. So an issue is, can you treat the
8 ADHD in the context of bipolar illness? So this is
9 the question that we are addressing
10 The results after treatment with
11 risperidone, quetiapine, whatever we treated, the
12 symptoms of ADHD were reduced enough that children
13 in general were not so severely affected with ADHD
14 to qualify for a trial of a stimulant but these
15 children were first treated with an atypical
16 neuroleptic.
17 MR. FIBICH: Object as nonresponsive
18 BY MR. FIBICH:
19 Q. My question is, the Concerta-Aterol
20 pediatric bipolar disorder trial, were the results
21 of that published in some paper?
22 A. No. We did not -- We discontinued the
23 study. We did not have enough patients
24 participating in it.
25 Q. Does the Stanley Center for Psychiatric
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 354

1 Research still exist today, to your knowledge?
2 A. The Stanley Foundation exists. Our center
3 does not.
4 Q. Does the Stanley center currently sponsor
5 any programs for the psychiatric department at
6 Mass. General, as far as you know?
7 A. I have no idea.
8 Q. You have no idea?
9 A. No. They may. The department is a very
10 large department and some investigators may receive
11 funding from the Stanley Foundation.
12 Q. I'm asking you as to your knowledge, sir.
13 A. To my knowledge, the Stanley family funds
14 the broad institute that is affiliated with
15 Mass. General, a very large effort at improving the
16 genetics of bipolar illness. I'm not sure if it's
17 the Stanley Medical Institute. I believe it's the
18 Stanley family itself.
19 Q. Doctor, as a member of either Harvard
20 Medical School or Massachusetts General Hospital,
21 were you required to disclose to either of those
22 institutions outside income derived from
23 pharmaceutical companies?
24 A. Yes.
25 Q. And to whom were you required to make
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 355

1 those disclosures?
2 A. To both Harvard and Mass. General
3 Q. And on what basis were you supposed to
4 make those insofar as time? Is that an annual
5 requirement, reporting requirement? Is it a
6 requirement as you receive money from those
7 pharmaceutical companies? Or how or on what time
8 basis is it supposed to be reported?
9 A. It was very unclear up till recently
10 Harvard had cycles that they decided periodically
11 that it's a new cycle and required reporting
12 Mass. General had the chairman designated individual
13 researchers to report.
14 Q. Let's take Harvard. How long have you
15 been a member at Harvard Medical School?
16 A. I started as a resident in 1977
17 Q. And at what point in time did Harvard
18 impose upon you an obligation to report outside
19 income from pharmaceutical companies?
20 A. I believe in the late '80s
21 Q. And that would be the '88-'89 time period,
22 approximately?
23 A. I don't remember.
24 Q. Okay. Your memory is not that good today
25 on that issue. Right?

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 356

1 A. Not very good.
2 Q. So from whatever time it was first imposed
3 upon you through 2006, did you fulfill those
4 requirements accurately and completely?
5 A. To the best of my abilities.
6 Q. How often would you make annual reportings
7 to Harvard with respect to outside income from
8 pharmaceutical companies?
9 A. They had cycles, usually occurred every
10 three years or more. The last cycle was in 2007 to
11 '8. So 2007? Yes.
12 Q. 2007?
13 A. Yes, the last -- Let me just think for a
14 moment. It was two thousand -- ? Yes, it was 2007.
15 Q. And before that was it a three-year cycle?
16 A. Before that was three years prior. I
17 don't remember. It was a little bit even at random,
18 so it's not that it had a precise cadence.
19 Q. Were you supposed to make these
20 disclosures to this institution at the end of the
21 year or at what particular time during the year?
22 A. When the cycle request came.
23 Q. So it would be a written request from
24 Harvard and then you would have to fulfill that. Is
25 that correct?

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 357

1 A. That's correct.
2 Q. And when is the last time that you
3 received a request from Harvard to disclose your
4 outside income from pharmaceutical companies?
5 A. I believe that was the end of 2007, I
6 believe.
7 Q. And from whom does this request come?
8 A. From the university.
9 Q. And who at the university?
10 A. I don't know. It's a request. Probably
11 from the dean.
12 Q. You're guessing?
13 A. I'm guessing.
14 Q. Who did you turn the requested information
15 in to?
16 A. It was electronic, so it was a website
17 that I turned the information in.
18 Q. So you would receive an e-mail. Is that
19 correct?
20 A. Yes.
21 Q. Saying let us know how much income you
22 had?
23 A. Complete the form for conflict of interest
24 and the instructions are here; complete it and
25 submit it.

Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 358

1 Q. And you did that sometime in 2007?
2 A. Yes, toward the end of 2007. To best of
3 my recollection.
4 Q. Now, did you have the same reporting
5 requirements with respect to Massachusetts General?
6 A. Massachusetts General has a different
7 system. In 2007 and '8 they developed an electronic
8 Web-based reporting system.
9 Q. And before that -- Excuse me. Were you
10 finished?
11 A. Yes.
12 Q. Before that, what type of system did they
13 have?
14 A. Before that, the requirements were
15 nomination by the chairman to report to individual
16 faculty. So the chairman requested from individual
17 faculty to report their activities outside the
18 institution.
19 Q. And who is the chairman?
20 A. The chairman of psychiatry is Dr. Jerry
21 Rosenbaum.
22 Q. And how long has he been the chairman?
23 A. About five years.
24 Q. So from 2002 to 2007 that's who you would
25 report your outside income to?

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Joseph Biederman
February 27, 2009

Page 359

1 A. The reporting -- The request came from the
 2 chairman and the information went to the president
 3 of the institution.
 4 Q. The president of the institution would be
 5 the president of Mass. General?
 6 A. Yes.
 7 Q. And who is that?
 8 A. Now it's Peter Slavin.
 9 Q. And before Mr. Slavin, who was it?
 10 A. I don't remember what was the name of --
 11 Q. When did Mr. Slavin become the president
 12 of that institution?
 13 A. I'm going to say about five or six years
 14 ago.
 15 Q. So you would receive a request to report
 16 to the president of the institution?
 17 A. I would receive a request from the
 18 chairman to report to the institution. I usually
 19 returned the response to the chairman and the
 20 chairman submitted it to whatever the agency or the
 21 department in the institution was recipient of that
 22 information.
 23 Q. And for how long were you requested by the
 24 chairman to submit this information to the president
 25 of the institution?

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Joseph Biederman
February 27, 2009

Page 360

1 A. How long? I think I was requested a few
 2 times. Every time that the request came, I
 3 completed the request.
 4 Q. I want to know, is this something that you
 5 did yearly?
 6 A. The yearly is only recently. It has been
 7 implemented by Mass. General, yearly reporting, but
 8 before that, was not yearly.
 9 Q. And typically how would the reporting go
 10 prior to it becoming a policy of doing it yearly?
 11 A. It was random and sporadic.
 12 Q. So it just varied. Correct?
 13 A. Yes.
 14 Q. And on each occasion that you were
 15 requested by Mass. General to report to them your
 16 outside income, did you do so accurately and
 17 completely?
 18 A. I did accurately and completely to the
 19 best of my abilities.
 20 Q. When you say to the best of your
 21 abilities, does that mean that there were on
 22 occasion mistakes made?
 23 A. On occasions mistake could have been made.
 24 Q. I'm not asking whether could have been.
 25 We can all make mistakes. Correct?

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 361

1 A. Correct.
 2 Q. Anybody can make a mistake. Right?
 3 A. Correct.
 4 Q. I'm asking you as you sit here today,
 5 Doctor, under oath, at the time that you fulfilled
 6 your responsibilities to submit to Massachusetts
 7 General your outside income from pharmaceutical
 8 companies as requested by your chairman, were
 9 mistakes made?
 10 A. At the time that I completed the forms I
 11 believed that I did them completely accurately.
 12 Q. And did you later determine that a mistake
 13 had been made?
 14 A. Later others determined that some small
 15 mistakes were made.
 16 Q. Who were the others that determined that?
 17 A. There was a committee at Harvard
 18 University that was set up after Senator Grassley's
 19 complaint that investigated all outside activities
 20 for last ten years.
 21 Q. And when was this committee set up?
 22 A. How?
 23 Q. When was the committee set up?
 24 A. The committee was set up I believe in two
 25 years ago.

Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 362

1 Q. And did the committee come about in your
 2 opinion as a result of Senator Grassley's
 3 investigation into pharmaceutical income to clinical
 4 trial investigators?
 5 MR. SPIVACK: Objection, calls for
 6 speculation, no foundation.
 7 A. Harvard has a standing committee and I do
 8 not know whether the committee was active before
 9 this or not. But it is a standing committee.
 10 Q. Why did they investigate you?
 11 MR. SPIVACK: Objection, calls for
 12 speculation.
 13 A. Senator Grassley sent a complaint to the
 14 university about me, and so they investigated me.
 15 Q. And who was the committee? Who was on the
 16 committee?
 17 A. They are sitting professors. I cannot
 18 remember their names, but you can probably find them
 19 in the Harvard website.
 20 Q. What would be the name of that committee?
 21 A. The Committee on Outside -- Committee on
 22 Conflict of Interest and Conflict of Commitment
 23 Q. Conflict of interest and --
 24 A. And conflict of commitment
 25 Q. Conflict of commitment. And you cannot

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Joseph Biederman
February 27, 2009

Page 363

1 remember any of the members of this committee?
2 A. I don't. But they are public, in public
3 domain, so it's not a problem. If my memory fails,
4 you can find the names on the website.
5 Q. Did you appear before this committee?
6 A. I did.
7 Q. And when did you appear before the
8 committee?
9 A. In July of last year.
10 Q. Were you represented by counsel at that
11 meeting?
12 A. I was.
13 Q. You were?
14 A. I was.
15 Q. Who represented you?
16 A. Mr. Spivack.
17 Q. And was testimony taken at that committee?
18 A. Yes.
19 Q. Were you under oath?
20 A. No.
21 Q. Now, you indicated -- And how long a
22 hearing was this that they investigated you?
23 A. How long was the hearing?
24 Q. Yes.
25 A. It was three hours.

Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 364

1 Q. And was a determination made that you had
2 made mistakes in your reporting to Massachusetts
3 General?
4 A. There was a determination that came later
5 that they found some relatively small mistakes.
6 None of them are mistakes that Senator Grassley
7 accused me of making.
8 Q. Was there an investigation into your
9 disclosures to Harvard Medical School?
10 A. That was the investigation.
11 Q. It was the same investigation?
12 A. Yes.
13 Q. And were determinations made that you had
14 made errors with respect to your filings with
15 Harvard Medical School?
16 MR. SPIVACK: Objection, asked and
17 answered.
18 A. The investigators alleged that there were
19 some small discrepancies that they identified in
20 their report. Their report has not been issued, so
21 I don't think that there is a final report on that.
22 Q. Do you expect a report to be issued?
23 A. Yes.
24 Q. Were there preliminary findings with
25 respect to their findings?

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 365

1 A. The preliminary findings as I understood
2 them were small amounts over the last nine years,
3 eight years, they identified. None of them were the
4 problems that Senator Grassley put in the
5 Congressional Record.
6 Q. My question probably wasn't clear to you.
7 Let me rephrase it. Was there a written report as
8 to the findings which you have characterized as
9 somewhat small mistakes?
10 MR. SPIVACK: Let me just interpose an
11 objection to the extent it calls for attorney-client
12 information. Joe, to the extent it involves
13 communications between you and me, don't answer. If
14 you can answer the question without that, please do.
15 A. Well, report is in process and the
16 information that I have is information that was
17 discussed with Mr Spivack. So the report is not
18 final, so --
19 Q. So all you know is what you've learned
20 from your lawyer?
21 A. Yes.
22 Q. There's been no written documentation of
23 their findings insofar as you know?
24 A. The report, there was a draft report. A
25 final report has not been issued.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 366

1 Q. And have you seen the draft report?
2 A. I have seen the draft report.
3 Q. Do you have the draft report with you?
4 A. No.
5 Q. Do you know where I can get a copy of the
6 draft report?
7 A. You need to ask the medical school.
8 Q. Now, as I understand it, you were
9 investigated by the medical school. Correct?
10 A. I was investigated following Senator --
11 not spontaneously because they had concerns about
12 me, but because of due diligence secondary to
13 Senator Grassley's complaint to the medical school.
14 Q. My question was, you were investigated by
15 the medical school. Correct?
16 A. And my response is to explain to you the
17 context of that investigation. It's not that they
18 suddenly out of the clear blue became concerned
19 about my activities. They could have investigated
20 the other ten thousand faculties equally.
21 Q. Well, that's a good point. How many
22 others did they investigate for this alleged
23 potential conflict of interest and conflict of
24 commitment?
25 A. Only those that the senator brought to the

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 367

1 fore.
2 Q. And who is that?
3 A. They also lodged complaints against two of
4 my colleagues, Dr. Timothy Wilens and Dr. Tom
5 Spencer.
6 Q. Mett, did you say?
7 A. No; Dr. Tom Spencer and Dr. Timothy
8 Wilens.
9 Q. And are these doctors that are
10 psychiatrists?
11 A. They are psychiatrists.
12 Q. And these are doctors that had ties to
13 drug companies?
14 A. That what?
15 Q. Had ties to drug companies.
16 A. Yes.
17 Q. Was the committee hearing with respect to
18 you separate from the committee hearings with
19 respect to the others?
20 A. They interviewed me separately than the
21 interviews that they conducted with them. But the
22 report I believe is going to be a report on all
23 three of us.
24 Q. Do you know if the medical school did any
25 inquiry into the pharmaceutical companies as to the
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 368

1 amounts of money that had been paid to you?
2 A. I do not know what they inquired
3 Q. Were you required to produce any
4 documentation to this committee relative to the
5 income you had earned from pharmaceutical companies?
6 A. I provided them with extensive financial
7 information of my entire earned income over last
8 eight years
9 Q. Were there any rights or privileges of
10 yours suspended pending this investigation?
11 A. Not rights or privileges. I agreed not to
12 do any work with pharmaceutical companies until the
13 investigation is complete.
14 Q. That was an agreement by you. Is that
15 correct?
16 A. That's correct.
17 Q. Was that a negotiated agreement?
18 A. Yes. I think that the request, we decided
19 while the investigation is completed that I will
20 withdraw from activities with pharmaceutical
21 companies, speaking, doing research, or any
22 activities of that type
23 Q. Have you appeared before Senator
24 Grassley's committee?
25 A. No.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 369

1 Q. Have you had any contact whatsoever with
2 Senator Grassley's committee investigators or the
3 people that are assisting him?
4 A. No.
5 Q. Have you provided any information to
6 Senator Grassley's committee relative to the
7 accusations that have been made against you?
8 A. The information -- Senator Grassley sent
9 his inquiries to Mass. General and Harvard, so
10 Harvard asked me; I provided them; they provided the
11 senator with the information.
12 Q. And why is it, if you know, that the
13 information relative to your relationship with
14 pharmaceutical companies is important?
15 A. I am not sure if I understand your
16 question.
17 Q. Why does Massachusetts General, why do
18 they care what income you get from pharmaceutical
19 companies? If you know
20 A. Well, the major issue is that there are
21 guidelines. When a researcher is doing
22 investigation for a particular company, you cannot
23 make more than an allowed maximum. So those are the
24 things that they have to --
25 Q. What is the allowed maximum?
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 370

1 A. \$20,000 a year per company.
2 Q. Is that total? In other words, if Lilly
3 gives you 5,000 and AstraZeneca gives you --
4 A. It's per company.
5 Q. It's per company?
6 A. (Witness nodded.)
7 Q. So if I understand what you're telling me,
8 and I just need you to clarify it for me, if you
9 receive in a calendar year more than \$20,000 from
10 one drug company, you are prohibited as a matter of
11 policy by Massachusetts General from doing any
12 clinical trials or work for that company?
13 A. I have to disclose and the institution
14 needs to decide if the research can be carried on.
15 That's the way that is handled. They need to know
16 about that and they need to decide if the research
17 or new investigator has to be put on that study.
18 Q. You have to disclose it to the
19 institution. Correct?
20 A. To the institution, yes.
21 Q. And then the institution can determine
22 whether or not that creates an issue of your going
23 forward with any clinical research you may want to
24 do for that company. Is that correct?
25 A. That's correct.
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Joseph Biederman
February 27, 2009

Page 371

1 Q. Did the committee that investigated you
2 determine that you had earned more than those
3 minimums and failed to reveal that to the
4 institution?
5 A. There were a few instances. The committee
6 determined that I was probably 99 percent compliant.
7 There were a few instances of small non-deliberate
8 violations, small violations.
9 MR. FIBICH: Objection, nonresponsive.
10 BY MR. FIBICH:
11 Q. My question to you is, sir, did the
12 committee in their preliminary findings or tell you
13 orally that you had violated that policy by not
14 disclosing to them that you had earned more than
15 \$20,000 in a period and were doing work for a
16 pharmaceutical company that had paid you that?
17 MR. SPIVACK: Objection, asked and
18 answered.
19 A. There were small non-deliberate mistakes
20 that they uncovered.
21 Q. That's not my question, sir.
22 A. Well, this is my response.
23 Q. Sir? What did you say?
24 A. This is what I can tell you.
25 Q. Okay, let me ask it this way. Did the
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 372

1 committee say that you had acted deliberately?
2 A. No
3 Q. Did the committee say that you had acted
4 with reckless disregard?
5 A. The committee is not going to say that.
6 Q. Who is Libby Seaman?
7 A. Libby Seaman is a counsel for Harvard
8 MR. FIBICH: You want to take a break?
9 I've got only one copy of something I want to ask
10 him about
11 MR. SPIVACK: Okay.
12 THE VIDEOGRAPHER: The time is 9:51. We
13 are off the record.
14 (Short recess taken.)
15 THE VIDEOGRAPHER: We are back on the
16 record. The time is one minute after 10:00
17 BY MR. FIBICH:
18 Q. Doctor, are you ready to proceed?
19 A. Yes
20 Q. Doctor, we were talking about your
21 disclosures to Massachusetts General and to Harvard
22 And you understand the purpose of that disclosure
23 requirement, do you not?
24 A. I understand.
25 Q. Tell the jury the reason that Harvard and
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 373

1 Massachusetts General requires that you disclose to
2 them your outside income from pharmaceutical
3 companies.
4 MR. SPIVACK: Objection, asked and
5 answered.
6 A. The policy is that if I conduct research
7 with a pharmaceutical company, I cannot do outside
8 activity exceeding the minimums.
9 Q. Why do they have that requirement? What
10 difference does it make what amount of money you
11 make from the pharmaceutical company?
12 A. The money is arbitrary. The idea is to
13 minimize potential bias.
14 Q. Do you believe that money that is used to
15 fund studies creates bias?
16 A. Moneys that are given to support studies
17 are funding the study; they are not biased.
18 Research is expensive and require funding. It
19 cannot be done without funding.
20 Q. Do you believe that pharmaceutical
21 companies that fund studies create bias by the fact
22 that they are funding studies on their product?
23 A. I don't. I think that they contract with
24 investigators to conduct studies that are expensive
25 to execute; and without funding, research cannot be
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 374

1 conducted.
2 Q. Not asking you whether you need funding
3 for research, Doctor. That wasn't my question.
4 Okay? My question is a very simple one. Do you
5 believe that when a pharmaceutical company funds a
6 study of one of its products, that that can create
7 bias?
8 MR. SPIVACK: Objection, asked and
9 answered.
10 A. I don't think so.
11 Q. Now, you consider yourself -- Do you
12 consider yourself primarily a clinician or an
13 academician?
14 A. I am a clinician researcher.
15 Q. So you consider yourself both?
16 A. Yes.
17 Q. And as a researcher, you consider yourself
18 a scientist?
19 A. Yes.
20 Q. Science is a discipline of very certain
21 exactitude. Correct?
22 A. Science has a process.
23 Q. And it's called the scientific process.
24 Right?
25 A. Yes.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 375

1 Q. And the purpose of the scientific process
2 is what?
3 A. You are in a study, you are testing, you
4 are addressing a question, you are testing a
5 hypothesis. You subject the data to statistical
6 analysis to examine whether the findings are chance
7 or not likely to be chance, and you draw conclusions
8 based on your findings.
9 Q. It is a search for the greatest truth that
10 can be obtained. Correct?
11 A. It is a method to investigate.
12 Q. And the method to investigate that you use
13 requires that you be very precise. Correct?
14 A. As precise as the field allows.
15 Q. And you are a very precise individual, are
16 you not?
17 A. I am.
18 Q. You are a very deliberate individual, are
19 you not?
20 A. I am not sure what you mean by that.
21 Q. Well, what you do is a result of your
22 intentional conduct?
23 A. Well, what I do is I ask questions that I
24 have about how to improve the life of the people
25 under my care. So all my research is based on
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 377

1 of my scientific work, not the only work that I do
2 or the only type of research that I do.
3 Q. When the Grassley committee hearing or the
4 Grassley investigation was initiated, you were the
5 subject of newspaper comments, were you not?
6 A. I was.
7 Q. And I have today a copy of a page from The
8 New York Times, November 25, 2008. Was that
9 approximately when this issue came to the public's
10 eye? Approximately.
11 A. November 2008, I think The New York Times
12 published e-mails that you released to the press
13 from some attempt to quash the subpoena. This is
14 what I think happened in the paper in 2008. There
15 was an article, there are articles before that, but
16 the 2008 I believe is related to e-mails that you
17 released to the press.
18 Q. You think I released something to the
19 press?
20 A. Obviously somebody released.
21 Q. Well, you said "you" and you looked at me.
22 Do you think I released it?
23 A. I am using the "you" generically.
24 Q. Okay. So the "you" could be anybody in
25 the world. Right?
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 376

1 trying to understand the diseases that the children
2 that are under my care are afflicted and how to
3 better approach them therapeutically, with medicines
4 and with psychosocial treatments.
5 Q. Now, you've already told us that you
6 consider yourself a world-renowned scientist.
7 Correct?
8 A. It is not what I consider myself. It is
9 what others consider myself.
10 Q. So you're familiar with your reputation
11 across the world. Correct?
12 A. I am familiar with my reputation.
13 Q. And your reputation is that you are a
14 specialist in the field of bipolar disease in
15 children?
16 A. I am a specialist in pediatric
17 psychopharmacology.
18 Q. Which includes bipolar mania?
19 A. It is one of many conditions that afflict
20 children.
21 Q. Well, I thought you indicated to me
22 yesterday -- and correct me if I'm wrong -- that
23 your two subspecialties within the field of
24 psychopathology are bipolar mania and ADHD.
25 A. I indicated that that's the predominance
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 378

1 A. No, could be somebody related to this
2 case.
3 Q. Well, who?
4 A. I don't know. It's not -- I have no
5 access to that information.
6 Q. Well, the purpose for this is that in this
7 document, and I only have one copy but I will
8 represent to you that I'm going to read it
9 accurately, it says "Dr. Joseph Biederman, a
10 world-renowned child psychiatrist." And that's how
11 people see you, do they not?
12 A. Yes.
13 Q. Would you consider yourself the leading
14 psychiatrist in the world for the treatment of
15 bipolar mania or bipolar disease in children?
16 A. One of the leaders.
17 Q. One of the leaders?
18 A. (Witness nodded.)
19 Q. Are you a football fan?
20 A. Fair-weather.
21 Q. Fair-weather. We had a football coach in
22 Texas named Bum Phillips. You ever hear of Bum
23 Phillips?
24 A. No.
25 Q. His son Wade Phillips is actually the
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 379

1 coach of the Cowboys now. You know them, don't you?
2 A. I know the Cowboys, yes
3 Q. Bum Phillips had a running back one time
4 and he was asked if he's the best running back ever
5 and Bum Phillips said "I can't tell you he's the
6 best running back, but he's in a class where it
7 doesn't take long to call the roll." And my
8 question to you is, are you in a class where it
9 doesn't take long to call the roll with respect to
10 experts in the treatment and diagnosis of bipolar
11 mania in children?
12 A. I would say that there are probably four
13 or five people at my level.
14 Q. And who are they?
15 A. Dr. Janet Wozniak, Dr. Barbara Geller,
16 Dr. Gabrielle Carlson, Robert Findling, people like
17 that that have done a substantial amount of work on
18 the subject.
19 Q. So in the entire world as we know it
20 sitting here today, it is those individuals and
21 yourself that are the leading experts in the field
22 of bipolar disease in children?
23 A. I would say there are probably about one
24 hundred people that in one way or another do
25 research in child psychiatry, but these are the most
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 380

1 prominent investigators
2 Q. I understand there's a lot of people that
3 do research in child psychiatry. As a matter of
4 fact, there's people --
5 A. In pediatric bipolar illness.
6 Q. As a matter of fact, there are people that
7 disagree with you as to whether --
8 A. Sure
9 Q. -- this disease even exists. Isn't that
10 correct?
11 A. Absolutely.
12 Q. As a matter of fact, you have compared
13 yourself, because this disease as you see it has
14 come under criticism, and you've compared yourself
15 to Galileo, haven't you?
16 A. I have not compared myself to Galileo.
17 I only said that Earth was once flat.
18 Q. Okay. Well, are you familiar with a
19 Boston Globe article where you indicated that
20 although you were under criticism for saying
21 pediatric bipolar exists, that you felt like Galileo
22 who said the world was not flat?
23 A. I only said that in science there is an
24 evolution. The first response to new ideas is to
25 demonize them. So the first answer, the people that
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 381

1 described the HIV virus that won last year Nobel
2 Prize in medicine were ridiculed for a decade until
3 the reality hit that they may have been right.
4 Bruce Jenner, when they discovered the smallpox
5 vaccine, had to inoculate his children to make the
6 point that a vaccine is a good idea.
7 So I think that the fact that new ideas
8 are met with skepticism occurs in all fields of
9 knowledge that I am aware of. This is part of the
10 scientific discourse.
11 Q. And part of the scientific discourse with
12 respect to your suggestion that bipolar disorder
13 occurs pediatrically is that others disagree with
14 you. Correct?
15 A. I'm not sure if I understand what you are
16 saying. Could you repeat it?
17 Q. Yes. You've indicated that new scientific
18 studies are often or new scientific discoveries are
19 often met with skepticism. Correct?
20 A. Yes, in all fields of knowledge, yes.
21 Q. And the world being flat was one of them.
22 Correct?
23 A. The world being flat is one of them.
24 Q. The vaccine, smallpox vaccine that you
25 just referred to?
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 382

1 A. (Witness nodded.)
2 Q. And you have compared your determination
3 that bipolar mania or bipolar disease exists in
4 pediatric populations has been met with the same
5 skepticism, has it not?
6 A. I alluded to the fact that there is a
7 history in the evolution of science that new ideas
8 are met with skepticism.
9 Q. Sir, I'm not talking about the history of
10 science or anything else. I'm talking specifically
11 about your position as a spokesman for the
12 proposition that pediatric bipolar disease exists.
13 And that has been met by some with skepticism?
14 A. Yes.
15 Q. And challenge?
16 A. Skepticism
17 Q. And challenge?
18 A. The people that --
19 Q. Do you disagree with "challenge"?
20 A. Yes. The people that express skepticism
21 are people that did not conduct research to support
22 their skepticism. And I used the Galileo experience
23 because one thing is to say "I don't like any of
24 that" and other thing is to say that "I conducted
25 similar research and I was able to show the
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 383

1 opposite." That research is not forthcoming.
2 So the people, the mostly vocal critics
3 are people that have not done any critical body of
4 research disputing the findings. They're only
5 saying I don't like it, which in science is not the
6 same. You're not having the same interlocutors by
7 saying I don't like that. You can say it about a
8 hamburger or a hotdog but not in science. In
9 science in order for you to say that this is not
10 true, you need to show equal amount of work that
11 shows the opposite result, and that's the dispute.
12 Today pediatric bipolar illness is accepted by the
13 practicing community.

14 MR. FIBICH: Object to that as being
15 nonresponsive.

16 BY MR. FIBICH:

17 Q. Do you disagree with this statement: The
18 diagnosis of pediatric bipolar disease is
19 controversial?

20 A. I disagree. The controversy is about how
21 to best define, what are the best ingredients.
22 That's the controversy, not that a group of children
23 that are very sick with high levels of morbidity and
24 disability exist. That controversy is over. The
25 controversy today is about how to best define it.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 384

1 That's the controversy.

2 MR. FIBICH: Mark this as the next
3 exhibit. And we're skipping one but I'll come back
4 to it.

5 MR. BURNEY: So I'm sorry. The number on
6 this is 19 or 20? You said the next exhibit but
7 we're skipping one.

8 MR. FIBICH: Hold on.

9 THE WITNESS: This is 18.

10 MR. FIBICH: This is going to be 20.

11 MR. BURNEY: This is going to be 20?

12 Okay.

13 (Biederman Deposition Exhibit 20 marked
14 for identification.)

