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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.

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

Civil Action
Docket Number
L-6661-06

Video Deposition of Joseph Biederman, M.D.
Thursday, February 26, 2009
Dwyer & Collora, LLP
Federal Reserve Plaza - 12th Floor
600 Atlantic Avenue
Boston, Massachusetts 02210

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on behalf of Hogan & Hartson

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9 Article entitled Risperidone Treatment for Juvenile Bipolar Disorder: A Retrospective Chart Review, Jean A. Frazier M.D., Journal of The American Academy of Child and Adolescent Psychiatry. August 1999 pages 960 through 965 — 204

10 Document headed Case Report, Treatment of Risperidone-Induced Hyperprolactinemia with a Dopamine Agonist in Children, Louise Glassner Cohen and Joseph Biederman, M.D., Journal of Child and Adolescent Psychopharmacology, Volume 11, Number 4, 2001, pages 435 through 440 — 208

11 Article entitled No Seizure Exacerbation From Risperidone in Youth With Comorbid Epilepsy and Psychiatric Disorders: A Case Series, Joseph Gonzalez-Heydrich, M.D., Journal of Child and Adolescent Psychopharmacology, Volume 14, Number 2, 2004, pages 295 through 310 — 210

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13 Sheet headed Key Points From 2003 Child & Adolescent Business Planning Session 2-6/12/02 (Bates JJRE 00057039) — 264

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15 E-mail sent Friday, March 22, 2002, at 9:38 a.m. from Gahan Pandina to Christine Cote, subject: Feedback regarding MGH pediatric seminar (Bates JJRIS 00566318) — 289

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(ORIGINAL EXHIBITS RETURNED TO ATTORNEY LaMACCHIA)

MORNING SESSION
9:00 a.m

MR. FIBICH: Why don't we go on the audio record and announce our respective representations and then discuss the issue we were discussing off the record.

MR. SPIVACK: Good morning. Peter Spivack, Hogan & Hartson, for Joe Biederman.

MR. BURNEY: Keith Burney, Hogan & Hartson, for Joe Biederman.

MR. PECK: Jeffrey Peck, Drinker Biddle, for Janssen and Johnson & Johnson.

MR. ESSIG: Bill Essig, Drinker Biddle, for Janssen and Johnson & Johnson.

MS. KOLE: Deirdre Kole, Drinker Biddle, for Janssen and Johnson & Johnson.

MR. LeGOWER: Don LeGower from Dechert, for AstraZeneca.

MR. TRAMMELL: Fletch Trammell, plaintiffs

MR. FIBICH: Tommy Fibich, plaintiffs

MR. SMITH: Ken Smith, Sheller, P.C., plaintiffs.

MS. LaMACCHIA: Leslie LaMacchia, plaintiffs.

MS. HO: Jennifer Ho, plaintiffs.

MR. FIBICH: Mr. Spivack, I would like to raise an issue that has come to our attention. That is that, surprisingly, there's been a second videographer arranged by your law firm to evidently record the questioner in the deposition. Evidently we find that to be unprecedented and unnecessary. We know of no reason for that. Furthermore, this deposition has been the subject of numerous court hearings and at no time was the issue of whether a videographer would be placed on the questioner raised to the court to give us the opportunity to object.

Furthermore, the rules that are governing this proceeding, particularly 4:14-9(b) says that "A party intending to videotape a deposition shall serve the notice required by Rule 4:14-2(a) not less than ten days prior to the date therein fixed for the taking of the deposition." There was no such notice that was filed by your firm giving us notice that you intended to videotape the questioner, so we object to that and ask that you direct the videographer that you have obtained to focus on the

questioner leave the room
MR. SPIVACK: Your objection is noted. And you know since the purpose of videotaping a deposition is to replicate for the courtroom, we think it's appropriate to have a videographer focused on the questioner. I'm not going to direct the videographer to leave the room; I'm going to ask him to stay. If you don't want to proceed with the deposition, that's fine
MR. FIBICH: No, we're going to proceed with the deposition. But I am going to direct the videographer, the second one, to place the camera on Mr. Biederman's feet so that we can replicate what it looks like in a courtroom and we can see him moving around nervously when he's asked questions.
So, Mr. Videographer, I want you to find a way to videotape the witness's feet. Will you do that, sir?
MR. DÖBRENTEY: That would be the -- I can't do that.
MR. SPIVACK: If you want to stop the deposition, that's fine.
MR. FIBICH: No. I'm going to tell the videographer not to focus on Mr. Trammell as he starts the questioning.

MR. SPIVACK: You can tell him whatever you want.
MR. FIBICH: All right
Mr. Videographer --
MR. SPIVACK: Since he's hired by us, he will unfortunately not pay attention to what you tell him.
MR. FIBICH: Well, he may not.
Are you the videographer that is focusing on the questioner?
MR. SLATER: I am, yes, the questioner. I mean, not the questioner, the witness.
MR. DÖBRENTEY: I'm the videogrpaher focusing on the questioner.
MR. FIBICH: And I am telling you there is no such notice that allows that, and I am asking you not to do it.
MR. DÖBRENTEY: I have to defer to the person who hired us.
MR. FIBICH: So you're going to take directions from Hogan & Hartson?
MR. DÖBRENTEY: Yes.
MR. FIBICH: Okay.
My initial comment, Mr. Spivack, was a request because I don't think it's right. It's a

request Now I'm going to make -- And I presume you're not going to accommodate my request?
MR. SPIVACK: You are correct.
MR. FIBICH: Okay. For the record, I am now going to object for the record and we will raise this issue with the Court and we will proceed with the understanding that these sorts of things will just be the first shot over the bow.
MR. SPIVACK: If that's a threat, go ahead, take your best shot.
MR. FIBICH: We intend to, sir.
MR. SPIVACK: I think that, as we all will, I'm sure you will abide by the laws governing the lawyers in Texas and you just had a nice statement of how lawyers are supposed to behave in depositions and otherwise I'm sure that you'll be polite, and I will as well, when we have our disagreements, but we can do so respectfully
MR. FIBICH: Well, I think so too, and I intend to do that. My point is that insofar as obeying the law, we've got a rule that applies to videotaping and I don't appreciate what you're doing today, because my option is to proceed or alternatively come back and raise this as an issue I don't find that to be very professional on your

behalf, so that is something we disagree on.
MR. SPIVACK: Okay.
MR. FIBICH: We may have the opportunity on many other occasions to take Dr. Biederman's deposition. I was hoping today would be the only day. But if this is the sort of activity that we're going to have to deal with, then we'll do it the best way we can. For the purpose of the record, I intend to be as professional as I know how to be and I'm sure you will too
MR. SPIVACK: Absolutely.
Since we are making objections for the record, I would like to object for the record to you, Mr. Trammell and Mr. Fibich, asking any questions in this deposition since I understand you haven't complied with the New Jersey rules on admission pro hac vice as an attorney. I know that you have made your application, you have been accepted, but my understanding is that you have not paid the fees required into the New Jersey Client Trust Account.
MR. FIBICH: Anything else?
MR. SPIVACK: Not at this moment.
MR. FIBICH: Let's swear the witness in and get on the videotape

MR. LeGOWER: Counsel, before we swear in the witness, I think I have something a lot less controversial, though I could be wrong.

AstraZeneca has reviewed Dr. Biederman's document production and has identified a few documents that we believe contain confidential information that AstraZeneca would like to mark as protected documents under the Court's protective order I have exchanged with counsel for all the parties and for the witness a document that lists those documents by Bates number, and I would just like to mark it