15 BY MR. FIBICH:

16 Q. Let me show you what I've marked as
17 Exhibit 20, Dr. Biederman.

18 A. Mm-hmm.

19 Q. And this is an article out of The
20 Washington Post, February 2005 Do you see that?

21 A. Mm-hmm.

22 Q. And if you would turn to page 3 and under
23 the heading Very Disturbed Children, read the
24 comments that are attributed to you, sir.

25 A. Mm-hmm.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 385

1 Q. Did you talk to The Washington Post?

2 A. I don't remember who I talked to, but
3 apparently I talked to this person.

4 Q. The comments that are contained in the
5 first two paragraphs are comments of yours and you
6 were quoted accurately. Correct?

7 A. This is not a quote, this is an
8 interpretation of what I said.

9 Q. Is it a correct interpretation of what you
10 said?

11 A. I said the same as I said to you. I did
12 not compare myself to Galileo. I said that Earth
13 was once flat. The reporter is not quoting me here.
14 It is her interpretation. She could have said that
15 I am comparing myself to God. This is her
16 interpretation of what I said. I said that Earth
17 was once flat. This is what I said.

18 Q. Well, why didn't you compare yourself to
19 God?

20 A. Because I am not God. I am saying that
21 the interpretation of my statement is her
22 interpretation.

23 Q. Is her interpretation of your statement an
24 accurate statement?

25 A. I said that Earth was once flat. I did
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 386

1 not compare myself to Galileo.

2 Q. Sir, I'm asking you, what she says is
3 "Joseph Biederman, a professor of psychiatry at
4 Harvard and one of the most forceful advocates of
5 the aggressive treatment of preschoolers, thinks
6 bipolar disorder has been severely underdiagnosed in
7 children." Is that a correct statement?

8 A. That is correct. That's a quote.

9 Q. Okay, that's a quote. And the next
10 statement is "He likens the criticism he has
11 encountered to the outrage that greeted Galileo's
12 challenge to the notion that the Earth was flat."
13 Is her interpretation of what you said accurate?
14 Yes or no.

15 A. Yes, it was accurate.

16 Q. And do you agree that you are one of the
17 most forceful advocates of the aggressive treatment
18 of preschoolers?

19 A. It is her statement about me.

20 Q. I didn't ask you if it was her statement
21 about you. I'm asking you if you agree that you are
22 one of the most forceful advocates of the aggressive
23 treatment of preschoolers.

24 A. I am.

25 Q. Doctor, what is the purpose of publishing
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 387

1 scientific papers?

2 A. To advance knowledge.

3 Q. And the way you advance knowledge is that
4 you come to scientific conclusions that have met,
5 and I'm talking about you yourself, some level of
6 scientific rigor that you publish in papers for
7 others to read. Correct?

8 A. Papers are published disseminating
9 information for others to read.

10 Q. And you believe that the conclusions that
11 are contained in the scientific papers that you have
12 published with respect to bipolar disease and in
13 particular Risperdal have met your standards of
14 scientific rigor?

15 A. All papers that I publish are data-driven.
16 Papers that have insufficient amount of information
17 to draw more definitive conclusions, that level of
18 uncertainty is highlighted in the paper.

19 Q. Dr. Biederman, I'm only asking you about
20 the bipolar papers with respect to the use of
21 Janssen products with respect to this question. Do
22 you believe that those papers that you've published
23 have met your definition and your standards of
24 scientific rigor?

25 A. My papers described the facts that I
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 388

1 noticed and whatever limitations the paper had, they
2 were appropriately noted. I published a paper on
3 the treatment of children with bipolar illness with
4 risperidone. I recognized it was an open study. My
5 paper, my results were fully replicated ten years
6 later in a controlled clinical trial that is the
7 most rigorous type of evidence that you can provide
8 the field.

9 MR. FIBICH: I object to that as being
10 nonresponsive.

11 BY MR. FIBICH:

12 Q. The papers that you publish have
13 disclosures as to any things that may influence
14 their conclusions, such as whether it's open label
15 or randomized. Correct?

16 A. Correct.

17 Q. But other than the limitations that you
18 yourself put in your papers, do you believe that
19 they have met your standards of scientific rigor?

20 A. They met my standards of what I was able
21 to do at that point in time, yes.

22 Q. And as one of the leading proponents in
23 the world of the disease of pediatric bipolar
24 disease, do you feel that you have an input with
25 respect to the people that read your studies?

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 389

1 MR. SPIVACK: Objection, vague, calls for
2 speculation.

3 A. Could you -- ? I'm not sure what are you
4 asking me? Can you reframe the question?

5 Q. Thank you. Doctor, if I ask you any other
6 questions that you don't understand, please feel
7 free to ask me to rephrase it so that there's no
8 miscommunication between the information that I'm
9 seeking and the answer that you're giving. Okay?

10 A. Sure.

11 Q. My question to you is: Do you believe
12 that scientific papers, not just yours but all
13 scientific papers, influence doctors in how they use
14 that information insofar as their prescriptive
15 behaviors?

16 A. Knowledge is not necessarily influence.
17 The papers are given for people to evaluate. So if
18 I have a piece of information on any subject and
19 people read that information, it is something that
20 they can keep in mind in their body of knowledge.
21 Every day medicine has advances in ideas and not all
22 of them are great, so doctors and clinicians are
23 exposed to new ideas, and it is for them to evaluate
24 if the information is useful for their practice.

25 MR. FIBICH: Object as being
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 390

1 nonresponsive.

2 BY MR. FIBICH:

3 Q. Do you read the American Journal of
4 Psychiatry?

5 A. I do.

6 Q. Is this a prominent journal in the field
7 of psychiatry?

8 A. It is.

9 Q. Are you familiar with the editorial of
10 Dr. Kevin Hill regarding conflict of interest?

11 A. I don't remember.

12 Q. I am going to mark this later but let me
13 just read you one sentence from it. It says
14 "Surveys of physicians," and this is from the
15 American Journal of Psychiatry, April 2006, "Surveys
16 of physicians find that over 90 percent of us look
17 to original articles in medical journals as our most
18 preferred source of new information for help in
19 treating patients."

20 Assume I read that correctly. Do you
21 agree with that statement?

22 A. If he says it, it sounds correct.

23 Q. So 90 percent of the doctors get their
24 information for help in treating patients from
25 medical journals?

Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 391

1 MR. SPIVACK: Objection, calls for
2 speculation, misstates the document.
3 A. Medical journals provide a very large
4 amount of information. The doctors read the
5 information and evaluate the quality of the report,
6 the usefulness, and make decisions accordingly.
7 Q. And if they evaluate your reports on
8 pediatric bipolar, they ought to be able to draw
9 firm conclusions. Correct?
10 MR. SPIVACK: Objection, calls for
11 speculation.
12 A. When they read my papers, I provide data;
13 I discuss limitations. It's descriptive; it's not
14 ideologic.
15 MR. FIBICH: Object, nonresponsive.
16 BY MR. FIBICH:
17 Q. Let's go back to your investigation at
18 Harvard. You were not precise and exact in the
19 information that you provided Massachusetts General
20 about the income you received from pharmaceutical
21 companies, were you?
22 A. At the time that I provided information,
23 I believed that I was precise and correct.
24 Q. So you just made a mistake.
25 A. I made a mistake on a few occasions.
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 392

1 Q. Was there a transcript or a draft report
2 that you've seen? I think you said there was.
3 A. Yes.
4 Q. Were there findings in that draft report?
5 A. There were findings in that report.
6 Q. Were the findings against you termed
7 deliberate and reckless disregard for the policies
8 of Massachusetts General?
9 A. In the first draft those words were
10 included. I disputed those, and in the next draft
11 they were eliminated.
12 Q. So how many drafts have there been?
13 A. Two.
14 Q. And then we're still looking at a final
15 draft. Right?
16 A. That's correct.
17 Q. Well, what happened between the first
18 draft and the second draft to cause the committee to
19 take out that terminology that you just testified
20 was taken out?
21 A. I disputed that I did not do anything
22 deliberate or reckless, and they agreed with me.
23 Q. Was there a transcript of these
24 proceedings?
25 MR. SPIVACK: Objection, vague.
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 393

1 BY MR. FIBICH:
2 Q. Was there a court reporter or a tape
3 recording of these proceedings where we could look
4 to see what was exactly said and the questions that
5 were asked, to your knowledge?
6 MR. SPIVACK: Objection, vague as to time.
7 A. This was a non-court proceeding
8 environment.
9 Q. I understand it was non-court. Let me
10 rephrase my question. How many times have you
11 appeared before the committee?
12 A. Once.
13 Q. When was the first time? Or what time was
14 that?
15 A. The single time was in July of 2008.
16 Q. And at the time that you appeared before
17 the committee, was there any means to your knowledge
18 that recorded in any form the testimony that was
19 given to the committee?
20 A. I think that people took notes.
21 Q. Other than taking notes, was there a tape
22 recorder or any recording device or court reporter
23 or any other means other than taking notes of the
24 testimony that was given?
25 A. I am not aware of anything like that.
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Joseph Biederman
February 27, 2009

Page 394

1 Q. Let me show you what we've marked as
2 Biederman 19. If you would, sir, turn to the second
3 page. This appears to be an e-mail from you to Mike
4 and Jerry. Is that correct?
5 A. Mm-hmm.
6 Q. Does that mean "yes"?
7 A. Could you repeat the question? Sorry.
8 I cannot read and listen to you. Could you repeat
9 your question?
10 Q. I'm sorry. Who is Mike and Jerry?
11 A. Mike is the president of Newton-Wellesley
12 Hospital and Mike Jellinek is the chief of child
13 psychiatry at Mass. General.
14 Q. Tell me who Mike is again. I'm not --
15 A. Mike Jellinek, J-e-l-l-i-n-e-k.
16 Q. And he is what?
17 A. He is the president of Newton-Wellesley
18 Hospital and the chief of child psychiatry at
19 Mass. General. And Jerry is Jerry Rosenbaum, the
20 chairman of psychiatry.
21 Q. It says on the -- Go ahead and read it.
22 A. (Pause) Yes.
23 Q. In this, you reference that there were
24 five issues that they had identified. What were
25 those five issues?
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Joseph Biederman
February 27, 2009

Page 395

1 A. There was a -- This is one of them, the
2 \$7,000 exceedance because of some misunderstanding
3 about the presence or absence of a conflict. There
4 was a thousand dollars in one year from Lilly in
5 exceedance. There was another thousand dollars in
6 2006 for an exceedance which are considered
7 technical violations and there were a few others,
8 two others of a few thousand dollars. The total
9 amount of those five instances with five different
10 pharmaceutical companies, only one from Janssen, did
11 not exceed 26, 26 or 27 thousand dollars over eight
12 years.

13 Q. And based upon what occurred at that
14 hearing, they called your violations deliberate and
15 reckless disregard?

16 MR. SPIVACK: Objection, misstates the
17 testimony.

18 A. They --

19 Q. Initially

20 A. Initially. I argued that none of them
21 were deliberate or reckless disregard, and in the
22 new draft those epithets were eliminated.

23 Q. Why are they considering the Stanley
24 Foundation contributions to go against the limit
25 that was imposed upon you since Stanley Foundation
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 397

1 very different and the rules of engagement re
2 conflict of interest were hardly clear." Correct?

3 A. Correct.

4 Q. "At best this is a legitimate mistake but
5 not a deliberate act, as they conclude." Correct?

6 A. That's correct.

7 Q. And why are you sending your side of
8 things to Mike and Jerry?

9 A. Because they are my superiors.

10 Q. And then subsequent to this e-mail you
11 went before the committee and persuaded them that
12 your actions were not deliberate or reckless
13 disregard. Correct?

14 A. I sent a letter disputing the argument of
15 reckless disregard and deliberate.

16 Q. And you say there has been now a
17 subsequent draft that takes that terminology out?

18 A. Yes.

19 Q. And we're now awaiting a final draft?

20 A. Yes.

21 Q. So we don't know as we sit here today what
22 the final conclusions of the committee are going to
23 be. Correct?

24 A. We do not know.

25 MR. FIBICH: Let's mark this.
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Joseph Biederman
February 27, 2009

Page 396

1 is not a pharmaceutical company?

2 A. Well, that was my understanding. Because
3 the study included risperidone and risperidone is
4 made by Janssen. That kind of leap was not clear to
5 me at the time. I would never have exceeded the
6 minimums if I were to have suspected. But because
7 the grant was from the Stanley Foundation and not
8 from Janssen, but I was testing risperidone, Zyprexa
9 and Seroquel, so they thought that that should have
10 been a violation.

11 Q. This one says "This situation occurred in
12 2001 when the COI environment," COI, is that
13 conflict of interest?

14 A. Conflict of interest.

15 Q. "Was very different and rules of
16 engagement for conflict of commitment were hardly
17 clear "

18 A. This is conflict of interest.

19 MR. SPIVACK: Objection. Objection,
20 misstates the record. You might want to read that
21 again.

22 MR. FIBICH: Okay.

23 BY MR. FIBICH:

24 Q. "This situation occurred in 2001 when the
25 COI" -- conflict-of-interest -- "environment was
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Joseph Biederman
February 27, 2009

Page 398

1 (Biederman Deposition Exhibit 21 marked
2 for identification.)

3 BY MR. FIBICH:

4 Q. Dr. Biederman, let me show you what we've
5 marked as Biederman 21. Can you identify this?

6 A. Yes.

7 Q. What is it?

8 A. It's an analysis that we conducted.

9 Excuse me. Let me just read the paper before I tell
10 you.

11 Q. We've only got a few minutes left on the
12 tape, so why don't you read it; we'll just go ahead
13 and take a break.

14 A. I'm ready.

15 Yes, this is an analysis that we conducted
16 on Dr. Aman's study in the American Journal of
17 Psychiatry and that examined the effects of
18 risperidone in children with conduct disorder and
19 mental retardation.

20 Q. And you were the lead author on this
21 study?

22 A. Yes.

23 Q. Were you the lead investigator?

24 A. Yes.

25 Q. And the other individuals that are listed
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<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 399</p> <p>1 with you, Mr. Mick, Mr. Faraone, Ms. Wozniak, 2 Mr. Spencer -- 3 A. Dr. Spencer. They are all doctors. 4 Q. Dr. Spencer. Excuse me, all doctors. 5 They're all Mass. General doctors? 6 A. With the exception of Steve Faraone, who 7 works, used to be at Mass. General, now he's in 8 Stony Brook -- Where is he? He's in Albany, State 9 University of New York at Albany; and Gahan Pandina 10 is from Janssen. 11 Q. That's G-a-h-a-n P-a-n-d-i-n-a. He is a 12 Ph.D., not a medical doctor. Correct? 13 A. He's a Ph.D. psychologist, yes. 14 Q. And he was one of the authors on this 15 study? 16 A. Yes. 17 Q. And he's from Janssen? 18 A. He is from Janssen. 19 Q. And Faraone is also not a medical doctor 20 Correct? 21 A. He is a Ph.D. psychologist. 22 Q. And at the time he was with Mass. General? 23 A. Yes. 24 Q. Now, when you listed earlier the leading 25 experts in the world, the short list of which you Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 400</p> <p>1 consider yourself one, you listed Dr. Wozniak and 2 Dr. Spencer. 3 A. No, I did not list -- Dr. Spencer is in 4 pediatric bipolar illness. I listed Dr. Gabrielle 5 Carlson, I listed Dr. Barbara Geller, Robert 6 Findling, myself as the lead, and Dr. Wozniak. 7 Q. And the ones that you listed as being in 8 this small group of leading experts, how many of 9 those are at Mass. General? 10 A. Dr. Wozniak and myself. 11 Q. And the other doctors are where? Geller 12 is where? 13 A. Geller is in St. Louis at Wash.U. 14 Gabrielle Carlson is at Stony Brook. Robert 15 Findling I believe is in Cincinnati. Different 16 centers. 17 MR. FIBICH: We've got the tape running 18 out. Let's take a break. 19 MR. SPIVACK: Okay. 20 THE VIDEOGRAPHER: The time is 10:35. 21 We're off the record. 22 (Short recess taken.) 23 THE VIDEOGRAPHER: We're back on the 24 record. This is tape number 2. The time is ten 25 minutes to 11:00. Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 401</p> <p>1 BY MR. FIBICH: 2 Q. Dr. Biederman, you have an association 3 with virtually every pharmaceutical company doing 4 business in the United States today, do you not? 5 MR. SPIVACK: Objection, argumentative. 6 A. I have an association with pharmaceutical 7 companies doing work on ADHD molecules or drugs and 8 pediatric bipolar medicines. 9 Q. So is the answer to my question yes? 10 A. I have an association with many but not 11 all. 12 Q. Let's go to page 798 of your -- 13 A. 798? Yes. 14 Q. Your publication in Clinical Therapeutics 15 and it lists on the back certain acknowledgments. 16 And why do you list these acknowledgments, sir? 17 A. It is actually disclosures, not 18 acknowledgment. Different journals use different 19 words for that. 20 Q. This one uses "acknowledgment." Right? 21 A. I understand. But I usually submit when 22 I submit a paper, I send all my associations with 23 pharmaceutical companies as disclosures. 24 Q. So at least with respect to 2006 these 25 were the pharmaceutical companies that you Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 402</p> <p>1 acknowledged having some relationship with. Right? 2 A. Yes. 3 Q. If you would, sir, follow along with me 4 and make sure that I'm accurate. 5 A. Mm-hmm. 6 Q. You received research support from 7 Supernus Pharmaceuticals. Did I say that correctly? 8 A. Yes. 9 Q. You received, and that was formerly Shire 10 Laboratories. You received support from Eli Lilly 11 and Company. Correct? 12 A. Yes. 13 Q. Pfizer, Incorporated. Correct? 14 A. Correct. 15 Q. McNeil Consumer & Specialty 16 Pharmaceuticals. Correct? 17 A. Correct. 18 Q. Is that now a part of Johnson & Johnson? 19 A. Yes. 20 Q. Abbott Laboratories. Correct? 21 A. Correct. 22 Q. Bristol-Myers Squibb. Correct? 23 A. Correct. 24 Q. New River Pharmaceuticals. Correct? 25 A. Correct. Stratos Legal Services 800-971-1127</p>

<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 403</p> <p>1 Q. Cephalon, Incorporated. Correct? 2 A. Correct. 3 Q. Janssen Pharmaceutical Products Correct? 4 A. Correct. 5 Q. NeuroSearch A/S. Correct? 6 A. Correct. 7 Q. Stanley Medical Research Institute. 8 That's not a pharmaceutical company. Correct? 9 A. No 10 Q. Novartis Pharmaceuticals? 11 A. Correct. 12 Q. The Lilly Foundation Correct? 13 A. Correct. 14 Q. The Prechter Foundation, as well as the 15 National Institute of Mental Health. 16 A. Yes 17 Q. And the National Institute of Child Health 18 and Human Development? 19 A. Correct. 20 Q. And the National Institute of Drug Abuse. 21 And then you were on the following speakers' 22 bureaus: Shire Laboratories, Eli Lilly and Company, 23 McNeil Consumer & Specialty Pharmaceuticals, UCB 24 Pharma, Novartis Pharmaceuticals, and you're a 25 member of the advisory board of Eli Lilly and Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 404</p> <p>1 Company, Shire Laboratories, McNeil Consumer & 2 Specialty Pharmaceuticals, Janssen Pharmaceutical 3 Products, Novartis Pharmaceuticals, and Cephalon, 4 Inc. Correct? 5 A. Yes. 6 Q. Now, as a result of those associations, 7 you make a lot of money, do you not? 8 A. I make money, yes, and -- 9 Q. As a result of your associations with the 10 pharmaceutical companies that you have listed in 11 this particular paper? 12 A. My activities with pharmaceutical 13 companies as an expert consultant or speaker are 14 professional activities and I make money, as you 15 make money doing what you are doing today with me. 16 Q. I don't make money for pharmaceutical 17 companies; I try to take their money. 18 A. Correct, I understand. But it will come 19 to you. 20 Q. The what? 21 A. No, nothing. Yes, what is your question? 22 Q. My question is, you make a lot of money 23 working for pharmaceutical companies? 24 A. I make money. "A lot" is -- 25 Q. A relative term? Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 405</p> <p>1 A. Yes. 2 Q. As a matter of fact, you make more than 3 your salary working for these pharmaceutical 4 companies do you not? 5 A. No. 6 Q. You make as much working for 7 pharmaceutical companies as you do your salary at 8 Mass. General. Right? 9 A. No, not correct. I think that my income 10 from pharmaceuticals is not larger than my salary. 11 My outside activities is about the size of my 12 salary, but not only from pharmaceuticals. My 13 outside income comes from pharmaceutical and non- 14 pharmaceutical sources. 15 Q. What other sources do you have income from 16 that's not nonpharmaceutical? And I'm not talking 17 about investments, I'm talking about -- 18 A. No, I don't have any investments in stock 19 of any pharmaceutical. Things like consultation 20 with lawyers, consultation with investment bankers, 21 consultation or CME activities, congresses, if I 22 speak in a congress, I get an honorarium. Things of 23 that type. 24 Q. So you're an expert witness for lawyers? 25 A. I am not an expert witness, purely Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 406</p> <p>1 consultant on legal matters sometimes pertaining to 2 cases of my practice. I don't do any forensic work. 3 Q. And when you're dealing with investment 4 bankers, are you dealing with pharmaceutical 5 products? 6 A. The investment bankers are interested to 7 know about the diseases that I treat and if there is 8 potential for a particular compound or how the 9 market is shaping up. But the consultation is to 10 investment bankers. 11 Q. And you're paid for those consultations? 12 A. I am paid for those consultations. 13 Q. What investment bankers have you consulted 14 with and what products? 15 A. There is not a specific product. I 16 consulted to agencies like Deutsche Bank, things of 17 that type, and there are other kind of investment 18 organizations that do this type of analysis of what 19 the market is and where it's going and so on and so 20 forth. 21 Q. What are you paid for that work, sir? 22 A. Depending on my time. I charge by time. 23 Q. And you charge by the hour? 24 A. By the hour. 25 Q. And I saw where several years ago in some Stratos Legal Services 800-971-1127</p>

<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 407</p> <p>1 papers you were charging \$550 an hour? 2 A. That sounds correct. 3 Q. What are you charging today? 4 A. Pretty much the same. 5 Q. Does that mean the same? 6 A. The same. 7 MR. SPIVACK: Objection, vague, I think, 8 when you say what are you charging today. 9 BY MR. FIBICH: 10 Q. Currently for consulting work, if someone 11 wanted to -- 12 A. Yes, \$550. 13 Q. And you understand that your ability to 14 earn these moneys from these pharmaceutical 15 companies is dependent upon you being favorable to 16 their products? 17 A. Being what? 18 Q. Favorable to their products. 19 A. Not necessarily. 20 Q. You don't think so? 21 A. No, I don't think so. 22 Q. Now, I also noticed in the reference part 23 of this paper -- And what are references in a 24 pharmaceutical paper? 25 A. This is a scientific paper, not a Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 408</p> <p>1 pharmaceutical paper. 2 Q. This is a scientific paper regarding a 3 pharmaceutical product. Right? 4 A. This is a -- Yes, regarding a condition 5 for which the pharmaceutical product was used. But 6 a major purpose of this paper is to point out that 7 children with a conduct disorder have a lot of 8 affective symptoms that benefited from the same 9 treatment that was shown to benefit the condition 10 that the investigators initially studied. 11 Q. The references in the back are used for 12 what purpose? 13 A. The references is to support an assertion. 14 So if I say depression affects 10 percent of the 15 population, I need to put a source of where I got 16 that information. 17 Q. And I noticed that in the reference 18 section that there are nineteen references. Do you 19 see that? 20 A. Let me see. Where are the references? 21 Q. Should be page 800. 22 A. Yes, I see it. 23 Q. There's nineteen references? 24 A. Nineteen references 25 Q. And eight of those references are to you, Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 409</p> <p>1 are they not? 2 A. Yes. 3 Q. Number 1, 7, 8, 14, 15, 17, 18 and 19. 4 A. Mm-hmm. 5 Q. Does that mean "yes"? 6 A. Yes. 7 Q. So you reference yourself a lot in an 8 effort to give this paper credibility. Correct? 9 MR. SPIVACK: Objection, argumentative. 10 A. I reference myself because I did the line 11 of work that the papers that I am referencing 12 alludes to. In other words, in science it's an 13 incremental process. It's like a big puzzle. So I 14 did the work up to that point and the references of 15 the work indicate that this type of activity was 16 preceded by other activities. 17 Q. Let's go to page 798, if you would, sir. 18 A. Yes. 19 Q. And the paragraph following this chart, 20 the first full paragraph that begins "Whether." Do 21 you see that, sir? 22 A. Mm-hmm. 23 Q. It says "Whether risperidone is effective 24 in treating affective symptoms outside the context 25 of comorbid DBD," and tell the jury what DBD is. Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 410</p> <p>1 A. It's disruptive behavior disorders. 2 Q. That's not bipolar disease. Correct? 3 A. No. 4 Q. "Whether risperidone is effective in 5 treating affective symptoms outside the context of 6 comorbid deceptive behavior" -- 7 A. Disruptive behavior disorders. 8 Q. -- "disruptive behavior disorders awaits 9 confirmation in future randomized clinical trials." 10 Do you see that? 11 A. Mm-hmm. 12 Q. And by randomized clinical trial, you mean 13 a double-blind compared to placebo randomized 14 prospective clinical trial. Correct? 15 A. Correct. Our study was a post hoc 16 analysis of a randomized clinical trial, but that 17 was not the purpose of the original study. 18 Q. But you're saying for a determination to 19 be made as to whether risperidone is effective with 20 respect to this particular population, you need a 21 gold standard clinical trial. Correct? 22 A. That's correct. That was done. 23 Q. You didn't -- Excuse me. Go ahead. 24 A. The randomized clinical trial that I 25 advocated to be done in bipolar illness was done. Stratos Legal Services 800-971-1127</p>

Joseph Biederman
February 27, 2009

Page 411

1 Q. You didn't do it, did you?
2 A. No, but it was done.
3 Q. I'm not asking you whether it was done
4 I'm asking you, you didn't do it, did you?
5 A. I didn't do it.
6 Q. Why is it that when pharmaceutical
7 companies want the gold standard, they go to
8 somebody else as opposed to you?
9 MR. SPIVACK: Objection, argumentative
10 A. They come to many. The request from the
11 Food and Drug Administration is to have a small
12 number of subjects from many, many sites.
13 Q. Do you lack credibility with the Food and
14 Drug Administration?
15 A. Well, I could not participate for
16 technical reasons. I was not available at that
17 time. I don't have the resources to participate in
18 this study. I would have been very happy to
19 participate if I could.
20 Q. You weren't asked to participate, were
21 you?
22 A. I was asked to participate. I couldn't.
23 Q. Tell me why you couldn't.
24 A. I was very busy with other studies. I did
25 not have the resources to deploy.
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Joseph Biederman
February 27, 2009

Page 412

1 Q. Sir, are you telling me that you turned it
2 down because you didn't have time, or was it turned
3 down because the institutional review board at
4 Harvard would not let you do it?
5 A. No. I don't recall exactly the details of
6 what was the particular issue, but I did not submit.
7 The institutional review board gets involved only
8 after I submit the application, not before. So I
9 believe I did not participate in this study.
10 These studies sometimes require recruiting
11 at high velocity and I am not always able to
12 provide. It's a lot of work for me to participate
13 in these multi-site studies. They usually have a
14 narrow window, so it's a huge amount of work, and my
15 judgment may have been that I would not be able to
16 recruit at the time that the study was interested in
17 recruiting, so they have to use other sites that
18 have more availability to recruit at the speed that
19 they wanted. That's my recollection to the best of
20 my recollection.
21 MR. FIBICH: Objection, nonresponsive.
22 BY MR. FIBICH:
23 Q. I'm asking you a very specific question.
24 Did you make application to do a double-blind
25 clinical trial as suggested in this paper to
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Joseph Biederman
February 27, 2009

Page 413

1 Harvard?
2 A. No.
3 Q. You did not?
4 A. No.
5 Q. And you're telling me the institutional
6 review board at Harvard did not deny that, a request
7 for Harvard or Mass. General or somebody at
8 Mass. General to do this study?
9 A. I can only do studies if I receive
10 funding. I did not receive funding to do a double-
11 blind study so I did not submit, to the best of my
12 knowledge, I did not submit any application to the
13 IRB. IRB approves studies all the time.
14 Q. Well, Doctor, here's what my problem is.
15 Maybe you can help me out and help our jury out.
16 You have told me what an authority you are in the
17 field of these behaviors. Right?
18 A. Mm-hmm.
19 Q. World-renowned. Right?
20 A. Mm-hmm.
21 Q. Leading authority in the world, one of the
22 leading authorities in the world. Right?
23 A. Yes.
24 Q. There may be others that are equal to you
25 but there's nobody that knows more about this field
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 414

1 than you do?
2 A. I do not know that that is true. But in
3 any event...
4 Q. Okay. But, in any event, you do studies
5 in this area that are all open label. Correct?
6 A. I do some double-blind studies too.
7 Q. The studies that you have done with
8 respect to --
9 A. My studies, they were open label, yes.
10 Q. And that creates a potential bias in these
11 studies, does it not?
12 A. The results of my studies have been fully
13 replicated in independent large-scale double-blind
14 randomized trials. In fact, the study of Zyprexa
15 replicated my open label study completely; the study
16 of risperidone replicated my initial open label
17 studies completely; and the study of Abilify, to the
18 best of my knowledge, fully replicated what I
19 reported in open label studies.
20 MR. FIBICH: Objection, nonresponsive.
21 BY MR. FIBICH:
22 Q. The studies you did with respect to
23 pediatric bipolar disease and risperidone were all
24 open label. Correct?
25 A. Yes.
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Joseph Biederman
February 27, 2009

Page 415

1 Q. And that has a potential for bias, does it
2 not?
3 A. That has a limitation.
4 Q. And there were additional limitations in
5 all the studies you did with respect to risperidone
6 and bipolar mania in children, that being small
7 sample size as well. Correct?
8 A. Small sample size were pilot studies, were
9 not definitive studies, were proof-of-concept
10 studies where there is a reason to pursue a large
11 randomized clinical trial. If an open study shows
12 absence of activity, there is no point in doing a
13 double-blind study.
14 Q. My question to you, sir, is if you have
15 the knowledge base that you claim to have and you've
16 done these studies that have limitations, why don't
17 you do one that you can call the gold standard?
18 MR. SPIVACK: Objection, misstates the
19 testimony, calls for speculation, argumentative.
20 A. The studies that will be definitive, there
21 are registration studies that have to be done by the
22 pharmaceutical company. I encouraged Janssen to
23 pursue and run a large-scale multi-site randomized
24 clinical trial. Those are the gold standard of the
25 field, so...

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Joseph Biederman
February 27, 2009

Page 416

1 Q. But what I don't understand and I want to
2 be clear on, and this is the last time I'm going to
3 ask it, you didn't do it because you didn't have
4 enough time. Correct?
5 A. I did not do it to the best of my
6 recollection because the window that they wanted to
7 recruit was too tight for me and I could not stop
8 doing other activities and just do this.
9 Q. Why do you keep telling me to the best of
10 your recollection? Isn't everything you're telling
11 me today to the best of your recollection?
12 A. Yes
13 MR. SPIVACK: Objection, argumentative.
14 A. I do many studies. I run a very large
15 laboratory. The majority of my studies have nothing
16 to do with pharmaceuticals and I cannot recall every
17 single detail of every study. It's impossible for
18 me to keep it in my active memory.
19 Q. What is Dove Publishing Company?
20 A. Say again?
21 Q. Dove Publishing
22 A. I have no idea.
23 Q. Do you not have a company called Dove
24 Publishing?
25 A. I don't have any companies.

Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 417

1 Q. On a paper entitled Risperidone Treatment
2 for ADHD in Children and Adolescents With Bipolar
3 Disorder. This is your paper, is it not?
4 A. Mm-hmm, yes.
5 Q. Down here it says 2008, Biederman et al.,
6 publisher and licensee, Dove Medical Press, Ltd. Is
7 that not your company?
8 A. No. I don't have any companies.
9 Q. Do you know what Dove Medical Press, Ltd.
10 is?
11 A. I have no clue.
12 Q. Do you know who Excerpta Medica is?
13 A. I believe it's a CME provider.
14 Q. Do you know what else they do?
15 A. No.
16 Q. What did they have to do with the paper
17 that we've been talking about, that is, your report
18 on risperidone for the treatment of affective
19 symptoms in children with disruptive behavior
20 disorder?
21 MR. SPIVACK: Objection, calls for
22 speculation.
23 A. I do not know.
24 Q. Do you know that they are listed in this
25 paper?

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 418

1 A. If they are, they are listed
2 Q. Well, I'm asking you if you know.
3 A. I do not know.
4 Q. Okay, look at Conclusions. You see at the
5 bottom?
6 A. Yes.
7 Q. It says "Accepted for publication,
8 copyright Excerpta Medica" --
9 A. Wait. Where are you reading? Sorry.
10 Q. At the bottom of the Conclusions
11 paragraph.
12 A. After the acknowledgment, the conclusion
13 says "The results of this post hoc analysis of
14 affective symptoms using data from a previously
15 published" --
16 Q. The bottom of that, sir.
17 A. Says "suggest that risperidone was
18 effective in treating the factors of explosive
19 irritability; agitated, expansive, grandiose; and
20 depression."
21 Q. Is that the bottom of the paragraph?
22 A. Of the Conclusions? Yes.
23 Q. So the sentence that follows that isn't at
24 the bottom of the paragraph, to your knowledge?
25 A. As I see it here. Are you reading

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Joseph Biederman
February 27, 2009

Page 419

1 somewhere else?
2 Q. Let me see it. My fault. The other
3 Conclusions, on the first page. It says "copyright
4 2006 Excerpta Medica, Incorporated." Do you see
5 that?
6 A. Yes.
7 Q. And then it goes down and says "copyright
8 Excerpta Medica, Incorporated."
9 A. Mm-hmm.
10 Q. What did Excerpta Medica have to do with
11 this paper, to your knowledge?
12 A. We submitted the paper to Clinical
13 Therapeutics, not Excerpta Medica. I think that
14 Clinical Therapeutics belongs to Excerpta Medica, I
15 guess. But our transactions --
16 MR. SPIVACK: Don't speculate.
17 THE WITNESS: Okay.
18 BY MR. FIBICH:
19 Q. Clinical Therapeutics belongs to Excerpta
20 Medica. Is that what you said?
21 A. I do not know.
22 Q. Why do you say that?
23 A. I guessed.
24 Q. You just pulled that out of the air?
25 A. Well, it's listed here.
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Joseph Biederman
February 27, 2009

Page 420

1 MR. SPIVACK: Objection, argumentative.
2 A. I don't know. I do not know.
3 Q. You don't know?
4 A. No.
5 Q. Well, why did you say it?
6 MR. SPIVACK: Objection, asked and
7 answered, argumentative.
8 BY MR. FIBICH:
9 Q. Are you just pulling your answers out of
10 the air today?
11 MR. SPIVACK: Objection, argumentative.
12 A. No.
13 Q. What is Excerpta Medica?
14 MR. SPIVACK: Objection, asked and
15 answered.
16 A. I believe it's a medical education
17 company.
18 Q. That's all you know about it?
19 A. Yeah.
20 Q. You don't know that they're a company that
21 ghostwrites papers?
22 MR. SPIVACK: Objection, calls for
23 speculation, argumentative, misstates the testimony.
24 A. No.
25 MR. SPIVACK: Lacks foundation.
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Joseph Biederman
February 27, 2009

Page 421

1 BY MR. FIBICH:
2 Q. Do you know what the responsibilities and
3 duties are of a company by the name of Excerpta
4 Medica?
5 A. No.
6 Q. Have you ever had communications from the
7 company Excerpta Medica?
8 A. I don't recall.
9 Q. So you might have, you just don't know?
10 A. I don't recall.
11 Q. So you might have, you just don't know?
12 A. I don't recall.
13 MR. SPIVACK: Objection, asked and
14 answered.
15 BY MR. FIBICH:
16 Q. Do you know that Excerpta Medica owns
17 journals that are thought to be scientific journals?
18 MR. SPIVACK: Objection --
19 A. I have no idea.
20 MR. SPIVACK: -- lacks foundation.
21 A. I do not know who they are.
22 Q. Have you ever dealt with Excerpta Medica?
23 A. I don't remember.
24 Q. You don't remember?
25 A. (Witness nodded.)
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Joseph Biederman
February 27, 2009

Page 422

1 Q. Is that your testimony?
2 A. Yes.
3 MR. SPIVACK: Objection, asked and
4 answered.
5 BY MR. FIBICH:
6 Q. Has Excerpta Medica ever written papers
7 for you?
8 A. No.
9 Q. Have they ever modified papers for you?
10 A. All my papers were written by me.
11 Q. It's not my question, sir. My question
12 was, has anybody at Excerpta Medica modified any
13 paper that you've written?
14 MR. SPIVACK: Objection, asked and
15 answered.
16 A. Not that I know.
17 MR. SPIVACK: Excuse me. Let me
18 interject, please.
19 THE WITNESS: Okay, sorry.
20 BY MR. FIBICH:
21 Q. You say you have a good memory. Correct?
22 MR. SPIVACK: Objection, asked and
23 answered.
24 BY MR. FIBICH:
25 Q. Are you going to answer that question?
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Joseph Biederman
February 27, 2009

Page 423

1 A. I have decent memory.
 2 Q. Decent? I thought it was great this
 3 morning. Has it diminished as we've been sitting
 4 here?
 5 MR SPIVACK: Objection, argumentative
 6 A. I think so. I'm tired.
 7 Q. Are you too tired to go on?
 8 A. No.
 9 Q. Well, if you're too tired to answer my
 10 questions because your memory has diminished, let me
 11 know, because I want your best answers
 12 A. I will let you know
 13 Q. You understand today is an important
 14 proceeding, do you not?
 15 A. I do.
 16 Q. Even though we're here in the informality
 17 of Mr. Spivack's office and we're doing this with
 18 professional courtesies to each other, today is very
 19 important. You understand that?
 20 A. I understand it.
 21 Q. Who did you submit the paper to at
 22 Clinical Therapeutics? Or, strike that. Let me ask
 23 another question. When you prepare a paper and it
 24 is submitted to a scientific journal such as
 25 Clinical Therapeutics, do you personally direct that
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Joseph Biederman
February 27, 2009

Page 424

1
 2
 3 Q. Do you do a cover letter? What is the
 4 process by which it's submitted?
 5 A. Every journal has a procedure for
 6 submission of papers and we follow those procedures.
 7 Q. Okay. The papers that you have written
 8 with respect to risperidone or bipolar disease, were
 9 those all submitted directly to scientific journals
 10 or were they submitted to some third party that
 11 would then try to get them published in scientific
 12 journals?
 13 A. We submit the papers directly to the
 14 journal.
 15 Q. So you've never submitted a paper to a
 16 different party that would then try to get them
 17 published in a scientific journal?
 18 MR. SPIVACK: Objection, asked and
 19 answered.
 20 MR. FIBICH: No, it's a different
 21 question.
 22 MR. SPIVACK: Same objection.
 23 A. I submit the papers directly to the
 24 journal.
 25 Q. You have never submitted a paper for
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Joseph Biederman
February 27, 2009

Page 425

1 publication to any third party for submission to a
 2 journal?
 3 MR. SPIVACK: Objection, asked and
 4 answered.
 5 BY MR. FIBICH:
 6 Q. Is that your testimony? I want to make
 7 sure --
 8 A. My testimony is that to the best of my
 9 recollection my papers are submitted directly to the
 10 journal.
 11 (Biederman Deposition Exhibit 22 marked
 12 for identification.)
 13 BY MR. FIBICH:
 14 Q. Dr. Biederman, if you would review a
 15 series of e-mails that we've marked as 22 (Pause)
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Joseph Biederman
February 27, 2009

Page 426

1 that was published in Clinical Therapeutics that
 2 we've been talking about. Correct?
 3 MR. SPIVACK: Objection, calls for
 4 speculation, asked and answered.
 5 BY MR. FIBICH:
 6 Q. Let me ask you this: Can you determine
 7 whether this poster presentation applies to the
 8 report that you had published in Clinical
 9 Therapeutics? Read it and tell me whether you can
 10 do that.
 11 A. (Pause) It appears to be the same
 12 dataset.
 13 Q. It's the same dataset. And will you agree
 14 with me that this is a poster presentation arising
 15 from the dataset that was the basis of your paper
 16 published in the Clinical Therapeutics journal?
 17 A. It seems to be.
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<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 427</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 428</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">MR. SPIVACK: Objection, calls for speculation.</p> <p style="text-align: center;">A. Posters requires a production So you have a limited amount of space in a poster for a scientific meeting to put your tables, your figures You have much less space than 10 or 15 written pages in a journal, so the production of the poster requires an investment of time on how to arrange. So Excerpta Medica may have been asked to put it together as a poster and they had some quality control issues that the numbers did not match or something like that.</p> <p style="text-align: center;">Q. So Excerpta Medica is preparing drafts of Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 429</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>things that are later disseminated in some form to physicians. Correct?</p> <p style="text-align: center;">MR SPIVACK: Objection, vague, misstates the testimony.</p> <p style="text-align: center;">A. This is a poster based on analysis of data that we conducted The data that we conducted were submitted for peer-review evaluation to a scientific journal that's called Clinical Therapeutics. In addition to having the paper in a journal, this information was sent as a scientific poster that is also peer-reviewed to the American Academy of Child and Adolescent Psychiatry.</p> <p style="text-align: center;">During that process Excerpta Medica appears from these e-mails to have been involved in the production of the poster, not in our analysis. The analysis was conducted, the data are factual, so the poster is just a production that requires some artistic abilities, takes time, you need to have the right colors to be presentable, et cetera, et cetera. So they were helping in the technical aspects of preparing a poster for a scientific meeting.</p> <p style="text-align: center;">Q So when you testified you didn't remember Excerpta Medica preparing any drafts of scientific matters for you, that was inaccurate?</p> <p style="text-align: center;">Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 430</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">MR. SPIVACK: Objection, misstates the testimony.</p> <p style="text-align: center;">BY MR. FIBICH:</p> <p style="text-align: center;">Q. Correct?</p> <p style="text-align: center;">A. I testified that I did not remember.</p> <p style="text-align: center;">Q. And now you remember. Correct?</p> <p style="text-align: center;">A. It's written in this e-mail, because you showed me the e-mail. It's not that it comes flying from my head.</p> <p style="text-align: center;">Q. And now you remember -- Excuse me. And now you remember that Excerpta Medica prepared a poster that contained your name on it for presentation at a medical seminar. Correct?</p> <p style="text-align: center;">MR. SPIVACK: Objection, misstates the testimony, misstates the document.</p> <p style="text-align: center;">A. I do not know what exactly Excerpta Medica did. I interact with many pharmaceutical companies, with many different organizations. I cannot remember who did what ten years ago.</p> <p style="text-align: center;">Q. But, sir, you said you wrote every word of your scientific papers.</p> <p style="text-align: center;">A. The papers that I wrote, I wrote every word. The production of the poster requires some bullet points and it's a different technique than a paper, so you have much less space. And in a</p> <p style="text-align: center;">Stratos Legal Services 800-971-1127</p>

Joseph Biederman
February 27, 2009

Page 431

1 limited space you have to present material that
 2 needs to be condensed.
 3
 4
 5 MR SPIVACK: Objection, misstates the
 6 testimony, misstates the document.
 7
 8
 9
 10
 11 A. Making edits to make sure that the poster
 12 is written under the limitations of the space that
 13 you have in a poster in a way that is clear and with
 14 acceptable syntax. So maybe the sentence was a
 15 run-on sentence or something like that.
 16 Q. Tell me what revisions he made, sir,
 17 specifically.
 18 A. I don't remember.
 19 Q. You're just making that up out of whole
 20 cloth, aren't you?
 21 MR. SPIVACK: Objection, argumentative.
 22 MR. PECK: Objection, argumentative.
 23 BY MR. FIBICH:
 24 Q. You're just making it up? You're
 25 speculating what you think Mr. Pandina did.
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Joseph Biederman
February 27, 2009

Page 432

1 MR. SPIVACK: Objection, argumentive.
 2 BY MR. FIBICH:
 3 Q. Aren't you?
 4 A. The process --
 5 Q. Let me ask my question. All right? You
 6 do not know what revisions Mr. Pandina made to the
 7 draft poster presentation that Excerpta Medica
 8 prepared, do you?
 9 A. I don't remember the specific ones.
 10 Q. Was it customary for Excerpta Medica to do
 11 all of your poster presentations or some of your
 12 poster presentations?
 13 MR. SPIVACK: Objection, calls for
 14 speculation, misstates the --
 15 A. I do not remember
 16 Q. I'm sorry, I didn't mean to interrupt you
 17 Do you --
 18 A. I do not remember.
 19 MR. SPIVACK: Let Mr. Fibich ask the
 20 question.
 21 A. I'm sorry I was responding to a previous
 22 question.
 23 Q. Now that you have seen the exhibit that we
 24 have marked as 22, has that refreshed your
 25 recollection about the role of Excerpta Medica in
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Joseph Biederman
February 27, 2009

Page 433

1 any other poster presentations?
 2 A. Refresh my memory about this poster.
 3 Q. No others?
 4 A. I submit many posters, many meetings, and
 5 I interact with many educational organizations that
 6 from time to time help in the preparation of those
 7 posters. Not in the content but in the display.
 8 Q. You're a very busy man, aren't you?
 9 A. I am.
 10 Q. Probably get up early?
 11 A. Yes.
 12 Q. Work late?
 13 A. Yes.
 14 Q. It's what you have to do to be world-
 15 renowned. Right?
 16 MR. SPIVACK: Objection, argumentative
 17 A. I am world-renowned because the quality of
 18 my work. I could work 24 hours a day and not be
 19 world-renowned. Okay? Like I am not world-renowned
 20 in playing baseball or being a chess champion.
 21 Certain things I do well and it is the quality of
 22 what I do, not the hours I spend, that make it
 23 possible.
 24 MR. FIBICH: Mark this, please.
 25 (Biederman Deposition Exhibit 23 marked
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Joseph Biederman
February 27, 2009

Page 434

1 for identification.)
 2 BY MR. FIBICH:
 3 Q. Let me ask you to describe for our jury,
 4 what is the difference between an abstract and a
 5 poster presentation?
 6 A. I'm not sure if I understand correctly.
 7 An abstract, every paper has an abstract. When we
 8 submit to a scientific meeting a poster, comes in
 9 the form of an abstract. If the poster is accepted,
 10 a poster has to be produced to be presented at a
 11 meeting.
 12 Q. When you say if a poster is accepted, does
 13 it undergo some sort of review process that would be
 14 equal to the peer-review process?
 15 A. It's a peer-review process. Posters
 16 submitted to scientific organizations undergo a
 17 peer-review process.
 18 Q. And can an abstract be presented at a
 19 medical seminar in some form other than a poster
 20 presentation?
 21 A. The scientific meetings have different
 22 venues of presenting information. Some are posters,
 23 some are oral presentations.
 24 Q. Some are written? Can you just hand out
 25 an abstract?
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Joseph Biederman
February 27, 2009

Page 435

1 A. No.
2 Q. So it's an oral presentation or a poster
3 presentation. Is that right?
4 A. That's correct.
5 Q. Are abstracts important, the information
6 contained therein?
7 A. Abstracts are a mechanism for submitting
8 material to a scientific meeting. The abstracts for
9 the meeting are published for people to know what
10 material the meeting contained. So the abstract
11 contains, as its name indicate, a very small
12 abridged amount of information that is not
13 sufficient to know exactly what the information is
14 unless you find the poster or get the paper and get
15 additional details.
16 Q. Well, my question is: Are abstracts
17 important, the information contained therein, that
18 are accepted for publication at a medical seminar?
19 MR. SPIVACK: Objection, asked and
20 answered.
21 BY MR. FIBICH:
22 Q. Are they important?
23 MR. SPIVACK: Same objection.
24 A. I don't know what you mean by important.
25 Q. Should they meet the standards of
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Joseph Biederman
February 27, 2009

Page 436

1 scientific rigor that you so champion in your
2 testimony here today?
3 MR. SPIVACK: Objection, argumentative.
4 A. Abstracts submitted to scientific meetings
5 are proposals to present information at the meeting.
6 By design, they contain a very small amount of
7 information to elicit the full evaluation of the
8 information contained.
9 Q. Well, let me ask you this way. When you
10 prepare or desire to present an abstract at a
11 meeting, do you prepare the abstract or does someone
12 draft the abstract for you?
13 A. My work, I prepare the abstract.
14 O. Let me show you Exhibit 23.
15
16
17
18 Q. Are you familiar with it?
19 A. I am reading it.
20 Q. Okay.
21 A. (Pause) What is your question?
22 Q. You just told me that you always prepared
23 your abstract. Do you want to stand by that
24 testimony or do you want to change it, having read
25 this document?
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Joseph Biederman
February 27, 2009

Page 437

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10 Q. So you're asking a Janssen employee to
11 draft an abstract for you. Correct?
12 A. I asked him to help me in putting an
13 abstract for this particular meeting in a very rapid
14 turnaround time on material that we already
15 developed. I did not ask him to create anything.
16 Q. You asked him to draft the abstract.
17 Correct?
18 A. I asked him to draft an abstract, to help
19 me with the draft of the abstract from material that
20 we already developed.
21 Q. He was taking material that you had and
22 putting it in abstract form. Correct?
23 A. Correct. It was a rapid turnaround that
24 this required, and I was not able to put it together
25 at the time frame that this required, so I asked him
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Joseph Biederman
February 27, 2009

Page 438

1 to help me out because he's a co-author of the
2 paper, as you saw.
3 Q. So when I asked you earlier do you always
4 draft your abstracts, what you should have said was
5 I always draft them unless I don't have enough time.
6 That would have been an accurate statement.
7 Correct?
8 MR. PECK: Objection.
9 A. The abstract for the paper was drafted by
10 me. I asked --
11 Q. Then why are you asking him to draft it?
12 A. I asked him to complete the material
13 necessary for the submission for this journal, for
14 this meeting, at the rapid turnaround this required
15 from the material that we already have. Being a
16 co-author of the paper, a co-author has access to
17 the information; it was not a secret activity. He
18 is a co-author of the paper that you saw when you
19 showed me one of the previous exhibits.
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Stratos Legal Services
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<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 439</p> <p>1</p> <p>2</p> <p>3 Q. I want to go back to your study that was</p> <p>4 copyrighted by Excerpta Medica. Do you know why</p> <p>5 they copyrighted the study?</p> <p>6 A. I think all scientific journals copyright</p> <p>7 the papers.</p> <p>8 Q. Well, they're not a scientific journal,</p> <p>9 are they?</p> <p>10 MR. SPIVACK: Objection, calls for</p> <p>11 speculation.</p> <p>12 BY MR. FIBICH:</p> <p>13 Q. Do you know if Excerpta Medica is a</p> <p>14 scientific journal?</p> <p>15 A. Clinical Therapeutics is</p> <p>16 Q. Well, Clinical Therapeutics didn't</p> <p>17 copyright it, Excerpta Medica copyrighted it, and</p> <p>18 I'm asking you if you know why.</p> <p>19 A. I have no idea.</p> <p>20 Q. Now, if you would, sir, pull your paper</p> <p>21 out.</p> <p>22 MR. BURNEY: Which exhibit?</p> <p>23 MR. FIBICH: Excuse me. 21.</p> <p>24 BY MR. FIBICH:</p> <p>25 Q. Sir, this is one of your papers that you Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 440</p> <p>1 say you drafted. Correct?</p> <p>2 A. Yes.</p> <p>3 Q. And this is one of those papers that you</p> <p>4 say meets your high standards of scientific sanctity</p> <p>5 and rigor. Correct?</p> <p>6 MR. SPIVACK: Objection, argumentative.</p> <p>7 BY MR. FIBICH:</p> <p>8 Q. Correct?</p> <p>9 MR. SPIVACK: Objection.</p> <p>10 A. I don't think that "sanctity" is a word</p> <p>11 that applies to science.</p> <p>12 Q. Okay. Is this paper that we have</p> <p>13 identified as Biederman 21 representative of the</p> <p>14 type of scientific work that you customarily do?</p> <p>15 A. Yes.</p> <p>16 Q. Now, I want to make sure that our jury</p> <p>17 understands what was done here. Okay?</p> <p>18 A. Mm-hmm.</p> <p>19 Q. Because I doubt that any of the members</p> <p>20 will have the background that you have in this area.</p> <p>21 Okay?</p> <p>22 A. Yes.</p> <p>23 Q. So what I understand that you did was you</p> <p>24 had 110 patients and you had 49 that you gave</p> <p>25 Risperdal to and 61 that got a placebo. Is that Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 441</p> <p>1 correct?</p> <p>2 A. I would like to clarify that this is not a</p> <p>3 study that I conducted; this is a study that</p> <p>4 Dr. Aman conducted. What I did is I conducted a</p> <p>5 post hoc analysis from the published data that</p> <p>6 Dr. Aman conducted.</p> <p>7 Q. Okay, I understand that. You took a study</p> <p>8 that someone else did and evaluated that study for a</p> <p>9 certain purpose. Correct?</p> <p>10 A. That's correct.</p> <p>11 Q. And the purpose for which you looked at</p> <p>12 that data was to determine whether risperidone was</p> <p>13 beneficial for the treatment of affective symptoms</p> <p>14 in children with disruptive behavior disorder.</p> <p>15 Correct?</p> <p>16 A. Correct.</p> <p>17 Q. So you took somebody else's data and</p> <p>18 analyzed it for this purpose. Correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And you came to certain conclusions.</p> <p>21 Right?</p> <p>22 A. Correct.</p> <p>23 Q. Now, in evaluating this dataset you looked</p> <p>24 at certain types of behavior that we call affective</p> <p>25 symptoms. Correct? Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 442</p> <p>1 A. Correct.</p> <p>2 Q. And affective symptoms are serious</p> <p>3 symptomatology associated with disruptive behavior</p> <p>4 disorder. Correct?</p> <p>5 A. Correct. The symptoms, the analysis that</p> <p>6 we did used information from the rating scale that</p> <p>7 this study relied upon that is called the Nisonger</p> <p>8 rating scale. So we did a statistical technique</p> <p>9 that is called factor analysis in which we</p> <p>10 aggregated mathematically and empirically certain</p> <p>11 symptoms from the 100 items or so that the scale had</p> <p>12 that alluded to agitation, euphoria and depression.</p> <p>13 MR. FIBICH: I object to that as being</p> <p>14 nonresponsive.</p> <p>15 BY MR. FIBICH:</p> <p>16 Q. My question is, you were looking at</p> <p>17 affective symptoms. Correct?</p> <p>18 A. Yes.</p> <p>19 Q. And you used a rating scale to do that.</p> <p>20 Correct?</p> <p>21 A. No. I used data from a rating scale that</p> <p>22 Dr. Aman used in his study, double-blind study of</p> <p>23 risperidone showing that children with conduct</p> <p>24 disorder or disruptive behavior disorder, mental</p> <p>25 retardation, had a very striking benefit under Stratos Legal Services 800-971-1127</p>

Joseph Biederman
February 27, 2009

Page 443

1 double-blind conditions to risperidone.
2 MR. FIBICH: I object as being
3 nonresponsive.
4 BY MR. FIBICH:
5 Q. Dr. Aman had information about how these
6 children reacted when they were on risperidone.
7 Correct?
8 A. That's correct.
9 Q. And you took the description that he made
10 of these children and applied that to the Nisonger
11 rating scale. Correct?
12 A. I took the Nisonger rating scale and
13 subjected that to a technique that is called factor
14 analysis that examined a natural aggregation of
15 certain symptoms under certain categories. So the
16 way that the symptoms were aggregated were symptoms
17 that we called agitation, euphoria, and depression.
18 Those are symptoms that are known as affective
19 symptoms, and we reanalyzed the data that Dr. Aman
20 produced in light of those symptoms.
21 Q. Well, you also looked at one nonaffective
22 outcome variable. Correct?
23 A. Yes.
24 Q. And a nonaffective outcome variable, what
25 is a nonaffective variable?
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Joseph Biederman
February 27, 2009

Page 444

1 A. It means other symptoms that were not in
2 the category of depression, agitation or euphoria.
3 Q. These would be symptoms that are not as
4 extreme as affective symptoms?
5 A. No, they are different symptoms. These
6 are symptoms that are more in the disruptive
7 behavior category more strictly speaking. So I
8 extracted from the disruptive behavior disorders the
9 kind of symptoms that could be construed as
10 affective.
11 Q. Now, let me make sure that I understand
12 and hopefully our jury will understand. You looked
13 at affective symptoms, and these are grandiose,
14 depression, great irritability?
15 A. Yes.
16 Q. Those are affective symptoms. And then
17 you looked at nonaffective symptoms, and
18 nonaffective symptoms are symptoms that are just
19 kind of ordinary misbehavior?
20 A. Not misbehavior. These are symptoms of
21 children with disruptive behavior, lying, bullying,
22 these type of things.
23 Q. Lying and what?
24 A. Bullying.
25 Q. Bullying?
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 445

1 A. Yes, as examples. So then the rating
2 scale has more than one hundred items, so some items
3 were not in this mathematical analysis that we
4 concluded were not part of the affective symptoms.
5 We called them nonaffective or disruptive symptoms.
6 Q. And I'm trying to make sure that our jury
7 understands that, and so I'm going to try to put it
8 in words that hopefully you'll agree with.
9 Nonaffective behaviors are kind of like being a
10 brat, lying and bullying. Would you agree with
11 that?
12 A. I don't think so, that being a brat is the
13 right terminology. These are kind of behaviors
14 that, remember, these children were of subnormal
15 intelligence so some of the behaviors were aberrant.
16 I don't remember exactly the items, but we deemed
17 them nonaffective. But "brat" I don't think applies
18 to --
19 Q. Well, let me see if I can try another way.
20 Nonaffective symptoms are not as serious as
21 affective symptoms?
22 A. No, I don't say that. They are different.
23 Q. Okay. Nonaffective symptoms alone would
24 not be -- Nonaffective symptoms alone would not
25 constitute a diagnosis of disruptive behavior
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 446

1 disorder standing alone?
2 A. The symptoms in the scale are not a
3 diagnosis of anything. Children were entered into
4 the study; they had to qualify for a diagnosis of
5 conduct disorder based on the DSM.
6 Q. Okay, let me try it one more time. Tell
7 the jury the difference between affective symptoms
8 and nonaffective symptoms in lay language, if you
9 can.
10 A. Affective symptoms refer to problems with
11 mood regulation and include things as agitation,
12 aggression, depression, these type of examples.
13 Nonaffective symptoms could be distractibility,
14 inattention, oppositional, things that are more in
15 the behavior category. The symptoms by themselves
16 are not diagnostic. The rating scale is not a
17 diagnosis. A rating scale is a measurement of
18 severity.
19 Q. Okay. Now, let's look at your results, if
20 you would, sir. Go down to the sentence starting
21 "The treatment" --
22 A. Where are you reading?
23 MR. SPIVACK: Do we have a page number?
24 MR. FIBICH: The first page.
25 BY MR. FIBICH:
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Joseph Biederman
February 27, 2009

Page 447

1 Q. It says "The treatment effect analysis
2 found that the mean scores of all three independent
3 dimensions were significantly reduced with
4 risperidone compared with placebo at weeks two, four
5 and six." I read that correctly, right?

6 A. Yes.

7 Q. So what you did was you measured these
8 children or assessed these children based upon the
9 earlier data at weeks two, four and six. Correct?

10 A. I did not assess the children; I just used
11 the data from Dr. Aman. So it's not that I examined
12 these children.

13 Q. I understand that. And thank you for
14 clarifying that. The data that Dr. Aman had that
15 you looked at had validity at two, four and six
16 weeks. Correct?

17 A. Yes.

18 Q. And when you say "all three independent
19 dimensions," what are you talking about?

20 A. We mathematically extracted the three
21 areas, euphoria, aggression, I believe, and
22 depression. Those are the domains; and we
23 reanalyzed the data. In other words, children that
24 had those domains, we were able to examine how they
25 responded to risperidone in this study.

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Joseph Biederman
February 27, 2009

Page 448

1 Q. These were all three affective variables
2 that you looked at. Right?

3 A. That's correct.

4 Q. And so you say "The effect sizes of
5 improvement," and effect size would be a method of
6 determining how much improvement there was?

7 A. It is a statistical method that is used to
8 examine the magnitude of improvement. So the effect
9 sizes are divided into small, 1, .2; medium, 4 to
10 .6; and large, above .7.

11 Q. So it goes on and it says "The effect
12 sizes of improvement in these factors," and these
13 factors refer to the three independent dimensions
14 which you've identified as affective behaviors.
15 Right?

16 A. Yes.

17 Q. "Range from .44 to 0.95 at endpoint "
18 Correct?

19 A. To .95; close to 1.

20 Q. And that is a false statement, is it not?

21 A. Say again?

22 MR. SPIVACK: Objection, argumentative.

23 BY MR. FIBICH:

24 Q. That is a false statement, is it not?

25 MR. SPIVACK: Objection, argumentative.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 449

1 A. What do you mean by false?

2 Q. I mean it's wrong. Well, let's look back,
3 if you would, sir, and turn to Table 4 on page 799.

4 A. Mm-hmm.

5 Q. Now, the .95 effect size applies to
6 nonaffective conduct. Correct?

7 A. Yes.

8 Q. But in this Results section you say .95
9 applies to affective behaviors. And that's not
10 right, is it?

11 A. Just let me read it. Okay? (Pause)
12 There appears to be a mistake here.

13 Q. The way this is written is misleading, is
14 it not?

15 MR. SPIVACK: Objection, argumentative.

16 A. It has an error that you pointed out to me
17 that I did not pick up before.

18 Q. It is misleading, is it not?

19 MR. SPIVACK: Objection.

20 A. It has an error.

21 Q. It attributes an effect size that is
22 larger than the effect size that is attributable to
23 the factors you looked at. Correct?

24 A. It is an error.

25 Q. You took the largest effect size you could

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 450

1 find and applied it to nonaffective behavior.
2 Correct?

3 A. There was an error in that report.

4 Q. You took the largest effect number you
5 could find and attributed it to other behaviors, did
6 you not?

7 MR. SPIVACK: Objection, asked and
8 answered, argumentative.

9 A. There was an error. We made an error.

10 Q. You wanted this paper to come out to show
11 that Risperdal helped these children more than it
12 did, didn't you?

13 MR. SPIVACK: Objection, argumentative,
14 misstates the testimony.

15 A. I am not. If you look at --

16 MR. SPIVACK: I'm sorry, Doctor. If you
17 would just let me finish. Thank you.

18 BY MR. FIBICH:

19 Q. Did Excerpta Medica write this paper?

20 MR. SPIVACK: Objection, asked and
21 answered.

22 A. No.

23 Q. How did it pass the rigor of science that
24 you have so diligently tried to apply to this paper?

25 A. I think that there is a mistake here.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 451

1 Q. But it wasn't reckless disregard for the
2 truth, was it?
3 A. Absolutely not.
4 Q. It wasn't a disregard of the scientific
5 method, was it?
6 A. Not at all. If you look at the previous
7 number in the agitated depression, the effect size
8 of .74 is a very large effect size. The effect .69
9 in the explosive behavior is a large effect size.
10 Q. You're saying .74? Well, let me ask it
11 this way. Are you saying effect size has
12 definitions for small, medium, and large?
13 A. Yes.
14 Q. And it is your testimony under oath here
15 today as a scientist that those effect sizes, those
16 numbers represent a large effect?
17 A. Effect size above .7 are considered
18 large --
19 Q. You consider. Is that --
20 A. No, no, that's the convention.
21 Q. Refer me to a text on that, please.
22 A. It's Cohen. The person that described
23 that, his last name is Cohen. I can give you the
24 reference.
25 Q. I'm waiting.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 452

1 A. I don't have it in front of my memory.
2 Q. And in this study that we've been talking
3 about, these were retarded children, were they not?
4 A. Yes.
5 Q. Severely retarded, were they not?
6 A. No. They were mildly retarded.
7 Q. Minor retarded?
8 A. Mildly, mildly.
9 Q. Mild?
10 A. Yes.
11 (Biederman Deposition Exhibit 24 marked
12 for identification.)
13 BY MR. FIBICH:
14 Q. Doctor, let me show you Exhibit 24. This
15 is an article that appeared in The Boston Globe.
16 A. Mm-hmm.
17 Q. Now, you told us yesterday you didn't read
18 the paper. Did you read this article by chance or
19 was it called to your attention?
20 A. It was called to my attention. I did not
21 read it.
22 Q. This again goes down to, refers to Senator
23 Grassley. It says that Senator Grassley has accused
24 you of failing to tell Harvard until last March
25 about most of the more than 1.5 million the
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 453

1 pharmaceutical industry had paid him in consulting
2 fees from 2000 to 2007. Has the pharmaceutical
3 industry paid you an amount, approximately that
4 amount from 2000 to 2007?
5 A. This is the total earned income from
6 multiple pharmaceutical and nonpharmaceutical
7 sources.
8 Q. It goes on in the next paragraph where it
9 talks about the doctor's critics say these payments
10 are troubling because you have been the leading
11 proponent of the idea that bipolar disorder can
12 affect young children. Do you consider yourself the
13 leading proponent of the idea that bipolar disorder
14 can affect young children?
15 A. I am one of the leading proponents, not
16 the only one.
17 Q. And earlier I referred to a New York Times
18 article, which I'm going to also mark as 25. And in
19 this article it says "Dr. Biederman's work helped to
20 fuel a fortyfold increase from 1994 to 2003 in the
21 diagnosis of pediatric bipolar disorder." Do you
22 believe your work helped -- helped -- to fuel a
23 fortyfold increase from '94 to 2003 in the diagnosis
24 of pediatric bipolar disorder?
25 MR. SPIVACK: Objection, calls for
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 454

1 speculation.
2 A. I think is the reporter giving you a
3 reference to suggest, to support that assertion?
4 The difference from scientific journals, in the
5 paper you can say whatever you want; it's a free
6 country. This is the writer's opinion, and opinions
7 are not the equal of data. So this is what the
8 author of the article thinks about the subject
9 matter, without any data to support it.
10 MR. FIBICH: Objection, nonresponsive.
11 BY MR. FIBICH:
12 Q. Do you feel you have helped create a
13 fortyfold increase in the diagnosis of bipolar mania
14 in children?
15 MR. SPIVACK: Objection, no foundation,
16 calls for speculation.
17 A. My work helped increase the awareness that
18 bipolar illness exists in children.
19 Q. Your work has helped increase the
20 awareness of bipolar disorder in children. Is that
21 correct?
22 A. That's correct.
23 Q. So you've had an effect, you just don't
24 know what effect, is what I understand you to be
25 telling me?
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 455

1 A. My work has had an effect of making
2 clinicians aware that bipolar illness exists in
3 children.
4 Q. But you don't have an idea of the
5 magnitude as we sit here today, do you?
6 A. I don't. And I am not the only one that
7 helped in this awareness. As I said to you before,
8 there are about one hundred laboratories and
9 researchers in the country and in the world that are
10 interested in the subject. Each one of these people
11 has contributed their part in making this diagnosis
12 more visible in the practicing community.
13 Q. Do you feel that you are the creator of
14 the diagnosis of pediatric bipolar --
15 A. Absolutely not.
16 Q. -- disorder?
17 A. Absolutely not. The famous psychiatrist,
18 Kroepflin, that described manic-depressive illness,
19 I mean, his textbook he already described that can
20 exist in children, so I did not invent anything
21 Q. When did you first start seeing children
22 at Mass. General Hospital, what year?
23 A. In '79.
24 Q. So that was 30 years ago, approximately?
25 A. Yes.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 456

1 Q. And during the 30-year period that you
2 have been a clinician at that hospital, how many
3 patients have you treated that you believe had
4 pediatric bipolar disease that were under the age of
5 six? Approximately.
6 A. It's hard for me to know. I would say two
7 dozens.
8 Q. And from six to age twelve, how many?
9 A. A few hundred.
10 Q. Two hundred?
11 A. A few hundred.
12 Q. Three hundred?
13 A. I cannot tell you exactly.
14 Q. And then what about 12 to 18?
15 A. Less than that.
16 Q. So it's a very rare disease?
17 A. No, it's not rare. We calculate it to
18 affect somewhere between 16 and 20 percent of our
19 referral pool.
20 Q. 16 to 20 percent of what?
21 A. Of our referral pool, the people that come
22 to our program.
23 Q. But still over a 30-year period you have
24 only seen --
25 A. Well, I am one of the clinicians. I think
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 457

1 that my program has many clinicians, so I am in
2 charge.
3 Q. You are aware that a lot of physicians do
4 not believe that the disease exists?
5 A. Some believe, some don't believe.
6 Q. And those that discount it are those that
7 don't have your knowledge about it. Correct?
8 A. Those that discount call these children
9 something different and treat them the same way. So
10 don't think for a moment that the fact that they
11 don't ascribe a diagnosis means anything different.
12 These children, as I told you a few times before,
13 are very disturbed, they will come to clinical
14 attention. So a clinician may call them something
15 different. That does not mean that the child does
16 not exist or has no problems or has a minor
17 headache. That clinician may call that patient with
18 other epithets. They may call them disruptive
19 behave disorder, they may call it oppositional-
20 defiant, they may call it conduct disorder.
21 So my argument was that if you ask for the
22 symptoms of bipolar illness, if the child has the
23 symptoms required for the diagnosis, this is
24 probably the more appropriate diagnosis than calling
25 them with some vague term and then treating them
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 458

1 with the same tools of the trade. They will get the
2 same treatment.
3 MR. FIBICH: Objection, nonresponsive
4 BY MR. FIBICH:
5 Q. Doctor, are you familiar with the
6 contents, generally familiar with the contents of
7 the label with respect to Risperdal?
8 A. I do not memorize them but I am familiar
9 with.
10 MR. FIBICH: I just heard somebody's
11 stomach growl. Did you hear it? Maybe we ought to
12 take a break for lunch.
13 THE WITNESS: It's about the right time.
14 THE VIDEOGRAPHER: The time is 11:58.
15 We're off the record.
16 (Luncheon recess at 11:57 a m)
17 -----
18 AFTERNOON SESSION
19 1:07 p.m.
20 -----
21 THE VIDEOGRAPHER: Okay, we're back on the
22 record. This is tape number 3. The time is seven
23 minutes after 1:00.
24 BY MR. FIBICH:
25 Q. Dr. Biederman, did I understand you to say
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 459

1 that you do not consider the research you do to be
2 what is termed clinical research?
3 A. No, it is clinical research.
4 Q. You what?
5 A. It is clinical research.
6 Q. Okay. There seemed to be some
7 misunderstanding about that.
8 Now, before we go any further, I'd asked
9 you if you generally understood what was in the
10 label for Risperdal.
11 A. Yes.
12 Q. And are you aware that the label contains
13 a statement that the mechanism of action for
14 Risperdal is unknown?
15 A. Correct.
16 Q. And what does that mean?
17 A. It means that the exact way that the
18 risperidone and other medications work in the brain
19 is not fully elucidated.
20 Q. Well, I'm not interested in other
21 medications. I'm just interested in Risperdal with
22 respect to that question. Okay?
23 A. Yes, yes.
24 Q. What it means is we don't know really how
25 it works. Right?

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 460

1 A. Fully. We have some ideas. For example,
2 the prolactin problem that we talked yesterday is
3 due to the effect of risperidone on a particular
4 type of receptors in the dopamine system that are
5 called dopamine 2 receptors. So other mechanisms
6 are not fully known.
7 Q. Well, basically we know that Risperdal
8 affects the chemistry in the brain. Correct?
9 A. The hypothesis, the reason that
10 risperidone, Clozaril and others are called atypical
11 neuroleptics is because they exert influences at
12 least in two brain systems. One is dopamine and the
13 other one is serotonin.
14 Q. And do children's brains develop over
15 time?
16 A. Children's brain and adults' brain develop
17 over time.
18 Q. And are there any studies on the long-term
19 effect of giving children Risperdal for any period
20 of time, the safety of that?
21 A. There are studies today of a few years,
22 not more than a few years' follow-up. When a drug
23 is, say, brought to market there is a requirement
24 that there is at least one or two years of
25 follow-up, so I believe that risperidone has some

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 461

1 type of follow-up data.
2 Q. You believe so? You don't know so?
3 A. I do not know for sure. As I told you, I
4 did not participate in the study so I do not know.
5 But that's a standard requirement of the FDA.
6 Q. And of course if the drug is being used
7 off-label, then the FDA would not have required that
8 type of study. Correct?
9 A. Physicians use all the time medicines
10 available to them to help their patients off-label.
11 It's a legal activity; it's done all the time; and
12 many of the discoveries in medicine, in psychiatry
13 and other fields occurred through using medications
14 off-label. So off-label is not a bad practice
15 necessarily. Only means that the pharmaceutical
16 company has not yet conducted the clinical study.
17 In the case of risperidone, as you know, the pivotal
18 studies were conducted.
19 MR. FIBICH: Object to that as being
20 nonresponsive.
21 BY MR. FIBICH:
22 Q. What I was asking you was, were there any
23 long-term studies of the effect of Risperdal on
24 children? And you said --

25 A. To my knowledge we, in our research, we
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 462

1 followed the children that responded to risperidone,
2 our small sample, for a year. So we had some small
3 data on long-term effects
4 Q. You have anecdotal evidence from your
5 practice. Correct?
6 A. No, it's -- Yes, I have anecdotal
7 evidence, but we followed in the studies of
8 risperidone that we conducted, we followed those
9 children that responded and were willing to be
10 followed, we followed them for a year and we
11 collected data.
12 Q. And my question is the long-term effect.
13 Are you aware of any published data that established
14 the safety of Risperdal on children for a long
15 period of time?
16 A. The risperidone -- I am not aware, but
17 there is no data on adults either, on long-term
18 effects.
19 Q. I didn't understand what you said.
20 A. There is not only absence of long-term
21 data in pediatrics, but there is neither long-term
22 data in adults.
23 Q. So this is a drug that we don't know how
24 it works and you propose giving it to certain
25 children under the age of six. Correct?

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 463

1 A. I propose to use it in children. The
2 pediatric age group, as we discussed, is a long
3 period of time.
4 Q. And you don't know the long-term effect on
5 the developing brains of children of that age if
6 Risperdal is given to them for a long period of
7 time, do you?
8 A. I do know the long-term effect of not
9 treating, so in this case --
10 Q. That's not what I asked you.
11 A. So in medicine doctors are trained to
12 weigh benefits and risks. So on the one hand I have
13 children that have in front of them a very rocky
14 clinical course with the possibilities of not being
15 able to remain at home, of being hospitalized. And
16 on the other hand I have tools to help some of them.
17 So even if I do not know fully the long-term
18 effects, I know what happens if I don't treat. That
19 will be very catastrophic outcome, including death
20 from suicide or possibilities of homicide with the
21 level of violence.
22 MR. FIBICH: Object to that as being
23 nonresponsive.
24 BY MR. FIBICH:
25 Q. You can't evaluate a risk if you don't
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 464

1 know what it is, can you?
2 A. The risks require long-term follow-up and
3 long-term follow-ups are not easy to do,
4 particularly if people are asked to come back for
5 follow-ups for a very long period of time. It's a
6 very difficult practical thing to do.
7 Q. And when doctors use Risperdal for an
8 off-label purpose, they don't know what the risk of
9 that drug is on that particular population, do they?
10 MR. PECK: Object to form.
11 A. They know some of the risks. Some of the
12 risks are monitorable. For example, the
13 neuroleptics can produce abnormal movements, so
14 those are monitored clinically. The neuroleptics
15 can produce metabolic changes that can be monitored.
16 So when doctors prescribe these type of medications,
17 they monitor their patients for safety for whatever
18 is known.
19 Q. So that's what ought to happen when a
20 doctor uses a drug for a purpose other than its
21 approved use. There ought to be certain monitoring
22 to ensure that there's not adverse effects
23 Correct?
24 A. That's correct.
25 Q. Now, although you have testified you are
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 465

1 unaware of the long-term effects of Risperdal, there
2 are some effects that have adverse effects that you
3 are aware of. Correct?
4 MR. SPIVACK: Objection, misstates the
5 testimony.
6 A. Yes, there are adverse effects. They are
7 listed in the package insert and also known to
8 clinicians that these drugs can produce.
9 Q. And you have observed -- You're aware that
10 not only are some of those adverse effects listed in
11 the Physicians' Desk Reference or the label, but you
12 have also observed those in your practice. Correct?
13 A. Sometimes. I think that in general my
14 experience with this line of treatments has been
15 positive and not negative.
16 Q. I'm not asking you whether you think it's
17 positive or negative. I'm only asking you --
18 A. No, I'm saying --
19 Q. Excuse me. Adverse effects that you may
20 have observed in the population that you prescribe
21 this medication for. Okay? And what is the number
22 one adverse effect that you've observed in the
23 population that you treated with Risperdal?
24 A. The most common adverse effect is weight
25 gain.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 466

1 Q. And that weight gain can be relatively
2 significant, can it not?
3 A. Sometimes.
4 Q. And as a clinician and as a physician, you
5 are aware, are you not, that weight gain can
6 oftentimes lead to metabolic syndrome?
7 A. I am aware of that and I monitor for that
8 in my practice.
9 Q. And that's how you guard against it, you
10 monitor for it. Correct?
11 A. Yes.
12 Q. And have you also seen -- You indicated
13 some movement disorders. Are you referring to
14 tardive dyskinesia?
15 A. Tardive dyskinesia refers to long-term
16 effects. There are other problems that are called
17 extrapyramidal reactions that can include tremor,
18 rigidity, things of that type that occur, that can
19 occur more acutely or more proximately to the onset
20 of treatment.
21 Q. Have you seen in your population that
22 you've treated with Risperdal extrapyramidal
23 effects?
24 A. Sometimes. It's quite uncommon.
25 Q. And have you also in the population that
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 467

1 you've treated discovered cases of tardive
2 dyskinesia?
3 A. I have seen children that developed
4 movements, extremely rarely. And in those cases I
5 discontinue the treatment.
6 Q. Right. But you're aware, are you not,
7 based upon your clinical practice, your education,
8 your background, your training and your studying of
9 this drug, that Risperdal can cause weight gain and
10 subsequent glucose dysregulation?
11 A. I am aware of that.
12 Q. And it can also cause tardive dyskinesia?
13 A. Very rarely, I am aware of that too.
14 Q. And also extrapyramidal side effects?
15 A. Yes.
16 Q. And in the adult population, you're aware
17 that it is often associated with strokes?
18 A. In the geriatric population.
19 Q. The geriatric population.
20 A. I would not say often. It's a risk.
21 Q. You're aware that Risperdal can cause
22 strokes in the --
23 A. It's a small --
24 Q. Let me finish. He can't take us both
25 down.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 468

1 A. I apologize.
2 Q. I'm as anxious to get through as you are.
3 A. I apologize.
4 Q. That's okay. It's probably my fault.
5 In the geriatric population, you're aware
6 that Risperdal can cause strokes?
7 A. Yes. It's a very rare event, but it can
8 happen.
9 Q. That's your opinion. Right?
10 A. No, the statistics on stroke in the
11 elderly are larger than placebo but they are small
12 in size. It is not a frequent occurrence.
13 Q. You are aware, are you not, that there's a
14 black box warning in the label for the use of
15 Risperdal with dementia?
16 A. I am aware.
17 Q. And the adverse effect that is warned
18 against is strokes. Correct?
19 A. Correct. I am only --
20 Q. Go ahead.
21 A. I am only saying that the risk is small,
22 but there. I am only qualifying that this is not a
23 one-to-one correspondence that all geriatric
24 patients that take risperidone will have stroke.
25 What I'm saying is that the risk is there, but it's

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 469

1 uncommon. Still a risk.
2 Q. It is a significant-enough risk that the
3 FDA has required that Janssen put in its label a
4 bolded black box around that particular risk.
5 Correct?
6 A. It's statistically significant but small.
7 MR. FIBICH: Object as being
8 nonresponsive.
9 (Biederman Deposition Exhibit 26 marked
10 for identification.)
11 BY MR. FIBICH:
12 Q. Doctor, let me show you what the court
13 reporter has been kind enough to mark as Exhibit 26.
14 (Pause)
15 This document contains a couple of e-mails
16 that reference a protocol, a draft version of a
17 protocol. Right?
18 A. Yes.
19 MR. SPIVACK: Objection, foundation.
20 BY MR. FIBICH:
21 Q. Are you familiar with what the e-mails
22 reference?
23 A. I vaguely recall that there was some kind
24 of interchange about this protocol.
25 Q. And this appears to be, it says marked
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 470

1 confidential. Do you see that?
2 A. Where?
3 Q. On the protocol outline itself
4 A. Yes.
5 Q. And this is a protocol outline that was
6 furnished to you, was it not?
7 A. I do not remember exactly, but I got it.
8 It was furnished to me.
9 Q. Go back to the first page, if you would.
10 A. Yes.
11 Q. There's an e-mail from Gahan Pandina
12 A. Mm-hmm
13 Q. Importance high, and he is e-mailing
14 somebody named Magali. Do you see that?
15 A. Yes.
16 Q. Do you know Ms. Magali?
17 A. I don't remember who she is
18 Q. It says "Hi, Magali. Here are a number of
19 e-mail with helpful documents, including the notes
20 on meetings with Gaye Carlson and Joe Biederman."
21 Do you remember having meetings with Gahan Pandina?
22 A. I had meetings with Gahan Pandina. I
23 don't remember the specific meeting about this.
24 Q. In any event, if you would, go back to the
25 protocol outline; and it appears to be a protocol
Stratos Legal Services
800-971-1127

<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 471</p> <p>1 outline for a study to be entitled The Efficacy and 2 Safety of Flexible Dose Ranges of Risperidone versus 3 Placebo in the Treatment of Manic or Mixed Episodes 4 Associated with Bipolar I Disorder in Adolescents. 5 A. Mm-hmm. 6 Q. Did you ever do this study? 7 A. No. 8 Q. Do you know why not? 9 A. I don't recall. 10 Q. Have you ever started a study with the use 11 of Risperdal for any purpose and not concluded that 12 study? 13 A. Not that I recall. 14 Q. It goes down on that first page, sir, 15 under the headline Rationale for Study, if you would 16 go down to the third paragraph, starts with "We." 17 A. Mm-hmm. 18 Q. And if you would then go down to the 19 middle of the fourth line where it says "In 20 addition." 21 A. Sorry. You are talking about a 22 subparagraph still? 23 Q. Third paragraph where it says -- 24 A. Yes, "In addition," I have it. 25 Q. It says "In addition, even though it is Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 472</p> <p>1 widely known that the typical age of onset of 2 bipolar disorder is in the second and third decades 3 of life," that would be in someone's twenties or 4 thirties. Correct? 5 A. Yes. 6 Q. "It is extremely rare to find bipolar 7 disorder with onset in childhood." Do you see that? 8 A. Yes. 9 Q. Do you disagree with that statement? 10 A. That was the wisdom of the day. 11 Q. And that was the wisdom in 2002. Correct? 12 A. That's correct. 13 Q. It goes on to say "In a retrospective 14 study performed by Loranger in adults with bipolar 15 disorder, less than 5 percent reported that onset of 16 this disease began before the age ten." Are you 17 familiar with the study of Loranger? 18 A. I am vaguely familiar, but I would like to 19 remind you that the more recent studies done by the 20 STEP program in close to 5,000 adults with bipolar 21 illness, a study funded by the NIH, finds that 70, 22 close to 70 percent of adults have onset in 23 childhood and less than 30 percent start before age 24 of twelve. 25 MR. FIBICH: Object to that as being Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 473</p> <p>1 nonresponsive. 2 BY MR. FIBICH: 3 Q. Let's go back to the body, and if you 4 would turn to Bates number -- 5 MR. SPIVACK: I'm sorry, Mr. Fibich. I 6 just wanted to ask for clarification. Did you read 7 this document to say that the typical age of onset 8 of bipolar disorder is in the second and third 9 decades of life and you interpreted that as the 10 twenties and thirties? Wouldn't that be the teens 11 and twenties? 12 MR. FIBICH: I suppose it could be. Good 13 point. Surprised a scientist didn't catch that. 14 MR. SPIVACK: But the lawyer did. That's 15 what's more surprising. 16 BY MR. FIBICH: 17 Q. Let's go back to Bates number 3927579. 18 A. What's the last digits? 19 Q. 7579. 20 A. 79, yes. 21 Q. This appears to be commentary on proposed 22 risperidone in adolescents mania study. See that at 23 the top? 24 A. Could you point out where you are 25 referring to? Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 474</p> <p>1 Q. Yes. Let me find it for you. (Pause) 2 Right there at the top it says Commentary, and it 3 says "Commentary on the protocol of this proposed 4 risperidone study in adolescent population." 5 Correct? 6 MR SPIVACK: Objection, foundation. 7 A. Could you ask me the question again? 8 Q. Read the top sentence on this page. 9 A. "There is no expert consensus that JB's 10 view is a valid one." 11 Q. Well, that one wasn't the one I wanted you 12 to read, but let's go to that one: "There is no 13 expert consensus that JB's view is a valid one." 14 And JB is Joe Biederman. Correct? 15 A. Correct. 16 Q. And then under Expert View that they're 17 referring to, it says "JB felt strongly that most 18 bipolars manifest first in this age group, that this 19 group is easily characterized and available for an 20 outpatient study. GC felt that this group was 21 important to study as it formed a significant part 22 of a child psychiatrist's practice in the U.S." And 23 then the commentary, whoever's making this 24 commentary, says they disagree with you. Correct? 25 MR. SPIVACK: Objection, foundation. Stratos Legal Services 800-971-1127</p>

Joseph Biederman
February 27, 2009

Page 475

1 BY MR. FIBICH:
2 Q. There's a comment that there is no expert
3 consensus that your view is a valid one. Correct?
4 MR. SPIVACK: Objection, foundation
5 A. This is what the writer of this note says
6 Q. And if you would, go on down to like the
7 middle paragraph, it says -- Let me mark it for you
8 so you don't have to look. I've drawn a line where
9 I want to call your attention. It says "We will be
10 hard-pressed to convince a significant group of
11 psychiatrists to come up with clear diagnostic
12 criteria, let alone convincing the FDA of how this
13 group comes under the umbrella of DSM-IV as
14 currently written."
15 And then it goes down, the last sentence
16 is "A study of this sort may well be feasible and
17 appropriate for Dr. Mahmoud's group rather than for
18 a regulatory focus study." What does that mean,
19 that this study may be more appropriate for Mahmoud?
20 MR. SPIVACK: Objection, foundation, calls
21 for speculation
22 A. I have no idea.
23 Q. You have no idea?
24 A. No.
25 Q. Go down to the expert view on this same
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 476

1 page of yours under the 12 to 17 age group.
2 A. Mm-hmm.
3 Q. Says "JB did not think that doing a study
4 of acute classical mania in this group was feasible
5 because he thought these kids would be too ill and
6 disturbed to participate in a study on a voluntary
7 basis, and that this type of mania was rare, so
8 recruitment would be difficult if not impossible."
9 Was that your view back in 2001?
10 A. I do not --
11 Q. Excuse me. '3.
12 A. I do not know what this alludes to.
13 Q. Well, the e-mails were in 2003. They
14 refer to this protocol outline and it says that your
15 view, and let's assume for the purposes of my
16 question it was 2003, that you do not think or that
17 you --
18 MR. PECK: Counsel, let me just point out
19 the bottom of the page says February 2002.
20 MR. FIBICH: Okay, thank you.
21 BY MR. FIBICH:
22 Q. February 13, 2002, it says that you
23 thought the type of mania that is sought to be
24 studied here is rare and recruitment would be
25 difficult if not impossible. Was that your view in
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 477

1 2003?
2 A. I do not know what was my view; and I also
3 do not know, this is a narrative of somebody
4 interpreting something that I may have said. I
5 don't know what they are alluding to.
6 Q. My question to you is, forget what's in
7 front of you. Did you have a view in 2003 that
8 acute classical mania was rare in the 12 to 17 age
9 group? Was that your view?
10 A. The thing that I do not know is, what is
11 this type of mania?
12 Q. It says acute classical mania.
13 A. Okay. So I assume -- The problem is it
14 has to be defined, what is the definition of acute
15 classical mania. So this could have many different
16 interpretations of what it means.
17 Q. Let me see the document, please.
18 In 2003 did you believe that acute
19 classical mania was rare in the 12 to 17 age group?
20 A. I believe then and today that most
21 children present with a mixed, what's called a mixed
22 presentation, a very chronic state and a kind of
23 what has been described by Kroeplin at the beginning
24 of the century as uncommon; and the most common
25 presentation is one of an agitated state with a lot
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 478

1 of mixed symptoms of mania and depression. This is
2 what we were seeing more commonly.
3 MR. FIBICH: Objection, nonresponsive.
4 BY MR. FIBICH:
5 Q. Pediatric bipolar disorder, what age group
6 does that apply to? When we say pediatric bipolar
7 disorder, what age group?
8 A. It's up to 18. And parenthetically the
9 controversy is not in adolescent mania. That was
10 never controversial. The controversy has been in
11 younger children.
12 MR. FIBICH: Objection, nonresponsive.
13 BY MR. FIBICH:
14 Q. Does pediatric bipolar disorder as you
15 understand it involve both manic and depressive
16 states?
17 A. The most common form is mixed, that both
18 are occurring together. Some children only have
19 manic symptoms and some children have manic and
20 depressive symptoms, the same as adults.
21 (Biederman Deposition Exhibit 27 marked
22 for identification.)
23 BY MR. FIBICH:
24 Q. Doctor, would you review briefly the
25 document that I've marked as Biederman 27.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 479

1 A. Mm-hmm.
2 Q. And this appears to be a planned letter to
3 the editor of The New York Times?
4 A. Appears to be.
5 Q. And Jellinek evidently you had review this
6 letter Correct?
7 A. He appears to have done it.
8 Q. And then sent it to you. Correct?
9 A. I sent it to him to look at the letter, he
10 reviewed it and sent it back.
11 Q. And what changes did he make?
12 A. I don't know because it does not have the
13 highlights, so I don't know what he edited.
14 Q. But, in any event, he made some changes to
15 your letter thinking it would enhance the purpose
16 for the letter. Right?
17 MR. SPIVACK: Objection, calls for
18 speculation.
19 A. He probably made cosmetic changes for --
20 English is not my primary language.
21 Q. But you understand English, do you not?
22 A. Pretty well.
23 Q. Did you send this letter to The New York
24 Times?
25 A. I did.
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 480

1 Q. Is the letter that you sent to The New
2 York Times the one that is contained here on Exhibit
3 27?
4 A. I do not know if I sent the letter with
5 Dr. Jellinek's edits or not
6 Q. Well, in any event, as of the date of this
7 document, which appears to be December of '08, which
8 was a few months ago --
9 A. Mm-hmm.
10 Q. -- this is what you were proposing to send
11 to The New York Times?
12 A. I did send a letter to The New York Times.
13 What I cannot remember if whether I incorporated
14 Dr. Jellinek's edits or not.
15 Q. In any event, this letter says to the
16 editor "Your reporting on my relationships with
17 pharmaceutical manufacturers is inaccurate. First,
18 my and my colleagues' work on pediatric bipolar
19 disorder focuses on this illness, its symptoms,
20 impairments, and neurobiology, not on medications
21 Our work helps understand this devastating disorder
22 and treatment options. Second, the J&J Center in
23 2002 to 2005 performed research on ADHD and bipolar
24 disorder. The center performed no clinical trials
25 on J&J products. It was called J&J Center to be
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 481

1 transparent about its funding "
2 It then goes on down to the fifth point,
3 says "I have not engaged in ghostwriting. The lead
4 author, a J&J researcher and expert scientist, wrote
5 the abstract." What abstract are they referring to
6 there? Are you referring to
7 A. There was an abstract in the Academy of
8 Child Psychiatry. I'm not totally sure which one,
9 but was an abstract that Dr. Pandina authored.
10 Q. Was that the abstract that we earlier went
11 through with respect to your study of the mildly
12 retarded children?
13 A. I am not sure which abstract, but I know
14 it was an abstract that Dr. Pandina authored. There
15 were no details in The New York Times which exactly,
16 what abstract that I could review.
17 Q. Then it goes on that J&J did not pay you
18 58,159 in 2001, that 50,000 was an educational grant
19 to Massachusetts General Hospital. What was that
20 educational grant for?
21 A. For a conference on pediatric bipolar
22 illness.
23 Q. And Massachusetts General would get the
24 money, and then what would they do with that money?
25 How was that money used?
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 482

1 A. The money was used to fund a conference
2 that brought 100 researchers from all over the
3 country to discuss issues pertaining to pediatric
4 bipolar illness.
5 Q. Well, was it used to pay travel expenses
6 or to rent a room, or what was the money actually
7 spent on?
8 A. For all of the above. It was to pay for
9 travel expenses, rent a room, and have a daylong
10 conference.
11 Q. And what was the conference on?
12 A. Pediatric bipolar illness.
13 Q. And was there a transcript made of this
14 particular presentation?
15 A. There was no transcript but there were a
16 series of papers that were published in the
17 scientific literature.
18 Q. Well, whether or not this is the actual
19 letter that was sent to The New York Times, are the
20 statements that are contained in this -- and let's
21 call it a draft letter or planned letter -- are the
22 statements that are contained in here true and
23 correct?
24 A. Yes.
25 (Biederman Deposition Exhibit 28 marked
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Joseph Biederman
February 27, 2009

Page 483

1 for identification.)
2 BY MR. FIBICH:
3 Q. Doctor, if you would, look at Exhibit 28.
4 A. Mm-hmm.
5 Q. And do you know what this is?
6 A. It's a presentation that we gave about the
7 J&J Center.
8 Q. And when did you give this presentation?
9 A. I do not know. Whenever the date. There
10 is no date here.
11 Q. Would it have been about the time that the
12 center was getting started?
13 MR. SPIVACK: Objection, calls for
14 speculation.
15 A. I do not know. We met with Janssen twice
16 a year, as I mentioned earlier.
17 Q. What was the purpose of the center? What
18 was the center's purpose?
19 MR. SPIVACK: Objection, asked and
20 answered.
21 A. The purpose focused on understanding the
22 illnesses that Janssen and McNeil had products. The
23 center focused on the diseases of pediatric bipolar
24 illness and ADHD.
25 Q. And why did you only study Janssen
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 484

1 products in connection with that goal?
2 A. Because Janssen had products that could
3 potentially treat those diseases, so there was in my
4 view a potential intersect between a commercial
5 entity like Janssen and McNeil and our interest to
6 advance science. And the premise was that if the
7 illnesses that we are studying are serious and
8 devastating, as we believed that they are, and if
9 the medicines that they have could provide relief to
10 those problems if proven effective and safe, then
11 that is the synergy between academia and a
12 commercial entity.
13 Q. Well, Doctor, there were other drugs that
14 would also potentially assist in the treatment of
15 the diseases you were going to study, were there
16 not?
17 A. But I was speaking to Janssen; I was
18 speaking to McNeil. So I wanted to engage -- The
19 intersect was with the medicines that they have.
20 I would not propose to study medicines of another
21 company to Janssen. They have risperidone and
22 McNeil has Concerta, and there were other medicines
23 that other companies have, like olanzapine for
24 example, or Topamax that we're also interested in
25 psychiatry.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 485

1 Q. Well, was there a limitation put on what
2 you could study by Janssen?
3 A. No.
4 Q. Only their products?
5 A. No. I did not just study their products
6 I wanted to engage their interest in supporting
7 science and I believed that this was a win-win
8 opportunity for scientists like myself and a
9 commercial entity. The idea was that they have
10 potential medicines to treat disorders. We need to
11 understand the disorders that they have medicines
12 that could help. And my proposal was to advance
13 knowledge on the disorders, not on the treatment of
14 the disorders.
15 MR. FIBICH: Objection, nonresponsive.
16 BY MR. FIBICH:
17 Q. My question to you is, did Janssen limit
18 your ability to use other products in whatever you
19 were going to study?
20 A. I did not study in the center other
21 products or any products. I studied the diseases.
22 As I have mentioned several times, the center had
23 five cores, none of them therapeutics. The cores
24 were on neuroimaging, on genetics, on paradigm
25 development, on assessment and analysis. Those were
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 486

1 the cores. There was no treatment in the center.
2 MR. FIBICH: Objection, nonresponsive.
3 BY MR. FIBICH:
4 Q. My question is: In the cores that you set
5 up for your center for pediatric psychopathology
6 research, did Janssen limit your use in your studies
7 to their products? Did they limit you?
8 A. No. This --
9 Q. The limitation was one that you imposed on
10 yourself. Correct?
11 A. I proposed a center, that we focus on ADHD
12 and bipolar illness in the sense that I was
13 interested in researching.
14 Q. Let me ask you another way because I don't
15 think I'm communicating very well with you.
16 A. Okay, please do.
17 Q. When you went to them and said "I need two
18 million dollars to do this study," this center, did
19 you say "I will only use Johnson & Johnson
20 products"?
21 A. The center did not use any medicines.
22 I proposed to them a center. A center was budgeted
23 for a year for \$500,000. I never knew if the center
24 will be refunded.
25 Q. Let me see that a moment.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 487

1 A. Sure.
2 Q. Was part of the plan for this center to do
3 clinical trials?
4 A. The center did not have any clinical trial
5 activity. The center could support clinical trial
6 activity but not do it.
7 Q. Okay, let's talk about that. The center
8 could support clinical trial activity. How would
9 they do that?
10 A. Well, the center had personnel that had
11 expertise in assessments. A clinical trial requires
12 assessment. The center has expertise in data
13 analysis. A clinical trial requires analysis. So
14 we have in-house the expertise that could allow to
15 rise to the occasion if we have additional funding
16 to do a clinical trial, so a clinical trial that we
17 conducted with Johnson was separate from the center
18 and was a clinical trial on risperidone.
19 Q. The clinical trials were separate from the
20 center?
21 A. Yes.
22 Q. But the center supported those trials?
23 A. The center did not support the trials.
24 The center funded personnel that had the expertise.
25 So if I have a person that knows how to do
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 488

1 structured interviews, that person can help me train
2 other people that they hire for the clinical trial
3 to conduct structured interviews.
4 Q. Okay, give me an example of what you're
5 talking about. You said the center funded
6 individuals that had expertise. What do you --
7 A. Well, we had from the center funding for a
8 core of psychometricians that are trained to do
9 structured interviews and cognitive assessments.
10 Takes us about a year to train a person like that
11 So having a core of people that are trained if we
12 need to hire additional people and train them, we
13 have people with expertise that can help train
14 additional personnel to conduct another study.
15 Q. And that's what some of the money that
16 Janssen gave you was used for. Correct?
17 A. Some of the money was to maintain a core
18 of psychometricians in our lab, yes.
19 Q. And the psychometricians would then help
20 with the clinical trials?
21 A. Would help train additional personnel that
22 are required for a clinical trial.
23 Q. This is a PowerPoint presentation that you
24 prepared, is it not?
25 A. Yes.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 489

1 Q. And the page that I've referred you to is
2 entitled Johnson & Johnson Center for Pediatric
3 Psychopathology Research, Mass. General Hospital,
4 Clinical Trials Program. Correct?
5 A. Yes. The clinical trial program was not
6 part of the center. What I meant, that the center
7 could have infrastructure that could allow us to
8 conduct clinical trials. The clinical trials that
9 we conducted with risperidone and Reminyl were done
10 with separate funding, not with the center funding.
11 They were a separate contract for those trials.
12 Q. So in addition to the two million dollars
13 to set up this center, you got additional funding to
14 do the Risperdal and the Reminyl clinical trials.
15 Correct?
16 A. The center had support for these cores
17 that supported neuroimaging, genetics, statistical
18 and paradigm development. The budget for the center
19 was half a million per year, roughly distributed
20 between the five cores of the hundred thousand
21 dollars. Remember that the 500,000 has a tax,
22 institutional tax of 25 percent, so the net payment
23 is 25 percent less than that. The center did not
24 have money to conduct a clinical trial.
25 MR. FIBICH: Objection, nonresponsive
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 490

1 BY MR. FIBICH:
2 Q. Were clinical trials done with respect to
3 the use of Risperdal?
4 A. We conducted a clinical trial of
5 risperidone in children, not as part of the center
6 but as a separate contract.
7 Q. And who did that clinical trial?
8 A. I did that clinical trial.
9 Q. And under what auspices did you do that
10 clinical trial?
11 A. The clinical trial was done in my program
12 and it was a separate contract with --
13 Q. What program?
14 A. This is a clinical and research program in
15 pediatric psychopharmacology.
16 Q. Say that again, please.
17 A. Clinical and research program in pediatric
18 psychopharmacology.
19 Q. Is that a center?
20 A. No. It's a program.
21 Q. A program?
22 A. (Witness nodded.)
23 Q. So you did a Risperdal clinical trial in
24 the clinical and research program in pediatric
25 psychopharmacology?
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 491

1 A. Yes.
2 Q. And did you do a clinical trial with
3 respect to Reminyl in that same program?
4 A. Yes.
5 Q. And did you do a clinical trial with
6 respect to Concerta in that same program?
7 A. Yes.
8 Q. And did you do a clinical trial with
9 respect to Topamax in that same program?
10 A. Yes.
11 Q. And were those clinical trials assisted in
12 some way by people that were hired by the Johnson &
13 Johnson Center for Pediatric Psychopathology
14 Research?
15 A. To a very small extent.
16 Q. That means yes?
17 A. No, that means to a small extent.
18 Q. That means yes. Correct?
19 A. Let me recap. The neuroimaging core paid
20 for neuroimagers to do neuroanatomical software
21 development. The paradigm development core paid
22 M.I.T. to develop a driving simulation, paid a Ph.D.
23 psychologist to develop work simulation paradigms;
24 provided a salary, part-time salary for a
25 statistician to conduct analysis from data that we
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 492

1 collected from other grants
2 So we have a small component that had this
3 assessment expertise that we were able to train
4 people for a clinical trial more rapidly, but to do
5 so with personnel on the salaries and expenses that
6 the center had.
7 MR. FIBICH: Object to that as
8 nonresponsive
9 BY MR. FIBICH:
10 Q. Sir, you represented in a planned letter
11 to The New York Times to the editor that the center
12 performed no clinical trials on J&J products
13 A. The center did not perform clinical
14 trials
15 Q. But you yourself through another program
16 did do clinical trials on four J&J products.
17 Correct?
18 A. Outside the center. The center did not do
19 clinical trials.
20 Q. Would you agree with me that this is
21 somewhat misleading to The New York Times about your
22 involvement with Janssen-sponsored clinical trials?
23 MR. SPIVACK: Objection, argumentative.
24 A. I don't think so.
25 Q. You don't think so?
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 493

1 A. No.
2 Q. Were most of the clinical trials in which
3 Risperdal was used sponsored by Janssen?
4 A. No. Some were sponsored by the Stanley
5 Foundation.
6 Q. My question was, were most of them
7 sponsored by Janssen?
8 MR. SPIVACK: Objection, vague.
9 BY MR. FIBICH:
10 Q. Or was a majority of them sponsored by
11 Janssen?
12 A. Yes.
13 Q. As a matter of fact, all but one of them
14 was sponsored by Janssen. Correct?
15 A. Well, yes. There is a study of
16 risperidone in children six to 18. Our principal
17 study was funded by the Stanley Foundation and we
18 had a study of spectroscopy funded by Janssen. So
19 there were two studies funded by Johnson and one
20 study funded by the Stanley Foundation.
21 Q. Well, there's more than that, isn't there,
22 sir?
23 A. Tell me more.
24 Q. Well, your open label eight-week trial of
25 olanzapine for treatment of bipolar disorder in
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800-971-1127

Joseph Biederman
February 27, 2009

Page 494

1 preschool age children, that was a Janssen-funded
2 study?
3 A. No, that was based on the Stanley
4 Foundation.
5 Q. Your open label trial of risperidone in
6 children and adolescents with bipolar disorder, that
7 was Janssen. Correct?
8 A. That was Janssen, yes.
9 Q. The risperidone for treatment of affective
10 symptoms in children with disruptive behavior
11 disorder, that was Janssen. Correct?
12 A. That was a data analysis; it was not a
13 clinical trial.
14 Q. That wasn't sponsored by Janssen?
15 A. The data analysis was done as part of our
16 data analytic efforts at the center.
17 Q. The Aman study was sponsored by Janssen.
18 You know that, do you not?
19 A. The Aman study I believe was sponsored --
20 And I am not totally sure about that either. I
21 believe the Aman study was part of the research unit
22 in pediatric psychopharmacology funded by the NIH.
23 I am not sure that they were funded by Janssen
24 completely.
25 Q. And the other studies that you did with
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 495

1 respect to Topamax and the other drugs that were
2 listed in your PowerPoint, the clinical trials you
3 did on those were sponsored by Janssen?
4 A. No. The Topamax study was sponsored by
5 non-Janssen. I don't remember. May have been the
6 Stanley Foundation. We added Topamax to Zyprexa and
7 examined the weight gain in people that took Zyprexa
8 with and without Topamax, and Topamax reduced the
9 weight lability of Zyprexa in half. The study of
10 Reminyl was funded by Ortho-McNeil, not Janssen.
11 Q. Funded by whom?
12 A. Ortho-McNeil. That was a separate company
13 from Janssen. And the Reminyl study, by the way,
14 was solidly negative
15 MR. PECK: I'm sorry. Could I have that
16 read back?
17 (The reporter read the answer.)
18 MR. FIBICH: Let's mark that.
19 (Biederman Deposition Exhibit 29 marked
20 for identification.)
21 BY MR. FIBICH:
22 Q. Sir, we have handed you Exhibit Number 29.
23 Let me find the page for you that I want to ask you
24 about. It's this page here. And I apologize;
25 that's been copied poorly.
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 496

1 A. Mm-hmm.
2 Q. But it's supposed to read Johnson &
3 Johnson Center for Pediatric Psychopathology
4 Research. You see that?
5 A. Yes.
6 Q. It says "Supports research on the
7 disorders that J&J products treat" and lists the
8 four products that we've been talking about
9 Correct?
10 A. Supports research on ADHD and pediatric
11 bipolar illness that these compounds potentially can
12 treat
13 Q. That's right. Do you want to turn back?
14 Go forward.
15 A. Forward?
16 Q. One more page. And here it talks about --
17 MR. PECK: Page, please?
18 MR. FIBICH: Johnson & Johnson Center for
19 Pediatric Psychopathology Research.
20 BY MR. FIBICH:
21 Q. It says "Puts J&J at the forefront of
22 pediatric psychiatric research." Do you see that?
23 A. Yes.
24 Q. "Provides ongoing consultation for
25 protocol development of new J&J products or new uses
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Joseph Biederman
February 27, 2009

Page 497

1 for existing compound." Do you see that?
2 A. Yes.
3 Q. And that was really the purpose of the
4 center, was to create new markets for Johnson &
5 Johnson products. Correct?
6 MR. SPIVACK: Objection, argumentative
7 MR. PECK: Objection, foundation.
8 A. I believe --
9 MR. SPIVACK: Calls for speculation,
10 misstates the testimony.
11 BY MR. FIBICH:
12 Q. Isn't that true?
13 MR. SPIVACK: Same objections.
14 A. No.
15 Q. If you're doing strictly scientific
16 research, why are you concerned with what this does
17 for Johnson & Johnson?
18 MR. SPIVACK: Objection, argumentative.
19 A. I am concerned with Johnson & Johnson
20 because Johnson & Johnson, Janssen-McNeil have
21 commercial interests. I need to find an intersect
22 Advancing science for a pharmaceutical company or to
23 do research that is removed from the most parochial
24 interest that most pharmaceutical companies do is a
25 leap. So what I was telling Janssen and McNeil,
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Joseph Biederman
February 27, 2009

Page 498

1 that supporting research on ADHD and pediatric
2 bipolar illness is a good thing for a responsible
3 pharmaceutical company.
4 MR. FIBICH: Object to that as being
5 nonresponsive.
6 BY MR. FIBICH:
7 Q. Who did you show this PowerPoint
8 presentation to?
9 A. We showed this PowerPoint presentation to
10 people in Janssen and McNeil that were involved with
11 the center.
12 Q. Well, did you do this for the purposes of
13 convincing them to make contributions to this center
14 or was this done after the center was agreed to be
15 funded by Johnson & Johnson?
16 A. This was an ongoing reporting that I
17 impose upon myself to make sure that the people that
18 fund us know what are we doing with their funds and
19 if it's scientifically sound from their perspective,
20 and in the hope that they will be interested in
21 continuing funding of the work.
22 So it is responsible. The same I do with
23 NIH grants, that I report periodically what I have
24 done with the funding, that I am fulfilling my
25 obligations. So this is a reporting to say what
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 499

1 have we done and what we would like to do in the
2 year to come.
3 MR. FIBICH: Object to that as being
4 nonresponsive.
5 BY MR. FIBICH:
6 Q. At the time that Johnson & Johnson agreed
7 to fund the Center for Pediatric Psychopathology
8 Research, was it a five-year commitment? Four-year
9 commitment, rather.
10 A. It was only one-year commitment.
11 Q. So they gave you \$500,000 for one year and
12 then you would do a PowerPoint presentation to
13 educate them on what you were doing so that they
14 would continue to support you. Is that correct?
15 A. I was describing reporting on what we have
16 done and what are the plans for the next year.
17 Q. Because you wanted them to continue to
18 support this center?
19 A. Yes.
20 Q. Were you disappointed after four years
21 that they decided not to support the center?
22 A. I consider that part of life. I think
23 that funding is never forever, so we have done four
24 years of activity and it was very productive. We
25 published dozens of papers.
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 500

1 Q. How many papers did you publish as a
2 result of this four-year tenure of this center that
3 was sponsored by Janssen?
4 A. Dozens of papers.
5 Q. When you say dozen, you mean twelve?
6 A. No, no, dozens. I am using the plural. I
7 don't know. Forty. I don't know. I didn't count
8 them.
9 Q. How many?
10 A. Forty.
11 Q. Forty?
12 A. Yeah. My program publishes seventy to
13 eighty papers a year.
14 Q. What program are you referring to now?
15 A. The program that I run as the clinical and
16 research program in pediatric psychopharmacology and
17 adult ADHD.
18 Q. Did you seek other pharmaceutical
19 companies to sponsor a similar center after Johnson
20 & Johnson decided not to fund anymore?
21 A. We seek funding from all sources possible,
22 pharmaceutical companies, private foundations and
23 the NIH. Research is very expensive and require
24 funding. Research cannot be conducted without
25 funding. We have been funded by each, with the
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 501

1 exception of Seroquel that did not fund in a
2 clinical trial, we had funding for Abilify, for
3 Geodon and for Zyprexa from the pharmaceuticals,
4 just to conduct the clinical trial, not to fund
5 research.
6 Q. So have the other makers of second-
7 generation antipsychotics also funded clinical
8 trials through your center?
9 A. Just one.
10 Q. And who is that?
11 A. Lilly for Zyprexa. We did a clinical
12 trial with them, a very similar clinical trial that
13 we did. Our clinical trial was eight weeks open
14 label, small studies. We had funding from Lilly.
15 We have funding from Pfizer for Geodon and we have
16 funding from Bristol-Myers to conduct the trial of
17 Abilify. We also had done a similar clinical trial
18 with Abbott with Depakote. We did two studies with
19 Depakote, in fact, one on the immediate-release and
20 one with the extended-release, that showed very poor
21 results. And we also did a study with Shire for
22 their anti-manic carbamazepine Equetro.
23 MR. FIBICH: Object to that as being
24 nonresponsive.
25 (Biederman Deposition Exhibit 30 marked
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 502

1 for identification.)
2 BY MR. FIBICH:
3 Q. Let me show you Number 30, Dr. Biederman.
4 A. Mm-hmm.
5 Q. And this was a presentation that was made
6 at the Four Seasons Hotel here in Boston, November
7 10, 2003. Do you see that?
8 A. Yes.
9 Q. Do you recall being at this presentation?
10 A. Yes.
11 Q. And I see there's an example of imaging
12 core, George Bush. That isn't our president, is it?
13 A. It was not our President.
14 Q. That's too bad.
15 It goes on and says that you do the
16 opening and overview of the center at Massachusetts
17 General. Do you see that?
18 A. Yes.
19 Q. And did you make that presentation?
20 A. Yes.
21 Q. Is the attachment to this the PowerPoint
22 presentation that you had?
23 A. Seems to be.
24 Q. And was this at the very beginning of the
25 center? Was this kind of the opening of the center?
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 503

1 A. No. This was at the end of the first year
2 of the center.
3 Q. Okay.
4 And if you would, go to page 222, the
5 Bates number.
6 A. Yes.
7 Q. And do you see the block in the left-hand
8 corner, says "Supports research on the disorders
9 that J&J products treat, Concerta, Risperdal,
10 Reminyl and Topamax." Do you see that?
11 A. Yes.
12 Q. Did you prepare this PowerPoint
13 presentation?
14 A. I did.
15 Q. And the attendees at this particular
16 conference were whom?
17 A. Were scientists that participated in the
18 center and teams from McNeil and Janssen.
19 Q. And then if you would, go to page 224, in
20 the middle left-hand side there is "Added value of
21 the center." Do you see that? Entitled Added Value
22 of The Center.
23 A. Mm-hmm.
24 Q. The third bullet point says "This fosters
25 a collaborative effort that prioritizes projects
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 504

1 central to the short and long-term goals and
2 interests of J&J." Is that correct?
3 A. Correct.
4 Q. And this was something that you felt was
5 sufficiently important that you wanted to present
6 this to the people at this meeting. Correct?
7 MR. SPIVACK: Objection, foundation.
8 BY MR. FIBICH:
9 Q. Well, you prepared this slide, did you
10 not?
11 A. I prepared these slides, yes.
12 Q. And you thought this was important that
13 you project this to them. Correct?
14 A. I thought that there is an intersect, a
15 win-win situation between our interest to advance
16 science and the commercial interest of Janssen and
17 McNeil.
18 Q. It was a win-win prospect because you were
19 going to advance science and they were going to have
20 an opportunity to expand the market for their drugs
21 Correct?
22 MR. SPIVACK: Objection, misstates the
23 testimony.
24 BY MR. FIBICH:
25 Q. Is that what you mean?
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Joseph Biederman
February 27, 2009

Page 505

1 A. No.
2 Q. Okay. Tell me why my statement is
3 inaccurate.
4 A. We thought about the center as advancing
5 science, so we need to study the diseases for which
6 they have compounds that can help the diseases. We
7 wanted to document if the diseases are morbid enough
8 that required treatment and if the treatment is
9 shown safe and efficacious, then the treatment can
10 be deployed and then the pharmaceutical company that
11 makes those treatments, if they are effective and
12 safe, can benefit
13 But it is a sequential process; it is not
14 a one-to-one correspondence. The pharmaceutical
15 companies usually support direct things that are of
16 benefit to them, clinical trials. For them to
17 support something that is quasi-esoteric science,
18 knowledge, is several steps removed from their
19 commercial agenda and is predicated on several steps
20 that have to occur for them to be successful
21 commercially with their product. The products have
22 to be tested; the diseases have to be tested as
23 serious enough to warrant treatment. So that's the
24 way that you predicate the --
25 Q. Well, Doctor, I object as being
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Joseph Biederman
February 27, 2009

Page 506

1 nonresponsive. These products had already been
2 tested; they had already gotten approval from the
3 FDA. Correct?
4 A. Not for the conditions that we are testing
5 that we are interested. Adult ADHD was not tested,
6 the pediatric bipolar illness was not tested.
7 Q. Was it a win-win for both parties?
8 A. I believed that supporting research on the
9 diseases that they could have successful compounds
10 is a very important part of their mission. Doing a
11 good thing, advancing research I believe is
12 eventually or potentially profitable. The steps
13 that are required have some risk. The diseases that
14 you are studying may not be warranting of treatment.
15 The treatments may not work. So those are things,
16 the steps that they take by advancing science.
17 But it is certainly several steps removed
18 from all the other pharmaceutical companies that
19 just want to do a clinical trial, the FDA kind of
20 clinical trial. So doing non-clinical trial
21 activities is a very different approach that the
22 pharmaceutical company took.
23 MR. FIBICH: Objection, nonresponsive.
24 BY MR. FIBICH:
25 Q. Was it a win-win result for the center and
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800-971-1127

Joseph Biederman
February 27, 2009

Page 507

1 Janssen, in your opinion?
2 MR. SPIVACK: Objection, asked and
3 answered.
4 A. I believed that has the promise of a
5 win-win situation.
6 Q. Okay, you believed it had the promise at
7 the time you started, correct, that it could be a
8 win-win?
9 A. Could be a win-win if all the forces
10 align, we can do the research that will lead to the
11 decision to do clinical trials and that in turn if
12 successful and safe and effective can lead to
13 their -- that will be the alignment with the
14 commercial interest, not before.
15 Q. And now we're seven years out from the
16 time this started, we can look back. In your
17 opinion was it a win for the Johnson & Johnson
18 Center for Psychopathology Research? Was it a win
19 for your center?
20 A. I believe that the center advanced
21 science. We did what we are paid to do.
22 Q. So the answer is yes, it was a win?
23 A. We did what we are paid to do. The
24 company, Janssen, did a registration type study that
25 showed, replicated our initial findings and showed
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 508

1 that it's safe and effective for children and
2 adolescents.
3 MR. FIBICH: Objection, nonresponsive.
4 BY MR. FIBICH:
5 Q. Was it a win for Janssen to contribute
6 this money to your center?
7 A. I believe it was the right thing to do.
8 Q. That's not my question. I object to that
9 as being nonresponsive. I'm not asking you whether
10 it was right, I'm not asking you whether it was
11 intended. I'm asking you, do you believe it was a
12 win for Janssen?
13 MR. SPIVACK: Objection, vague,
14 argumentative.
15 A. I do not know. I think that yes, they
16 invested in a good cause and at the end they had
17 approval of risperidone for pediatric bipolar
18 illness. They have shown it is safe and effective,
19 did not only rely on open or off-label use and open
20 label data. They did the right thing. But it was a
21 very lengthy process from the time that we started
22 investigating till the time that the approval
23 occurred.
24 MR. FIBICH: Objection, nonresponsive.
25 BY MR. FIBICH:
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 509

1 Q. If you would, go to page 225, the top
2 block, J&J Center Data Management and Biostatistics
3 Core. Do you see that?
4 A. Yes.
5 Q. It goes down to the last bullet point,
6 "These studies demonstrate the unique value of our
7 collaboration." And collaboration, that means your
8 center is working with Janssen. Correct?
9 A. Janssen is funding the center.
10 Q. Well, actually there was an individual
11 over there that helped you do some of your analysis,
12 a Dr. Wu.
13 A. I don't know who Dr. Wu is. I believe
14 that you are referring to the analysis of Dr. Aman
15 data. Since Dr. Aman data was not our data, we had
16 to ask the help of Janssen statistician for our
17 analysis.
18 Q. You asked the help of Janssen's
19 statisticians for your analysis for what?
20 A. For the secondary analysis of the Aman
21 study that we talked before.
22 Q. That's the one that had the mistake in it.
23 Right?
24 A. No, had only the mistake in reporting the
25 one number. That was not picked up by us, it was
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 510

1 not picked up by the reviewer, and it was not picked
2 up by the publishing company. It was a mistake.
3 Q. Excerpta Medica didn't pick it up, did
4 they?
5 A. It was not picked up by us, it was not
6 picked up by the reviewers, and it was not picked up
7 by the publisher, Clinical Therapeutics.
8 Q. Or the copyright holder, Excerpta Medica.
9 Right? They didn't pick it up either?
10 A. They did not pick it up.
11 Q. It says "The findings are critical steps
12 in meeting J&J's goals vis-à-vis product
13 development." Do you see that?
14 A. Say again where?
15 Q. The last bullet point in the block at the
16 top right-hand side: "The findings are critical
17 steps in meeting J&J's goals vis-à-vis product
18 development." I read that correctly, didn't I?
19 A. Yes.
20 Q. And that's really what you were trying to
21 do in your research, was help J&J meet its product
22 development goals. Correct?
23 MR. SPIVACK: Objection, argumentative,
24 misstates the testimony.
25 A. No. I argued that doing research on the
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800-971-1127

Joseph Biederman
February 27, 2009

Joseph Biederman
February 27, 2009

Page 511

Page 512

1 diseases that they have potential drugs will. could.
 2 may be profitable for them if they do the right
 3 clinical trials The entire idea of doing a
 4 clinical trial in pediatric bipolar illness was
 5 dependent on developing enough data to understand
 6 the illness in itself That is a necessary first
 7 step
 8 MR FIBICH: Objection. nonresponsive
 9 Let's take a short break
 10 THE VIDEOGRAPHER: The time is ten minutes
 11 after 2:00 We are off the record
 12 (Short recess taken)
 13 (Biederman Deposition Exhibit 31 marked
 14 for identification)
 15 THE VIDEOGRAPHER: We are back on the
 16 record This is tape number 4 The time is 2:29
 17 BY MR FIBICH:
 18 Q Dr Biederman, tell me again when the
 19 Johnson & Johnson Center for Pediatric
 20 Psychopathology began?
 21 A In 2002
 22 Q Do you remember the month?
 23 A No.
 24 Q Was it late in 2002?
 25 A I don't remember

1 Q You don't know whether it was the first
 2 part, the middle, or latter part of the year?
 3 A I don't remember.
 4 Q You just remember it was 2002?
 5 A Yes.
 6 Q Show you a document we've marked as 31.
 7
 8
 9
 10 Q
 11
 12
 13 What center is he
 14 referring to, if you know?
 15 A The J&J Center
 16 Q The J&J Center, that's the Johnson &
 17 Johnson Center for Pediatric Psychopathology
 18 Research?
 19 A Yes
 20 Q Can we just call that "J&J Center" and use
 21 that term?
 22 A Yes.
 23 Q Okay

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Joseph Biederman
February 27, 2009

Joseph Biederman
February 27, 2009

Page 513

Page 514

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 19 Q And that was one of the things that the
 20 J&J Center was to do. Right?
 21 A The center, I think there is a little bit
 22 of a misnomer here This core, we call it
 23 assessment core because, as you see in the
 24 activities, those are personnel that we reserve that
 25 had expertise in assessment, psychological testing
 and things like that that are necessary for clinical

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Joseph Biederman
February 27, 2009

Page 515

1 trials. So this program did not conduct clinical
2 trials but supported infrastructure of personnel
3 that could train people for clinical trials if we
4 get a contract for a clinical trial.
5 Q. Well, in any event, does it not appear to
6 you that Janssen viewed the center, the J&J Center,
7 as doing clinical trials?
8 MR. SPIVACK: Objection, calls for
9 speculation, no foundation.
10 A. I don't think so. As you see, the budget
11 was modest for that activity. Clinical trials
12 cannot be sustained with that budget.
13
14 Q. So technically the J&J Center didn't do
15 clinical trials, it trained and supervised clinical
16 trials staff. Correct?
17 A. The center supported a few personnel with
18 expertise in assessment. That expertise in
19 assessment can be used in clinical trials and non-
20 clinical trial activities. So, for example, if we
21 do a genetic family study of pediatric bipolar
22 illness, we need people that have expertise in
23 assessment to be able to do that. We can also train
24 people if we have a contract for clinical trial much
25 more rapidly than starting at point zero that I need
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 516

1 to start all over again.
2 So it's a body of competent, trained
3 individuals that can train other people if we have
4 additional funding.
5 Q. And who would make the determination as to
6 the percent of the funding that would go to these
7 respective cores?
8 A. Me.
9 Q. So the budgeted amount over there was
10 something that you came up with. Correct?
11 A. Yes. I distributed the total funds
12 available in the different activities depending on
13 what resources those activities required.
14
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21 ;
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23 Q. And who made the determination of the
24 allocation of J&J funds?
25 A. I did.
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Joseph Biederman
February 27, 2009

Page 517

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10 Q. And these were things that the J&J center
11 did. Correct?
12 A. The J&J center supported infrastructure,
13 so this is infrastructure quality assurance.
14 Reliability efforts are infrastructure activities.
15 Q. And then I don't understand. We've got a
16 J&J funds and a core allocation. What does that
17 mean?
18 A. That we are allocating these funds listed
19 here and the core allocation means we represented
20 what proportion of the core are for these expenses
21 Q. Do I understand you to be saying that the
22 J&J funds that are listed here are being allocated
23 for the clinical trials core?
24 A. Yes. These are the funds in dollars in
25 percentage of the core that were allocated to these
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Joseph Biederman
February 27, 2009

Page 518

1 activities.
2 Q. And then in addition to the J&J funds that
3 go to the respective cores, we have a center
4 allocation. Correct?
5 A. Yes.
6 Q. And where does the center allocation money
7 come from?
8 A. The center had the total budget that was
9 500,000 minus 25 percent, ;
10
11
12 Q. And what is the center contribution? What
13 is that?
14 A. I cannot tell you how we calculated that.
15 But it's all -- The dollar amounts are here probably
16 are the most straightforward. It's what percentage
17 -- Some of these calculations represent what
18 percentage of the total budget of the 500,000 minus
19 25 percent were allocated to these individual
20 activities
21 Q. Let me ask you this. If I took all of the
22 J&J funding that's listed in these respective cores
23 and added that up, would it or should it have come
24 up to \$500,000?
25 A. \$500,000 minus the 25 percent the hospital
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Joseph Biederman
February 27, 2009

Page 519

1 takes in overhead.
2 Q. And for the record, the attachments that
3 we have been looking at, these documents here that
4 are attached, are actually J&J Center documents.
5 Correct?
6 A. I don't know who they are.
7 Q. Well, you made the allocations and it
8 appears that they're assigned according to core.
9 You can't tell me that those are J&J documents?
10 MR. SPIVACK: Objection, asked and
11 answered.
12 A. I do not know.
13 Q. You don't know?
14 A. No.
15 (Biederman Deposition Exhibit 32 marked
16 for identification)
17 BY MR. FIBICH:
18 Q. Dr. Biederman, does it benefit you when
19 you do clinical trial research?
20 A. Could you define benefit?
21 Q. Is there some benefit to you? Does it
22 enhance your standing in the scientific community?
23 Does it enhance your standing with respect to your
24 university? You know, is there some benefit to you
25 in doing clinical research?
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Joseph Biederman
February 27, 2009

Page 520

1 A. Research is expensive and requires
2 continuous support.
3 Q. But as I understand you, you do clinical
4 research because of your background and knowledge
5 and you want to benefit mankind. Correct?
6 A. I do research to advance knowledge, yes.
7 Q. And in addition to that, is there a
8 benefit to you in doing this research?
9 A. You need to define what benefit means.
10 Q. Well, do you understand what the word
11 benefit means?
12 A. I know what benefit means.
13 Q. Something of value to you.
14 A. The value is advancing of science.
15 Q. That's the only value you get? You don't
16 get -- It doesn't help your prestige, it doesn't
17 help you with regard to your recognition by your
18 peers? It doesn't help you in any other way?
19 A. Not necessarily. To do research is to
20 advance science and knowledge and I'm very proud to
21 be able to advance science and knowledge. You are
22 using the word "benefit" as I understand by the
23 passage as a commercial benefit. I don't sell
24 T-shirts, I don't have any benefit of that kind.
25 Advancing knowledge is an abstraction and I believe
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Joseph Biederman
February 27, 2009

Page 521

1 that advancing knowledge is good for humanity. All
2 of us benefit from advancements in medicine that we
3 can have better treatments, save lives and so on and
4 so forth. That is very costly and cannot be done
5 without money.
6 Q. Now, Dr. Biederman, I didn't mean to
7 suggest that there's anything wrong in being
8 benefited by your science. And I object to your
9 last statement as being nonresponsive. I'm not
10 suggesting that there's something wrong with it. My
11 point is that if you go and do these things and you
12 publish, doesn't that benefit your standing in the
13 relevant scientific community that you practice in?
14 A. I do not do it to advance my standing. I
15 do it to advance knowledge.
16 Q. Then why do you make a big list of
17 everything and make your résumé or C.V. a hundred
18 and some pages long?
19 A. These are factual. These are facts on the
20 ground.
21 Q. The exhibit that I've given you, Exhibit
22 Number 32 -- is it?
23 A. Yes.
24
25
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Joseph Biederman
February 27, 2009

Page 522

1
2 A. May I read it?
3 Q. Sure.
4 A. Tell me, which part are you -- ? There
5 are several studies here. Which one are you
6 reading?
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Joseph Biederman
February 27, 2009

Page 523

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Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 524

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Q And when you would do clinical trials, you would get a principal investigator fee Right?

A Sometimes I collected very little solely from clinical trials I'm not sure in this study I collected anything

Q And you've earlier testified that risperidone can cause weight gain, hyperprolactinemia, and disturbances of glycemic and lipid control?

A Yes.

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Joseph Biederman
February 27, 2009

Page 525

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Q And can lead to diabetes?
A Yes
(Biederman Deposition Exhibit 33 marked for identification.)
BY MR FIBICH:
Q Doctor, let me show you what I believe is 33. I want to ask you what this is.

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Joseph Biederman
February 27, 2009

Page 526

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A I know Dr. Gharabawi, Dr Mahmoud, and Dr Pandina

Q How about Mr. Kent Bockes?

A I don't remember who he was

Q He's a marketing guy. Did you know that?

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<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 527</p> <p>1 A. I have no idea. 2 MR. SPIVACK: Objection, asked and 3 answered. 4 BY MR. FIBICH: 5 Q. I'm sorry? 6 MR. SPIVACK: Same objection. 7 A. I don't know who he was. 8 MR. FIBICH: Okay, you don't know who he 9 is, right. 10 (Biederman Deposition Exhibit 34 marked 11 for identification.) 12 BY MR. FIBICH: 13 Q. What is the Center for Child and 14 Adolescent Psychiatric Research? 15 A. I have no idea. 16 I think that this is the J&J Center; this 17 meant the J&J Center. Maybe at that time I did 18 not -- I wanted to make sure that the center's 19 funding are clear, so I renamed it the J&J Center 20 for the Study of Pediatric Psychopathology. 21 22 23 24 25</p> <p style="text-align: center;">Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 528</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Q. And who is Mr. Kent Bockes? A. I don't remember what his position was.</p> <p style="text-align: center;">Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 529</p> <p>1 Q. Then you are also in a foundation as a 2 director that is involved with research into issues 3 dealing with pediatric bipolar, are you not? 4 A. We had the funding from the Prechter 5 Foundation -- 6 Q. From which foundation? 7 A. Prechter. Prechter, it's the name of an 8 individual who has bipolar illness, he committed 9 suicide, and his family formed a foundation and the 10 money we got, I believe half a million dollars, to 11 study the genetics of bipolar illness. 12 Q. What is the name of that foundation? 13 A. Prechter, P-r-e-c-h-t-e-r. It's Michigan- 14 based; I think it's a Detroit-based foundation. 15 Q. Are you on the board of this foundation? 16 A. No. 17 Q. What do you have to do with the 18 foundation? 19 A. We applied for funds. 20 Q. And do you receive funds from it? 21 A. Yes. 22 Q. Is this foundation funded by 23 pharmaceutical companies in addition to -- 24 A. No. 25 Q. Let me finish my question, please. -- in Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 530</p> <p>1 addition to the Prechter family? 2 A. Not that I know. 3 Q. Not that you know. Are there any other 4 foundations that you have relationships with? And 5 in particular I'm concerned about directorships. 6 A. I am not in any directorship of any 7 foundation. 8 Q. Have you ever been a director of any 9 foundation? 10 A. No. 11 Q. No? Is that right? 12 A. That's right. 13 Q. Sir, has the issue of who funds a study 14 been studied by scientists to determine whether or 15 not that in and of itself may potentially create a 16 bias in the study? 17 A. Not that I know of. 18 Q. Are you familiar with a psychiatrist by 19 the name of John Davis? 20 A. I believe that John Davis is the president 21 of Mount Sinai Medical School. 22 Q. And he is a psychiatrist? 23 A. Yes. 24 Q. Do you know Mr. Davis? Dr. Davis. 25 A. I do not know personally. I know his Stratos Legal Services 800-971-1127</p>

<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 531</p> <p>1 name.</p> <p>2 Q. And do you know his reputation in the</p> <p>3 psychiatric community?</p> <p>4 A. I know that he is an expert in</p> <p>5 schizophrenia.</p> <p>6 (Biederman Deposition Exhibit 35 marked</p> <p>7 for identification.)</p> <p>8 BY MR. FIBICH:</p> <p>9 Q. Why is it that you think he is an expert</p> <p>10 in schizophrenia?</p> <p>11 A. Because he writes papers on schizophrenia.</p> <p>12 Q. And do you find him to be authoritative</p> <p>13 with respect to the papers that he has done with</p> <p>14 respect to schizophrenia?</p> <p>15 A. I don't have an opinion. Schizophrenia is</p> <p>16 not my area of expertise. I know that he writes on</p> <p>17 schizophrenia.</p> <p>18 Q. Let me show you an article that has</p> <p>19 appeared in The Washington Post. You probably</p> <p>20 haven't read this since you don't read newspapers.</p> <p>21 Sir, just on the first page, this article</p> <p>22 which was written in 2006 says "Pharmaceutical giant</p> <p>23 Eli Lilly & Co. recently funded five studies that</p> <p>24 compared its antipsychotic drug Zyprexa with</p> <p>25 Risperdal, a competing drug made by Janssen All Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 532</p> <p>1 five showed Zyprexa was superior in treating</p> <p>2 schizophrenia. But when Janssen sponsored its own</p> <p>3 studies comparing the two drugs, Risperdal came out</p> <p>4 ahead in three out of four. In fact, when</p> <p>5 psychiatrist John Davis analyzed every publicly</p> <p>6 available trial funded by the pharmaceutical</p> <p>7 industry pitting five new antipsychotic drugs</p> <p>8 against one another, nine in ten showed that the</p> <p>9 best drug was the one made by the company funding</p> <p>10 the study. 'On the basis of these contrasting</p> <p>11 findings in head-to-head trials, it appears that</p> <p>12 whichever company sponsors the trial produces the</p> <p>13 better antipsychotic drug,' Davis and others wrote</p> <p>14 in the American Journal of Psychiatry."</p> <p>15 Did you read the article that he prepared</p> <p>16 for the American Journal of Psychiatry on this</p> <p>17 subject?</p> <p>18 A. No.</p> <p>19 Q. Assume with me that this study contains</p> <p>20 the conclusion that is set forth in this article.</p> <p>21 Does it surprise you that the pharmaceutical company</p> <p>22 that sponsors the trial is the one that comes out</p> <p>23 ahead?</p> <p>24 MR. SPIVACK: Objection, argumentative,</p> <p>25 speculation, no foundation. Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 533</p> <p>1 A. I have no idea. I need to read the</p> <p>2 article.</p> <p>3 Q. What article?</p> <p>4 A. The article that Dr. Davis published in</p> <p>5 American Journal of Psychiatry.</p> <p>6 Q. And if you read that and his conclusions</p> <p>7 were that the company that sponsored the trial was</p> <p>8 the one that came out ahead, would that make you</p> <p>9 think that there is a potential money bias in who</p> <p>10 funds studies?</p> <p>11 MR. SPIVACK: Objection, multiple levels</p> <p>12 of speculation, no foundation, argumentative.</p> <p>13 A. A clinical trial is sensitive to the</p> <p>14 instrumentation that you use, the type of patients</p> <p>15 that you recruit, the length of follow-up,</p> <p>16 et cetera, et cetera. Doctors in practice in</p> <p>17 weighing risk and benefit take into consideration</p> <p>18 effective treatments.</p> <p>19 All of these studies show individually</p> <p>20 efficacy against placebo, so these are approved</p> <p>21 drugs. So the relative superiority of one over</p> <p>22 another is a matter of debate like saying that only</p> <p>23 Honda produces better cars than Chevrolet, so the</p> <p>24 Honda advertising will favor one over the other.</p> <p>25 But each of these compounds showed efficacy in their Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 534</p> <p>1 approved indications by the FDA for schizophrenia.</p> <p>2 In the decision about which drug to use,</p> <p>3 doctors not only take data from these head-to-head</p> <p>4 comparisons that are very difficult to execute,</p> <p>5 because when you have an effective treatment, it's</p> <p>6 very difficult to show superiority against another</p> <p>7 treatment. So the weighing of the evidence is, is</p> <p>8 the drug effective in the condition that I want to</p> <p>9 use it? What are the side effects of one or the</p> <p>10 other? And those are the decisions that clinicians</p> <p>11 use in selecting a drug.</p> <p>12 MR. FIBICH: Objection, nonresponsive.</p> <p>13 BY MR. FIBICH:</p> <p>14 Q. This article goes on to say "Such studies</p> <p>15 make up the bulk of the evidence that American</p> <p>16 doctors rely on to prescribe \$10 billion worth of</p> <p>17 antipsychotic medications each year." Were you</p> <p>18 aware of this figure as a proposed figure for the</p> <p>19 cost of antipsychotic medications each year?</p> <p>20 MR. SPIVACK: Objection, no foundation.</p> <p>21 A. I do not know how much money is spent on</p> <p>22 antipsychotic medications.</p> <p>23 Q. Do you currently use Risperdal at your</p> <p>24 clinics?</p> <p>25 A. Yes, I do. Stratos Legal Services 800-971-1127</p>

Joseph Biederman
February 27, 2009

Page 543

1 at the department of psychiatry, Beth Israel Medical
2 Center in New York City. Is that correct?
3 MR. SPIVACK: Objection, no foundation,
4 calls for speculation.
5 BY MR. FIBICH:
6 Q. Does the article suggest to you that this
7 is sponsored in part by the people at the department
8 of psychiatry, Beth Israel Medical Center?
9 MR. SPIVACK: Objection, calls for
10 speculation, no foundation.
11 A. The answer is yes.
12 MR. SPIVACK: Excuse me. Calls for
13 speculation, no foundation.
14 BY MR. FIBICH:
15 Q. The answer is yes?
16 A. There is a notice here, yes.
17 Q. Okay.
18 And the background is that pharmaceutical
19 industry funding of psychiatric research has
20 increased significantly in recent decades, raising
21 the question of the relationship between
22 pharmaceutical company funding of clinical
23 psychiatric studies and the outcomes of those
24 studies, and that this study examines that
25 relationship. Do you see that?
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Joseph Biederman
February 27, 2009

Page 544

1 A. I see that.
2 Q. And that's what we've been talking about
3 Correct?
4 A. We have been talking about a lot of
5 things
6 Q. Well, the most recent thing we were
7 talking about is the relationship between outcomes
8 of clinical trials and its relationship to
9 pharmaceutical funding. Correct?
10 MR. SPIVACK: Objection, misstates the
11 testimony
12 A. As I told you a few times before, the
13 studies that compare two compounds are different
14 than registration studies that establish safety and
15 efficacy that compare against placebo. Some studies
16 may examine the impact of medicines in several
17 aspects of the illness, such as quality of life. So
18 the basic studies that lead to registration and
19 approval of a compound for the FDA meet a very high
20 standard of quality that is acceptable to the most
21 stringent reviewer on the Earth, that is the FDA.
22 So what these studies, and I do not know
23 what are these studies, I suspect that they are
24 studies similar to what Dr. Davis was talking
25 before, this kind of head-to-head comparison trying
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 545

1 to see if there is some advantage to one compound in
2 a class versus another compound in the class. Which
3 is a different agenda than establishing safety and
4 efficacy of an individual compound.
5 MR. FIBICH: Objection, nonresponsive.
6 BY MR. FIBICH:
7 Q. Sir, under Results, would you read those
8 results for our jury as reflected in the abstract?
9 MR. SPIVACK: Objection, no foundation.
10 A. "The percentage of studies sponsored by
11 drug companies increased from 25 percent in 1992 to
12 57 percent in 2002." You want me to continue?
13 Q. Please. Read the entire results section.
14 MR. SPIVACK: Same objection, calls for
15 speculation, no foundation.
16 A. "Favorable outcomes were significantly
17 more common in studies sponsored by the drug
18 manufacturer, 78 percent, than in studies without
19 industry sponsorship, 48 percent, or sponsored by a
20 competitor, 28 percent. These relationships
21 remained after controlling for the effects of
22 journal, year, drug studies, studied -- sorry --
23 time since FDA drug approval, diagnosis, sample
24 size, and selected study design variables."
25 Q. And would you read the conclusion of the
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Joseph Biederman
February 27, 2009

Page 546

1 authors of this paper?
2 MR. SPIVACK: Same objection, calls for
3 speculation, no foundation.
4 A. "These data indicate an association
5 between pharmaceutical industry funding of clinical
6 studies and positive outcomes of those studies."
7 Q. And you --
8 A. Let me finish. "Further research is
9 needed to elucidate the mechanisms underlying this
10 relationship."
11 Q. And you had never read this study before
12 today. Is that correct?
13 A. I did not.
14 (Biederman Deposition Exhibit 37 marked
15 for identification.)
16 BY MR. FIBICH:
17 Q. Let me show you 37, ask you to review that
18 abstract for me. (Pause)
19 Have you had a chance to look over this,
20 sir?
21 A. The abstract, yes.
22 Q. And this is from another medical journal?
23 MR. SPIVACK: Objection, no foundation.
24 A. It is another medical journal, yes.
25 Q. Sir?
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 535

1 Q. Do you currently use Invega in your
2 clinics?
3 A. Yes, I do.
4 Q. Do you currently use generic Risperdal in
5 your clinics?
6 A. Yes, I do.
7 Q. Is the generic Risperdal as effective as
8 Risperdal?
9 A. I did not study that. I cannot tell you.
10 Patients frequently complain when they are switched
11 to generic that the efficacy is lost.
12 Q. But you have no basis to know whether
13 that's true or not, do you?
14 A. I have basis to know that patients
15 complain to me when switched to generic that they
16 are not doing as well as with the compound that I do
17 before.
18 Q. The next-to-last paragraph of this article
19 says "Reliance on industry-sponsored studies is not
20 limited to psychiatry, but experts say the problem
21 is exacerbated in areas of medicine where the goal
22 of trials is not to demonstrate cures but to measure
23 symptomatic relief, which allows more latitude in
24 how the results are interpreted and marketed." Do
25 you agree with that statement?

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Joseph Biederman
February 27, 2009

Page 536

1 A. Ninety percent or more of medicine is
2 symptomatic relief. Medicine can cure very little
3 conditions. With exception of infections, which are
4 bacteria, we are very ineffective in curing
5 anything. What we can do in medicine, however, is
6 to allow people to have a decent life despite having
7 the disease.
8 MR. FIBICH: Objection, nonresponsive.
9 BY MR. FIBICH:
10 Q. Do you believe you get a less biased
11 result from publicly funded studies than studies
12 that are funded by pharmaceutical companies?
13 A. No.
14 Q. If you would, turn to the second page,
15 down to the third paragraph starting with "Davis
16 warned." Do you see that?
17 A. Yes.
18 Q. And tell the jury who Davis is again.
19 A. Dr. Davis is I believe currently the
20 president of Mount Sinai School of Medicine.
21 Q. And where is that?
22 A. In New York.
23 Q. It says "Davis warned that the circular
24 results he found could undermine the confidence of
25 clinicians and patients and even cast doubt on
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Joseph Biederman
February 27, 2009

Page 537

1 medications that are genuinely superior. He and
2 Rennie," who is Drummond Rennie, the editor of the
3 Journal of The American Medical Association. Do you
4 know Dr. Rennie?
5 A. I do not know him personally.
6 Q. But you know he is the deputy editor of
7 the JAMA?
8 A. I actually do not know, and I'm glad that
9 you are pointing out to me.
10 Q. He says "He and Rennie also questioned
11 academic researchers' role in these studies." And
12 an academic researcher is someone such as yourself.
13 Correct?
14 A. Yes.
15 Q. "Says Davis, who joked in an interview
16 that he no longer gets to fly first class to Tokyo
17 and Monte Carlo since he stopped accepting money
18 from pharmaceutical companies, guessed that 90
19 percent of industry-sponsored studies that boast a
20 prominent academic as the lead author are conducted
21 by a company that later enlists a university
22 researcher as the author. 'We know that happens all
23 the time,' Rennie said. 'The only reason that the
24 company wants a non-company person as an author is
25 to give credence to an advertisement. The whole

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Joseph Biederman
February 27, 2009

Page 538

1 entire paper from start to finish is an
2 advertisement. It is a much more subtle and telling
3 ad than anything they can publish as an ad." Did
4 I read that correctly?
5 A. You read it very well.
6 Q. And do you agree that when a company uses
7 you as an author, it gives credence to an
8 advertisement if the paper promotes their product as
9 a safe and effective drug for the treatment of a
10 condition that you studied?
11 MR. SPIVACK: Objection, argumentative,
12 calls for speculation, no foundation.
13 A. A clinical trial is a scientific exercise.
14 Patients are blindly assigned to drug or placebo.
15 Patients from very different parts of the country,
16 different centers, parts of the world participate.
17 The findings are collected exhaustively. They are
18 judged by the FDA -- I am talking about registration
19 studies -- to be adequate to establish safety and
20 efficacy. I can hardly consider results of a
21 clinical trial as advertising.
22 MR. FIBICH: Objection, nonresponsive.
23 BY MR. FIBICH:
24 Q. Dr. Davis thinks so, does he not?
25 A. It's a free --

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Joseph Biederman
February 27, 2009

Page 539

1 MR. SPIVACK: Objection, calls for
2 speculation.
3 A. I said it's a free country. People can
4 think whatever they want.
5 Q. Well, if the position of Dr. Davis is
6 accurately reflected in the article that we've been
7 reading, he certainly thinks that a scientific paper
8 sponsored by a pharmaceutical company with an
9 academic researcher and author is an advertisement,
10 doesn't he?
11 MR. SPIVACK: Objection, argumentative,
12 calls for speculation, no foundation.
13 A. Dr. Davis can think whatever he wants. We
14 are a free society and we encourage free thinking.
15 If I agree to what he says or not is a different
16 question, and I don't
17 Q. And you have never seen any studies that
18 studied the relationship between an outcome of a
19 clinical trial and who pays for the clinical trial.
20 Is that correct?
21 MR. SPIVACK: Objection, asked and
22 answered.
23 A. I have seen clinical trials that were
24 negative funded by pharmaceutical companies, so...
25 Q That's not my question, sir. Objection,
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Joseph Biederman
February 27, 2009

Page 540

1 nonresponsive. Listen to my question; I'm trying to
2 get through.
3 Have you seen any studies that studied the
4 relationship between who funds a study and the
5 outcome of that study?
6 MR. SPIVACK: Objection, asked and
7 answered.
8 A. You mentioned this study here in this
9 article.
10 Q. But you'd never seen that study before
11 today, have you?
12 A. I have not seen this study specifically,
13 no.
14 Q. And if you were to see the studies, might
15 that help persuade you that who pays for a clinical
16 trial may determine in some part its outcome?
17 MR. SPIVACK: Objection, calls for
18 speculation, no foundation.
19 MR. FIBICH: Well, let's do it this way.
20 Let's mark that.
21 (Biederman Deposition Exhibit 36 marked
22 for identification)
23 BY MR. FIBICH:
24 Q. Doctor, have you had a chance to look over
25 Exhibit 36?
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Joseph Biederman
February 27, 2009

Page 541

1 MR. SPIVACK: If you're going to ask him
2 about this exhibit, I think he needs more than
3 25 seconds to take a look at it.
4 MR. FIBICH: Okay. Tell me when you're
5 ready.
6 A. What would you like me to read, the entire
7 paper or parts of it?
8 Q. You can read as much of it or as little of
9 it as you want. And if you want to read more,
10 I certainly don't want to deprive you of that
11 opportunity. Okay?
12 A. The only thing I can read is the abstract.
13 Is that agreed upon?
14 Q. Okay. Well, the abstract is a summary.
15 A. This paper has a few pages. I cannot read
16 in two minutes.
17 Q. No, no, my question to you, sir, is a
18 simple one. An abstract is a summary of the paper
19 itself, is it not?
20 A. It is. But does not have details of the
21 paper itself.
22 Q. Sure. Do you want me to ask you some
23 questions or do you want to study this?
24 A. Let me read it first and then --
25 Q. Please take your time.
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 542

1 A. Let me read it at least. No?
2 Q. Sure.
3 A. (Pause) Okay.
4 Q. All right. First of all, this is a
5 peer-reviewed article that has been published in a
6 scientific journal. Correct?
7 A. That's correct.
8 Q. And that scientific journal is the Journal
9 of Psychological Medicine. Correct?
10 A. It's called Psychological Medicine.
11 Q. Okay, Psychological Medicine. And that is
12 a scientific journal that you recognize as being
13 authoritative in the area in which it is
14 disseminated. Correct?
15 MR. PECK: Objection, foundation.
16 A. It's a good journal.
17 Q. It's a good journal, okay. And this is a
18 scientific study, is it not?
19 A. It appears to be.
20 Q. And it is done by a number of individuals.
21 Do you know any of these people that are listed?
22 A. No.
23 Q. None?
24 A. None.
25 Q. It appears that it was done by individuals
Stratos Legal Services
800-971-1127

<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 547</p> <p>1 A. It is another medical journal. 2 Q. This appears to be a medical journal from 3 Denmark. Is that correct? 4 MR. SPIVACK: Objection, no foundation. 5 A. I think it's a British Medical Journal. 6 Q. Okay. BMJ would be an acronym for British 7 Medical Journal. Is that correct? 8 A. Yes. 9 Q. And you understand British Medical Journal 10 to be a prestigious journal? 11 A. Yes. 12 Q. And this abstract concludes like the 13 abstract we previously looked at, that being that 14 industry-supported reviews of drugs should be read 15 with caution because they are less transparent and 16 have methodological limitations. Correct? 17 MR. SPIVACK: Objection, calls for 18 speculation, no foundation. 19 A. I think that this pertain to reviews, not 20 necessarily to the source studies. 21 Q. What do you understand the conclusion of 22 this research to be? 23 MR. SPIVACK: Objection, calls for 24 speculation, no -- 25 A. I need to read the paper more carefully. Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 548</p> <p>1 I have no idea what kind of analysis they are doing, 2 what areas of medicine they're investigating and so 3 on and so forth 4 Q. So you can't tell me what the conclusion 5 of this paper is from the abstract? 6 A. I cannot. 7 (Biederman Deposition Exhibit 38 marked 8 for identification) 9 BY MR. FIBICH: 10 Q. Doctor, I earlier understood you to say 11 that you were not associated with any foundations. 12 Is that correct? 13 A. You asked me if I am in the board of 14 directors of foundation. I have been a scientific 15 adviser for some foundations 16 Q. What foundations are you a scientific 17 adviser for? 18 A. I've been in scientific board of the Child 19 and Adolescent Bipolar Foundation and I have been in 20 scientific advisory board of, I do not remember the 21 name because it has changed, the Association of 22 Bipolar -- Depression and Bipolar -- I'm sorry, I 23 don't remember the correct name, but it's an 24 association that supports the patient in bipolar 25 illness Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 549</p> <p>1 Q. Let me show you 38. 2 3 4 A. I am in the scientific advisory board. 5 6 7 A. Professional, okay, sorry. Professional 8 advisory board. 9 Q. And with respect to this foundation, does 10 this foundation support research into bipolar 11 disease? 12 A. Not at all. The foundation supports 13 families in desperate straits with their young ones. 14 Q. So the answer is no? 15 A. The answer is no. 16 Q. And in this foundation, the development 17 director is asking Mr. Bockes with Janssen for a 18 contribution. Is that correct? 19 A. It appears to be. 20 Q. And are you paid for your work on this 21 advisory board? 22 A. No. 23 Q. Do you receive an honorarium? 24 A. No. 25 Q. Do you receive travel expenses? Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 550</p> <p>1 A. No. 2 Q. Do you attend meetings of this 3 organization? 4 A. Not particularly. The organization has 5 meetings during the child psychiatry meetings that 6 if I attend the child psychiatry meeting, I attend 7 their meeting. Otherwise I don't. 8 9 10 11 12 13 14 15 Q. How much have you contributed? 16 A. A few hundred personally. Not for the 17 institution. I contribute a few hundred dollars a 18 year as a charitable contribution. 19 Q. Do you have a relationship with the Sang 20 Foundation? 21 A. Yes, I have a relationship with the Sang 22 Foundation. 23 Q. What is the Sang Foundation? 24 A. The Sang Foundation is the Sang family had 25 the tragedy of losing their I believe 21-year-old Stratos Legal Services 800-971-1127</p>

Joseph Biederman
February 27, 2009

Page 551

1 young son from suicide secondary to bipolar illness,
2 so they are very interested in supporting activities
3 to educate the public on bipolar illness in the
4 young. So they have supported, agreed to support
5 the conference that I have been running for last six
6 years funded by the NIMH when I run out of funds
7 from NIMH. They agreed to continue the funding so
8 we can carry on the conference.

9 Q. And what conference are you talking about?

10 A. The pediatric bipolar conference that we
11 have been running for last six, seven years.

12 Q. And where is that bipolar conference held?

13 A. It has been held in different parts of the
14 country.

15 Q. Name some of them.

16 A. Boston, Miami, Washington.

17 Q. And this is funded by the Sang Foundation
18 sometimes?

19 A. No. The foundation only funds, is going
20 to fund it this year because the moneys that we got
21 from the NIMH run out. They did not renew. It was
22 a five-year grant and we run it for six years with
23 no cost extension and --

24 Q. I'm sorry. What is NAMH?

25 A. National Institute of Mental Health.
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Joseph Biederman
February 27, 2009

Page 552

1 Q. Okay, I didn't understand you. That's
2 federal funding. Correct?

3 A. Federal funding, yes.

4 Q. And they no longer are going to fund it,
5 so the Sang Foundation is going to fund it this
6 year. Correct?

7 A. Correct.

8 Q. And where is the conference going to be
9 held this year?

10 A. In Boston.

11 Q. And in what amount did they fund this
12 bipolar conference?

13 A. \$50,000.

14 Q. And what does that \$50,000 go to?

15 A. To travel stipends and renting a room at
16 the hotel.

17 Q. And when is that conference?

18 A. That conference should be held the last
19 Friday of March.

20 Q. Do you need something to drink?

21 A. Maybe. You know what? Maybe you can give
22 me some water. Thank you. I apologize.

23 Q. Was Mr. Sang a patient of yours?

24 A. No.

25 Q. Was he a patient of Mass. General?
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 553

1 A. No.

2 Q. The pediatric bipolar conference that will
3 be held in Boston in March, where will it be held?

4 A. The Charles Hotel. The Charles Hotel in
5 Cambridge.

6 Q. And will you be a presenter at that
7 conference?

8 A. I am the chair of the conference.

9 Q. Is there an agenda?

10 A. Yes, there is an agenda.

11 Q. If I wanted to attend that conference
12 would I be allowed in?

13 A. You need to get an invitation and a reason
14 to attend. The conference is limited to people that
15 are working on pediatric bipolar illness.

16 Q. So it's an invitation only?

17 A. It's by invitation for people. It's not
18 very difficult to get an invitation, but have to be
19 people -- It's not open to the public because we
20 don't have room for anybody that wants to walk in.

21 Q. Well, will you send me an invitation?

22 A. Why would I send you an invitation?

23 Q. Because I'm interested in the subject.

24 I've had the pleasure of meeting you here these last
25 two days and this issue of pediatric bipolar disease
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 554

1 is something of interest to me.

2 MR. SPIVACK: Objection, argumentative.

3 BY MR. FIBICH:

4 Q. Will you give me an invitation?

5 A. Probably not.

6 MR. SPIVACK: Same objection.

7 A. Probably not. I don't think that somebody
8 like yourself that has venomous views on the
9 subject, hasn't any good intentions for the field,
10 should attend the conference. The idea is to try to
11 advance the field, not to bury it.

12 Q. And is it your opinion I'm trying to hurt
13 that field?

14 A. I think that you don't hold great views on
15 the subject, from what I heard in your questioning.

16 Q. Well, who do you invite to this
17 conference?

18 A. People that are working on pediatric
19 bipolar illness.

20 Q. And who determines that? I mean, do you
21 have somebody that goes out and searches the
22 literature or do you solicit people that may be
23 interested? How does it work?

24 A. I invite my colleagues, people that
25 publish on the subject, and I encourage them to
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 555

1 invite their junior faculty that are interested,
2 residents and fellows that are interested on the
3 subject. But all the people that attend are people
4 that published something or has done some scientific
5 work on the subject of bipolar illness.

6 Q. Now, I thought you indicated that there'd
7 been one in Miami. There's one in Coral Gables. Is
8 that what you're referring to?

9 A. Yes, that's what I refer to.

10 Q. Will there be any industry people at this
11 particular conference? And by that I mean
12 pharmaceutical industry people.

13 A. Not that I particularly know. In some
14 pharmaceutical companies they have scientists that
15 are interested in pediatric bipolar and if so, they
16 will be invited.

17 Q. So there will be employees from
18 pharmaceutical companies invited that have a
19 particular interest in the subject of pediatric
20 bipolar disorder. Correct?

21 A. Sometimes they have been invited. It is
22 not something that I particularly court, but in some
23 pharmaceutical companies they are very involved in
24 pediatric bipolar.

25 Q. Well, you have one coming up at the end of
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 556

1 March. Have you gotten your invitation list
2 prepared yet?

3 A. I think we sent -- The invitations have
4 been sent long time ago. I am not sure. I cannot
5 tell you on top of my head if there is anybody from
6 pharmaceutical. But if there is somebody from
7 pharmaceutical, it's going to be isolated event.
8 The majority are scientists in the field in
9 academia.

10 Q. Do you know what a key opinion leader is?

11 A. I don't know how it's defined.

12 Q. Well, do you know whether or not you are
13 considered a key opinion leader by Janssen?

14 A. I believe I am.

15 Q. And what do you understand a key opinion
16 leader to be?

17 A. I do not know how Janssen thinks about key
18 opinion leaders, but I interpret as people that have
19 done good academic work.

20 Q. Someone that has a good reputation?

21 A. Someone that has good reputation.

22 Q. Someone that is a leader in forming
23 opinions?

24 A. I do not know what that means, forming
25 opinions.

Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 557

1 (Biederman Deposition Exhibit 39 marked
2 for identification.)

3 BY MR. FIBICH:

4 Q. Doctor, the court reporter has marked as
5 Exhibit 39 a Wall Street Journal article in July of
6 2006 entitled Financial Ties to Industry Cloud Major
7 Depression Study; At Issue: Whether It's Safe for
8 Pregnant Women to Stay on Medication; JAMA Asks
9 Authors to Explain. That's the title of this
10 article. Correct?

11 A. Correct.

12 Q. Now, this article cites psychiatrists at
13 Massachusetts General Hospital. You see that in the
14 first sentence of the second paragraph?

15 A. Yes, mm-hmm.

16 MR. SPIVACK: Objection, foundation.

17 BY MR. FIBICH:

18 Q. Are you aware of the controversy that is
19 referenced in this article?

20 A. Yes, I am.

21 Q. You said "yes and no"?

22 A. Yes, I am.

23 Q. Okay. Tell me what you understand the
24 controversy to be.

25 A. Dr. Cohen did a study funded by the
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 558

1 National Institutes of Health examining whether
2 women that are pregnant with depression should
3 continue on their antidepressants or not. The study
4 found that women that continue on antidepressant had
5 better outcomes than those that did not.

6 It was not a particular drug, was not
7 funded by any pharmaceuticals. The controversy
8 arose that Dr. Cohen did not disclose his ties to
9 pharmaceuticals. His understanding was that since
10 this study was funded by the National Institutes of
11 Health and not by a pharmaceutical company, he was
12 in no obligation to disclose.

13 So this is what actually happened. The
14 demonization of the study and the conduct is in the
15 eyes of the beholder.

16 Q. Well, are you saying that this statement
17 in the middle of the third paragraph, "The lead
18 author" -- You know Dr. Cohen, do you not?

19 A. I do know Dr. Cohen, yes.

20 Q. So the lead author, Lee S. Cohen, a
21 Harvard Medical School professor like yourself.
22 Correct?

23 A. Yes. Where are you reading?

24 Q. Go down to the third paragraph.

25 A. One, two, three.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 559

1 Q. The second sentence, starting with "The
2 lead author." You see that?
3 A. Yes.
4 Q. "Lee S. Cohen, a Harvard Medical School
5 professor and director of the perinatal and
6 reproductive psychiatry research program at
7 Mass. General, is a longtime consultant to three
8 antidepressant makers." Is that true?
9 A. I don't know Dr. Cohen's ties to
10 pharmaceuticals.
11 Q. Says he's a paid speaker for seven of
12 them. Is that true?
13 A. I have no idea. He does not share with
14 me --
15 Q. His research work is funded by four drug
16 makers. Do you know if that's true?
17 A. I do not know. I do know that the
18 research that was published in JAMA was funded by
19 none.
20 MR. FIBICH: Object as nonresponsive.
21 BY MR. FIBICH:
22 Q. That's not what I'm asking, sir. I'm
23 asking if this information that is contained in this
24 sentence is inaccurate to your knowledge.
25 A. I have no idea.
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 560

1 Q. "None of his financial ties were reported
2 in the study. In total, the authors failed to
3 disclose more than sixty different financial
4 relationships with drug companies." You don't know
5 what all his financial relationships with drug
6 companies are, do you?
7 A. I have no idea.
8 Q. Was Dr. Cohen one of the doctors that was
9 investigated by the committee at Mass. General?
10 A. No.
11 Q. Do you know if he was investigated because
12 of his ties to drug companies as a result of this
13 controversy?
14 A. To my knowledge, he was not investigated.
15 Q. It says "Dr. Cohen and some of his
16 co-authors subsequently hit the lecture circuit,
17 telling physicians about their findings while also
18 spotlighting flaws in other recent studies that have
19 found increased risks to babies born to mothers who
20 use antidepressants." And that's what you have done
21 on behalf of Janssen, you've gone on the lecture
22 circuit telling physicians about your findings with
23 respect to Risperdal and spotlighting flaws in other
24 companies' drugs. Isn't that correct?
25 MR. SPIVACK: Objection, to form, no
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 561

1 foundation --
2 A. Absolutely not.
3 MR. SPIVACK: Objection.
4 THE WITNESS: I'm sorry
5 MR. SPIVACK: Argumentative, misstates the
6 testimony.
7 BY MR. FIBICH:
8 Q. It goes on to say "The work of these
9 academic researchers highlights the role of opinion
10 or thought leaders coveted by drug companies because
11 of their ability to influence not only the practice
12 of doctors but popular opinion as well." Do you see
13 that, sir?
14 A. Yes, I see that.
15 Q. And that's what a key opinion leader does,
16 right, tries to influence the practice of doctors
17 and popular opinion?
18 MR. SPIVACK: Objection, argumentative,
19 misstates the testimony.
20 A. No. It's a free country and Mr. Armstrong
21 that also has similar views, toxic views about
22 psychiatry, writes venom. That does not mean that
23 it's true.
24 One more time, Dr. Cohen treats women that
25 have depression and bipolar illness and are
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 562

1 pregnant. It's a very difficult point in women's
2 life. Having an acute bout of depression or an
3 acute psychotic episode secondary to mania is a
4 catastrophic state of affairs for the women
5 affected. So I believe that Dr. Cohen is doing an
6 extraordinary job in consulting in one of the
7 highest-risk populations that are women during
8 pregnancy. His work did not allude to a particular
9 drug, did not say that use Prozac because it's
10 divine. His work compared women that continued
11 treatment with an antidepressant and women that did
12 not, and the work found that women that continued
13 with the antidepressant had better outcomes.
14 In going back to weighing risks and
15 benefits that doctors like Dr. Cohen and myself do,
16 you have to weigh the consequences and the tragedy
17 of a woman that wants to be a mother and may not be
18 able to be a mother because of depression. Those
19 are the women that he has to consult.
20 So the idea that there is some risk
21 potentially to the babies is something that he has
22 never said that it's absolutely free and it's a
23 vitamin. But the risk, the small risk that could be
24 to the baby pales compared to the risk to the baby
25 and the mother secondary to an acute bout of
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 563

1 psychiatric illness. This is the crossroad, this is
2 where the rubber meets the road, and this is the
3 same dilemma that I have: I have to weigh a child
4 that may kill or may commit suicide and I need to
5 treat. This is what is the intersection with my
6 clinical practice.

7 MR. FIBICH: Objection, nonresponsive.

8 BY MR. FIBICH:

9 Q. My question to you, sir, if you didn't
10 understand it, was that a key opinion leader's role
11 is to influence the practice of doctors and popular
12 opinion as well?

13 MR. SPIVACK: Objection.

14 BY MR. FIBICH:

15 Q. Isn't that right?

16 A. No.

17 MR. SPIVACK: Objection, asked and
18 answered, argumentative

19 BY MR. FIBICH:

20 Q. Now, the reason that Dr. Cohen in his
21 publication didn't mention any particular
22 antidepressant was because he's worked for all the
23 manufacturers. Right?

24 MR. SPIVACK: Objection, calls for
25 speculation, no foundation.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 564

1 BY MR. FIBICH:

2 Q. Do you know that?

3 A. No. He did not mention because the study
4 was funded by the National Institute of Health and
5 his understanding was that since the study was not
6 funded by pharmaceutical industry, the disclosure
7 may be irrelevant. This is the reason that he did
8 not disclose. Not to obscure critical information.

9 Q. So you think that ties to drug companies
10 is irrelevant information with respect to studies
11 that are published by someone that has those ties?

12 MR. SPIVACK: Objection, misstates the
13 testimony, argumentative

14 BY MR. FIBICH:

15 Q. Is that right?

16 MR. SPIVACK: Same objection.

17 A. Dr. Cohen did not disclose not because of
18 any demonic anything. Dr. Cohen's understanding of
19 his responsibilities of disclosing are limited to
20 studies that are funded by pharmaceutical companies.
21 To the best of my knowledge, Dr. Cohen has disclosed
22 extensively in his papers about his ties to
23 pharmaceutical companies. That's the reason that
24 this writer knows about that.

25 MR. FIBICH: Objection, nonresponsive.
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 565

1 MR. SPIVACK: If I might ask, Mr. Fibich,
2 do you know about how much longer you have?

3 MR. FIBICH: About an hour and twenty
4 minutes.

5 MR. SPIVACK: Then we should take a break
6 at this point.

7 MR. FIBICH: Okay, I think so too, give
8 our court reporter a break.

9 MR. SPIVACK: Yes.

10 THE VIDEOGRAPHER: The time is 3:38.
11 We're off the record.

12 (Short recess taken.)

13 THE VIDEOGRAPHER: We're back on the
14 record. This is tape number 5 and the time is
15 4:00 p.m.

16 BY MR. FIBICH:

17 Q. Dr. Biederman, we were talking about key
18 opinion leaders and their purpose, and you've
19 indicated that you recognize that you're a key
20 opinion leader of Janssen Pharmaceuticals. Correct?

21 A. I believe so.

22 Q. And what do you believe your
23 responsibilities are as a key opinion leader for
24 Janssen?

25 A. I don't have any responsibility as a key
Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 566

1 opinion leader. It is a designation that they use
2 to describe me. I don't have any contractual or
3 otherwise agreement to discharge my function of key
4 opinion leader.

5 Q. Earlier today you listed for us the people
6 that in your estimation form the group of most
7 renowned psychiatrists in the field of pediatric
8 bipolar disorder. Correct?

9 A. Correct.

10 Q. And that was yourself, Dr. Wozniak,
11 Barbara Geller, Gabrielle Carlson --

12 A. Carlson, yes.

13 Q. -- and Robert Findling. Right?

14 A. Yes.

15 Q. And are you aware that Gabrielle Carlson,
16 Robert Findling, Barbara Geller and Janet Wozniak
17 are also key opinion leaders for Janssen?

18 A. I have no idea.

19 Q. To your knowledge, does Dr. Wozniak have
20 relationships with Janssen?

21 A. I do not know. I have no idea what she
22 has.

23 Q. You don't know whether she consults with
24 them?

25 A. No.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 567

1 Q. You don't know whether she is an adviser
2 to them?

3 A. I do not know.
4 (Biederman Deposition Exhibit 40 marked
5 for identification.)

6 BY MR. FIBICH:

7 Q. It is your interpretation that key opinion
8 leaders is just a term that Janssen uses to describe
9 you, that they're not looking for anything in
10 particular when they want you as a key opinion
11 leader. Is that correct?

12 A. I have no idea what Janssen thinks about
13 the meaning of key opinion leader. You asked me a
14 different question. You asked me whether I think
15 that I am a key opinion leader. I think I am very
16 prominent and probably would be considered a key
17 opinion leader. My expertise is because of the
18 science that I have, not because of self-declaratory
19 anything. And so my influence in the field is
20 because of my scientific work.

21 Q. Regardless of the reason for you being a
22 key opinion leader, and let's assume it's because of
23 your standing in the scientific community, your
24 reputation, the body of work that you devoted your
25 life to, let's assume it's all of those things.

Stratos Legal Services
800-971-1127

Joseph Biederman
February 27, 2009

Page 568

1 What do you think the purpose of being a key opinion
2 leader is? To influence opinion?

3 A. I do not know.

4 Q. Do you think that being a key opinion
5 leader is related in any way to your status as a
6 principal investigator in scientific trials?

7 A. I don't think so. I think my status of
8 key opinion leader is because of the quality of my
9 research. I would say 80 to 90 percent of my work
10 has nothing to do with medications. And I
11 published, as you know if you looked at my C.V.,
12 I have more than 600 papers.

13 Q. Let me show you an exhibit that we've
14 marked as 40, if you would. Right there, sir.

Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 569

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11 (Biederman Deposition Exhibit 41 marked
12 for identification.)
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Q. And NIMH stands for what, sir?
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 570

1 A. National Institute of Mental Health.
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(Biederman Deposition Exhibit 42 marked
for identification.)

Stratos Legal Services
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<p>Joseph Biederman February 27, 2009</p> <p>Page 571</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Stratos Legal Services 800-971-1127</p>	<p>Joseph Biederman February 27, 2009</p> <p>Page 572</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>MR. FIBICH: I tell you what, let's do it this way. We'll come back to that question. (Biederman Deposition Exhibit 43 marked for identification.)</p> <p>Stratos Legal Services 800-971-1127</p>
<p>Joseph Biederman February 27, 2009</p> <p>Page 573</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Q. You don't remember. Are you getting tired? A. I am fine. Q. Okay. If for some reason your level of energy is such that you can't answer my questions, please let me know. A. I am more than capable to answer your questions.</p> <p>Stratos Legal Services 800-971-1127</p>	<p>Joseph Biederman February 27, 2009</p> <p>Page 574</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Stratos Legal Services 800-971-1127</p>

<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 575</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 Q. Who is she? 22 A. She's an administrative assistant. 23 Q. An administrative assistant for whom? 24 A. For my program. 25 Q. Does she work at the J&J Center or Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 576</p> <p>1 Massachusetts General? 2 A. Yes, she's an employee of my program at 3 Massachusetts General Hospital. 4 Q. Well, I don't understand; there's so many 5 different terms. Are we talking about the J&J 6 Center she's an employee? 7 A. No, she's an employee of Mass. General. 8 Q. Okay. But she works for you? 9 A. She works for me. 10 Q. Reports to you? 11 A. Yes. 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 577</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 Q. Let's assume that Janssen made it. Then 13 by labeling this an NIMH conference and not 14 referring to Janssen, that is misleading to the 15 participants, is it not? 16 MR. SPIVACK: Objection, calls for 17 speculation, no foundation, argumentative. 18 BY MR. FIBICH: 19 Q. Can you answer my question? 20 A. I think that if the grant were to have 21 been granted, that should have been disclosed. 22 Q. If the grant had been granted, that should 23 have been disclosed? That's your testimony? 24 A. (Witness nodded.) 25 Q. Tell the members of our jury why. Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 578</p> <p>1 A. Because the audience need to know all 2 sources of support for a conference. 3 Q. Did Janssen ever sponsor your pediatric 4 bipolar conference? 5 A. The first bipolar conference was funded by 6 Janssen. 7 Q. How many have there been? 8 A. Only one funded by Janssen. 9 Q. Well, no. How many conferences have there 10 been? 11 A. Six through NIMH and one by Janssen, so 12 seven. 13 Q. And one potentially by Janssen that you 14 can't recall? 15 A. One potentially that may have had 16 additional supplemental funds, not funded, because 17 most of the funding came from the NIMH. 18 MR. FIBICH: Mark that, please. 19 (Biederman Deposition Exhibit 44 marked 20 for identification.) 21 BY MR. FIBICH: 22 Q. Doctor, Exhibit 44 are some documents -- 23 excuse me; I didn't mean to pull it back like 24 that -- that were produced to us in response to the 25 subpoena that was served on you. Stratos Legal Services 800-971-1127</p>

<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 579</p> <p>1 MR. SPIVACK: Do you have copies? 2 MR. FIBICH: I do not. 3 BY MR. FIBICH: 4 Q. Can you identify what that is? 5 A. I don't know what this is. 6 Q. Is it your handwriting? 7 A. No. 8 Q. It's not your handwriting? (Pause) My 9 question to you is, do you know what that is? 10 A. Looks like worksheets of different 11 amounts. I'm not sure what this refers to. 12 Q. And neither am I because I didn't prepare 13 it. But it was produced by you and it appears to be 14 a rather haphazard way of recording moneys that may 15 have been paid to you. Would you look over that and 16 see if that is a fair characterization, or would you 17 characterize it in some other way if it's not? 18 MR. SPIVACK: Objection, no foundation, 19 calls for speculation, argumentative. 20 A. I don't remember what this is. 21 Q. Let me make sure that I understand your 22 testimony. The handwriting on this document, is it 23 yours? 24 A. No. 25 Q. You're certain of that? Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 580</p> <p>1 A. Yep. 2 Q. I'm sorry? 3 A. Yeah, it's not my handwriting. 4 Q. Let me see the document, if I may. 5 Now, the last two pages appear to be 6 invoices wherein \$2,000 was paid to you on two 7 occasions for a lecture on March 2nd of 2001 and 8 March 14th of 2001. Would you look over that and 9 see if you think my comment is correct? 10 A. Seems to be correct. 11 Q. So the last three pages you recognize as 12 evidence of payment to you by Janssen? 13 A. Yes. 14 Q. But the first pages, you don't know what 15 that is? 16 A. I don't remember what it is. I think it 17 looks like some kind of draft. 18 Q. Well, whatever it is, it appears to be 19 moneys and some relationship to pharmaceutical 20 companies. Would you agree with that? 21 MR. SPIVACK: Objection, no foundation, 22 speculation. 23 BY MR. FIBICH: 24 Q. Just read it and see if you would agree 25 with that characterization. Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 581</p> <p>1 MR. SPIVACK: Objection, no foundation, 2 calls for speculation. 3 BY MR. FIBICH: 4 Q. Does that appear to be what it is? 5 MR. SPIVACK: Objection, no foundation, 6 calls for speculation. 7 A. I'm not sure what it is. 8 Q. Okay. By what method did you keep up with 9 the money that was paid to you by pharmaceutical 10 companies? 11 A. By 1099s that the pharmaceutical companies 12 send at the end of the year. 13 MR. FIBICH: Mark that as an exhibit, 14 please. 15 (Biederman Deposition Exhibit 45 marked 16 for identification.) 17 BY MR. FIBICH: 18 19 20 21 22 23 24 25 Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 582</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 (Biederman Deposition Exhibit 46 marked 21 for identification.) 22 BY MR. FIBICH: 23 Q. Doctor, do you know who Joyce Myers is? 24 A. No. 25 Stratos Legal Services 800-971-1127</p>

Joseph Biederman
February 27, 2009

Page 583

1 MR. PECK: Do you have copies for counsel?
 2 MR. FIBICH: No.
 3 BY MR. FIBICH:
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 18 BY MR. FIBICH:
 19 Q. You looked at this document, did you not?
 20 A. I have no idea what this document is
 21 about.
 22 Q. Let me try this question. Have you looked
 23 at this document?
 24 A. I looked at the document.
 25 Q. Does this document contain your name?
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Joseph Biederman
February 27, 2009

Page 584

1 MR. SPIVACK: Objection, no foundation.
 2 A. The document contains my name.
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 9
 10 BY MR. FIBICH:
 11 Q. Does it contain a funding amount?
 12 MR. SPIVACK: Same objections.
 13 A. I have no idea what this document is.
 14 Q. Does it contain a funding amount?
 15 A. I have no idea what the document is.
 16 Q. Does it contain a funding amount?
 17 MR. SPIVACK: Objection, calls for
 18 speculation, no foundation.
 19 BY MR. FIBICH:
 20 Q. Does it contain a funding amount?
 21 MR. SPIVACK: Same objections.
 22 A. I have no idea what the document is.
 23 Q. Does it contain a funding amount?
 24 MR. SPIVACK: Same objections.
 25 BY MR. FIBICH:
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Joseph Biederman
February 27, 2009

Page 585

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 12 Q. Well, can you read it? It's right here.
 13 A. I can read it. I don't know what that
 14 amount represents or what is it.
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Joseph Biederman
February 27, 2009

Page 586

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Joseph Biederman
February 27, 2009

Page 587

1 Q. In your dealings with Janssen, have they
 2 ever said there's money on the table?
 3 A. I have no idea what that means.
 4 Q. I'm not asking you whether you know what
 5 it means. I'm asking you if that is a term that
 6 Janssen has used with you, money on the table.
 7 A. No.
 8 (Pause)
 9 MR. PECK: We will have to make copies
 10 because we're not given a courtesy copy.
 11 MR. FIBICH: What was that? What did you
 12 say?
 13 MR. PECK: I said we will have to make
 14 copies because we're not given a courtesy copy.
 15 (Biederman Deposition Exhibit 47 marked
 16 for identification.)
 17 BY MR. FIBICH:

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Joseph Biederman
February 27, 2009

Page 588

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Joseph Biederman
February 27, 2009

Page 589

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22 Q. And why would you be interested in using
 23 Meridia in conjunction with a regimen of Risperdal?
 24 A. Because we documented that risperidone
 25 produces weight gain.

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Joseph Biederman
February 27, 2009

Page 590

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11 Q. And you never did a study long enough to
 12 see what the long-term weight gain would be.
 13 Correct?
 14 A. We followed some of the children in our
 15 study of risperidone for up to one year.
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<p>Joseph Biederman February 27, 2009</p> <p>Page 591</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Stratos Legal Services 800-971-1127</p>	<p>Joseph Biederman February 27, 2009</p> <p>Page 592</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Stratos Legal Services 800-971-1127</p>
<p>Joseph Biederman February 27, 2009</p> <p>Page 593</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Stratos Legal Services 800-971-1127</p>	<p>Joseph Biederman February 27, 2009</p> <p>Page 594</p> <p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p>Stratos Legal Services 800-971-1127</p>

Joseph Biederman
February 27, 2009

Page 595

1 A. Depends. If the meeting has something to
2 do with a particular work that we did for a
3 pharmaceutical company, the pharmaceutical company
4 will support it.
5 Q. Well, what about if it -- Well, let me ask
6 it this way. Were any of these trips to these
7 national and international meetings done, paid for
8 by the J&J Center?
9 A. The J&J Center did not support travel.
10 Q. Well, where would you get the money to go
11 to these meetings if it were not given to you by
12 pharmaceutical companies?
13 A. I attend these meetings with or without
14 funding.
15 Q. Well, are you trying to say that you pay
16 it out yourself or are you reimbursed by MGH or
17 Harvard or any organization that you belong to?
18 A. If I have funds to reimburse for travel
19 expenses, I will submit the bill. If I don't have
20 funds, I will pay myself.
21 Q. Okay. So is there a set amount that you
22 receive each year for travel to professional
23 meetings such as these?
24 A. Not really.
25 Q. Well, you said if you had funds you would
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 596

1 get them. I don't understand what you're talking
2 about.
3 A. Well, sometimes I have some sundry funds
4 that allow for travel. The NIH studies all have
5 travel in them, so for every one of the grants that
6 we have for NIMH there is a set amount of funds to
7 travel. So those are funds that I have available to
8 travel.
9 MR. FIBICH: Let's take a five-minute
10 break. Let me get a copy for y'all. And this will
11 be the last thing I'll go over with the doctor.
12 THE VIDEOGRAPHER: The time is 4:43. We
13 are off the record.
14 (Short recess taken.)
15 (Biederman Deposition Exhibit 48 marked
16 for identification.)
17 THE VIDEOGRAPHER: We are back on the
18 record. The time is 4:51.
19 BY MR. FIBICH:
20 Q. Doctor, I want to show you what our court
21 reporter has marked as Biederman 48, and ask you to
22 look over this document. (Pause) And while you're
23 looking over it, I will represent to you that this
24 was a document that we obtained from the parties
25 that were submitted to us in response to the
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Joseph Biederman
February 27, 2009

Page 597

1 subpoena that was issued to you. My question would
2 be: Are you familiar with this document?
3 A. No.
4 Q. Have you seen this document before?
5 A. Not that I remember.
6 Q. Excuse me?
7 A. Not that I remember.
8 Q. Well, let me ask you a few questions, see
9 if it can refresh your recollection. The thing that
10 triggered this is you said you had some sundry
11 funds, and there is a cash balance on this sheet and
12 the sponsor's name is sundry. The first one is
13 \$21,834, sponsor is sundry, for a pediatric mania
14 conference. Do you have any idea what that is?
15 A. The pediatric mania conference was not a
16 sundry fund, it was a pediatric mania conference.
17 Maybe has been classified as a sundry, but was for a
18 pediatric mania conference.
19 Q. Well, let's go down to like one, two,
20 three, four, five, six, and the title is "Pediatric
21 psychopharmacology project fund, operating expenses"
22 and it's got \$1,006,509 and it's got "sundry" by
23 sponsor's name. Do you know what that is?
24 A. That is a conference that we have.
25 Q. Well, when you say you can go to sundry
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 598

1 funds for travel expenses, could you go to this for
2 travel expenses?
3 A. I could go to this.
4 Q. So any amounts that are on here as sundry
5 funds are funds that are available for you to travel
6 to these institutes that we're talking about?
7 A. This fund is primarily there for helping
8 maintain operations during times that we cannot
9 secure funding.
10 Q. I understand that. But my question to you
11 is that for you to go to these national and
12 international institutes for the purpose of
13 participating as an expert in the field of bipolar
14 disorder, you can take sundry funds from these
15 balances that are reflected on this sheet?
16 A. I could.
17 MR. FIBICH: Well, I have a lot more
18 questions, but I think we're at the end of the day,
19 so I'm going to terminate my exam at this time due
20 to time. And I think we have a statement we need to
21 put on the record as well about the production.
22 MS LaMACCHIA: It was represented to me
23 upon production by Dr. Biederman in response to his
24 subpoena duces tecum which has now been marked as
25 Exhibit 17 to his deposition that there were
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Joseph Biederman
February 27, 2009

Page 599

1 approximately 30,000 pages of documents included on
2 that CD, when it has come to my attention that there
3 are approximately 17,400 documents on that CD. And
4 also the privilege log as it was produced, it was
5 represented to me by Mr. Spivack that copies of
6 documents needed to be redacted because they
7 contained personal information and Social Security
8 numbers and information such as on 1099s. And after
9 viewing the documents, there was no such information
10 contained within the documents that were produced to
11 plaintiffs in this matter.

12 In addition to that, some documents that
13 were referenced on the privilege log which was
14 handed to me with five -- pardon me -- seven pages,
15 1, 2, 3, 4, 20, 21, 22 and 23, it appears that there
16 are pages missing, and they are Bates-numbered
17 documents that are represented within the privilege
18 log that were not turned over to me pursuant to the
19 subpoena duces tecum.

20 And I would like to go ahead and mark this
21 as Exhibit 49, as it appears plaintiff has been
22 handed an incomplete set of documents pursuant to
23 the subpoena duces tecum.

24 (Biederman Deposition Exhibit 49 marked
25 for identification.)

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Joseph Biederman
February 27, 2009

Page 600

1 (Pause)

2 MS. LaMACCHIA: Furthermore, plaintiff
3 wishes to reserve her right at this time to further
4 examine Dr. Biederman upon a complete and full
5 production of documents pursuant to the subpoena
6 duces tecum.

7 MR. SPIVACK: For the record,
8 Dr. Biederman has been subjected to two full days of
9 examination. We think that's more than enough for
10 someone who is a third party and really has no other
11 participation in this litigation. So to the extent
12 there's any reservation of additional examination,
13 we would object and will oppose attempts to examine
14 in the future if that arises.

15 As far as the production, we think that
16 the production actually was of all documents
17 responsive to the subpoena. I think it's actually
18 an issue with splitting up documents for the numbers
19 that you see in terms of the numbers that appear on
20 the CD. We actually think we produced everything.

21 Now, as far as the privilege log, we also
22 think that was a complete privilege log for
23 documents responsive or were potentially responsive
24 to this production. However, we will certainly go
25 back and check both, we'll confirm, and if we find

Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 601

1 anything that is inaccurate or is responsive and
2 should have been produced, we will undertake to
3 produce that.

4 With regard to any personal financial
5 information, that's another thing that we will
6 check. We actually believe that there were 1099s
7 which contain home addresses and Social Security
8 numbers. If there are such documents, as we
9 requested at the outset, what we will do is provide
10 you with a replacement CD and ask that you use that.

11 MS. LaMACCHIA: Okay, counsel, just so the
12 record is clear, upon my review of the entirety of
13 your production, there were documents contained
14 within the privilege log that were not in the
15 production. And I believe Mr. Burney made a
16 representation to the court in New Jersey that there
17 was approximately 30,000 pages of documents on the
18 CD. In actuality there were 17,474 pages of
19 documents.

20 MR. BURNEY: For the record, I told the
21 Court that I wasn't sure and that I thought there
22 was 30,000 pages. This was not because I -- I am
23 not giving you an empty CD, you know, or a CD that
24 only has half the documents. I misspoke.

25 MR. SPIVACK: We'll go back and confirm.

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Joseph Biederman
February 27, 2009

Page 602

1 MS. LaMACCHIA: And with a complete
2 privilege log, I'm unsure as to why plaintiff was
3 only provided with pages 1, 2, 3, 4, and then 21,
4 22, 23.

5 MR. BURNEY: It's a printing error that
6 occurs in Excel because those columns go beyond
7 That should have been shrunken down to beyond pages
8 1 through 4. So there's no intermittent pages. The
9 intermittent pages are blank. If you'd like, I can
10 print the entire document for you and you'll have 19
11 blank pages and then the last four pages will have
12 those columns that you see before you.

13 MR. SPIVACK: So we'll stipulate that we
14 don't know how to use Excel.

15 MS. LaMACCHIA: I would also like you to
16 stipulate that another production, a complete and
17 full set of documents will be produced to plaintiff.

18 MR. SPIVACK: If we haven't produced
19 anything, we will produce any responsive documents
20 if they exist.

21 MS. LaMACCHIA: Okay. Then I further
22 reserve my right upon the production of additional
23 documents.

24 MR. SPIVACK: Right, and we have already
25 made our objection, so we can restate or not. But I

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Joseph Biederman
February 27, 2009

Page 603

1 understand.
2 MS. LaMACCHIA: Thank you.
3 MR. SPIVACK: And we'll try to take a look
4 at that and confirm.
5 MS. LaMACCHIA: Thank you.
6 MR. FIBICH: And will you check with your
7 client about my invitation to the pediatric bipolar
8 disease conference?
9 MR. SPIVACK: I'll be happy to check with
10 him
11 MR. FIBICH: Thank you.
12 MR. SPIVACK: Is there any further
13 examination?
14 MR. PECK: Yes, there is. Actually,
15 before I get started, I'll move over to Mr. FIBICH's
16 seat, I would ask that he provide me with the
17 American --
18 MR. FIBICH: Hold on a minute. I'm not
19 through. I stopped because it was 5:00 o'clock.
20 MR. SPIVACK: You're not through?
21 MR. FIBICH: Through with my examination.
22 MR. SPIVACK: So are you saying that you
23 are intending to continue the deposition?
24 MR. FIBICH: Well, what I thought we were
25 going to do was stop at 5:00 o'clock like we did
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Joseph Biederman
February 27, 2009

Page 604

1 yesterday. I've got more examination.
2 MR. SPIVACK: Okay. That is between you
3 and Mr. Peck.
4 MR. FIBICH: So you want the witness to
5 continue to be -- ? Well, let me ask it this way.
6 If Mr. Peck is going to cross-examine him, then I
7 want cross-examination after Mr. Peck.
8 MR. SPIVACK: That's up to you and he to
9 discuss.
10 MR. FIBICH: Okay. So my question to you,
11 and I understand you're trying to stay out of this,
12 but my question to you is: Are you going to tell
13 the witness to leave so that I'm deprived of my
14 right of cross-examination of him after he examines
15 your witness?
16 MR. SPIVACK: Well, Dr. Biederman has
17 stayed till 5:00 o'clock, which was the agreed-upon
18 schedule.
19 MR. FIBICH: Right.
20 MR. SPIVACK: As a matter of courtesy, if
21 Mr. Peck has questions, we are going to afford him
22 that right for another fifteen minutes. We don't
23 intend to stay here for the rest of the evening.
24 MR. FIBICH: Well, that was what my
25 understanding was. I mean, I have more questions.
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Joseph Biederman
February 27, 2009

Page 605

1 I stopped because I thought that as a matter of
2 protocol we were stopping at 5:00 o'clock.
3 MR. SPIVACK: Well, in that case, then you
4 and Mr. Peck can work it out. We'll be happy to go
5 off the record while you and he discuss it.
6 MR. FIBICH: I don't want to discuss
7 anything off the record with him.
8 MR. SPIVACK: Okay. Well, discuss it on
9 the record. As you said, I'm going to stay out of
10 it.
11 MR. FIBICH: Well, here's the question.
12 Do you have more than fifteen minutes?
13 MR. PECK: I suspect I do.
14 MR. FIBICH: So what's your deal now? I
15 mean, we're at a dilemma, because I thought we were
16 going to go to 5:00 o'clock every day.
17 MS. LaMACCHIA: Mr. Spivack, in your
18 correspondence with plaintiff's counsel it wasn't a
19 deal, it was 9:00 to 5:00 for February 26th and 27th
20 and then from day to day until completed.
21 MR. SPIVACK: We have a different
22 interpretation of the order, so we think the order
23 gave you two days. We think that's more than
24 adequate. As I said five minutes ago, we're going
25 to raise an objection to any further examination of
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Joseph Biederman
February 27, 2009

Page 606

1 Dr. Biederman. So that's our position. If the
2 Court decides differently --
3 MS. LaMACCHIA: The order says what it
4 says and it goes from day to day till completed.
5 MR. FIBICH: Well, here's where we are.
6 I'm not going to pass the witness unless I have a
7 limitation on how many questions he's going to ask.
8 It's my right to continue my examination. I did not
9 get through with my examination. I will represent
10 that to you. I've got other questions that I want
11 to ask, other documents I want to go over. Quite
12 frankly, I've got quite a bit more to do. I made a
13 decision since it was 5:00 o'clock that we should go
14 ahead and stop and go on about our business because
15 that's how we do it.
16 If Mr. Peck wants to ask questions, then I
17 think I have the right of cross-examination
18 thereafter. He's now said that he is likely to take
19 longer than fifteen minutes, which means we're going
20 to go at least another thirty minutes or longer.
21 I'm willing to accommodate him. If it's fifteen
22 minutes, then I get fifteen minutes for recross. If
23 that's not the case, and if he's here to answer
24 questions, then I'll just keep going on my
25 examination.
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Joseph Biederman
February 27, 2009

Page 607

1 I am not trying to be difficult. But what
2 I don't want is to give Mr. Peck the right to cross-
3 examine or examine this client and me not have the
4 right to cross-examination. This was never
5 discussed before the Court, despite numerous
6 hearings that were held before the Court, that
7 Janssen would be asking questions and under what
8 conditions, for how long, and whether we split the
9 time up.

10 We have now utilized the entire time for
11 the examination of Dr. Biederman, so I suggest quite
12 frankly that we terminate the deposition today and
13 if Mr. Peck wants to take his deposition some other
14 time, then he can petition the Court.

15 He had the opportunity, I might add, to do
16 that before these hearings. He could have said if
17 this is our two days of Dr. Biederman, then Janssen
18 reserves the right to do an examination for some
19 period of time, and the Court could have allocated
20 what portion of the two days that he would be
21 entitled to. But in the absence of that, I don't
22 think we can go on like this.

23 So do you want me to keep asking
24 questions? Not really?

25 MR. SPIVACK: You know, it's up to you and
Stratos Legal Services
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Joseph Biederman
February 27, 2009

Page 608

1 Mr. Peck to work it out. We have tried to --

2 MR. FIBICH: Well, no, no, here's the
3 problem, Peter. You're saying he's going to stay
4 here and answer questions, so if he's going to stay
5 here and answer questions, then I'll ask my
6 questions, because I'm not through. If you tell me
7 that he's not going to stay here and answer
8 questions, then I'll finish as a matter of courtesy.
9 He's told me twice today he's tired. I'm tired,
10 we're all tired, it's Friday.

11 MR. SPIVACK: The Celtics are playing
12 tonight.

13 MR. FIBICH: And the Celtics. And the
14 Rockets beat the Cavaliers last night.

15 MR. SPIVACK: All right. Then in that
16 case, as far as my client's interest, it is now five
17 after 5:00 and --

18 THE WITNESS: Ten after 5:00

19 MR. SPIVACK: Ten after 5:00 by your watch
20 and we'll finish with the deposition then. I mean,
21 terminate it.

22 MR. FIBICH: All right

23 MR. PECK: For the record, Mr. Fibich, you
24 had fifteen hours. I can't agree to your offer of
25 fifteen minutes on cross-examination. I will
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Joseph Biederman
February 27, 2009

Page 609

1 reserve the right to continue the deposition and I
2 will object to any dissemination of this deposition
3 for any reason to any person anywhere any time
4 without my opportunity to examine Dr. Biederman on
5 the documents that you produced.

6 I will remind everybody of their
7 obligations under the protective order in the New
8 Jersey case, the Foti case and the other
9 litigations, that anything produced by Janssen in
10 this discovery in the litigation remains
11 confidential and is not to be disseminated.

12 Doctor, thank you for your time, and maybe
13 we meet again.

14 MR. FIBICH: Thank you.

15 MR. PECK: One more thing. One more thing
16 before we go off the record. Mr. Fibich quoted from
17 an article this morning from the American
18 Psychiatric Journal to the effect that 90 percent of
19 documents get -- I'm sorry -- 90 percent of
20 physicians get information for treating patients
21 from medical journals. That article was not marked
22 for identification. It was read from; it was
23 referred to. I'd appreciate that it be produced,
24 marked for identification, not given to guesswork.

25 MR. FIBICH: Where was it from? Do you
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Joseph Biederman
February 27, 2009

Page 610

1 recall?

2 MR. PECK: American Journal of Psychiatry.
3 It was produced and read by you --

4 MR. FIBICH: I tell you what's do

5 MR. PECK: -- Washington Post article,
6 which was Exhibit Number 20.

7 MR. FIBICH: I'm sorry. Say that again.

8 MR. PECK: It was produced and read by you
9 following Exhibit 20, which was The Washington Post
10 article regarding a rise in pediatric bipolar
11 diagnosis.

12 MR. FIBICH: Okay, I tell you what's do.

13 Let's terminate the deposition, let the doctor go,
14 let me look through my things, see if I can find you
15 a copy of it; and we can either mark it as an
16 exhibit --

17 MR. PECK: Let's mark it as an exhibit

18 MR. FIBICH: If I can't find it here
19 today, then I will get you a copy and send it to the
20 court reporter

21 MR. PECK: Fair enough

22 MR. FIBICH: Okay

23 MR. PECK: We are going to make a copy of
24 Exhibit 46, which we didn't have.

25 MR. FIBICH: I didn't have a copy.
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Joseph Biederman
February 27, 2009

Page 611

1 MR. PECK: And I think there were other
 2 exhibits that we didn't have a copy of. We're off
 3 the record.
 4 THE REPORTER: We have to let him go off
 5 the record.
 6 MR. PECK: Oh, I'm sorry
 7 THE VIDEOGRAPHER: The time is ten minutes
 8 after 5:00. We are off the record
 9 (Discussion off the record.)
 10 MR. FIBICH: Mr. Court Reporter, I have
 11 marked as Exhibit 50 an editorial that I read from
 12 this morning, and Mr. Peck has asked that it be made
 13 part of the record. So I tender to your possession
 14 Exhibit 50, entitled Conflict of Interest, an
 15 editorial that appeared in the American Journal of
 16 Psychiatry that I referred to this morning.
 17 (Biederman Deposition Exhibit 50 marked
 18 for identification)
 19 (Deposition concluded at 5:15 p m)
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Joseph Biederman
February 27, 2009

Page 612

1 COURT REPORTER'S CERTIFICATE
 2 I, J Edward Varallo, RMR, CRR, Registered
 3 Professional Reporter and Notary Public in the
 4 Commonwealth of Massachusetts (my commission expires
 5 12/24/2015), hereby certify that the deposition of
 6 Joseph Biederman, M D taken on February 27, 2009,
 7 in the matter of In re: Risperdal/Seroquel/Zyprexa
 8 Litigation, Case Code 274; Alma Avila, as next
 9 friend of Amber N. Avila, an individual case v
 10 Johnson & Johnson Company, Janssen Pharmaceutical
 11 Products, L.P., et al was recorded by me
 12 stenographically and transcribed; that the
 13 deponent's oath continued from the previous day
 14 I certify that the deposition transcript
 15 produced by me is true and accurate to the best of
 16 my ability.
 17 I certify further that I am not counsel,
 18 attorney, or relative of any party litigant, and
 19 have no interest, financial or otherwise, in the
 20 outcome of this suit
 21
 22
 23
 24
 25

DATED: 3/9/2009 J Edward Varallo
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Joseph Biederman
February 27, 2009

Page 613

1 WITNESS: Joseph Biederman, M D [Volume 2]
 2 DATE: February 27, 2009
 3 IN RE: Risperdal/Seroquel/Zyprexa Litigation,
 4 Case Code 274; Alma Avila, as next friend
 5 of Amber N Avila, an individual case v
 6 Johnson & Johnson Company, Janssen
 7 Pharmaceutical Products, L.P a/k/a
 8 Janssen, L.P., et al
 9
 10 DISTRIBUTION TO COUNSEL The original signature
 11 page/errata sheet was sent to Peter S Spivack,
 12 Esq., to obtain signature from the deponent When
 13 signed. please send original to Leslie LaMacchia,
 14 Esq., who will supply a copy of the signed errata
 15 sheet to other counsel present at the deposition.
 16
 17 WITNESS INSTRUCTIONS After reading the transcript
 18 of your deposition, please note any change or
 19 correction and the reason for it on the errata
 20 sheet DO NOT make any notations on the transcript
 21 itself. Use additional sheets if necessary
 22
 23 SIGN AND DATE THE ERRATA SHEET and return it, along
 24 with the transcript, to your counsel.
 25

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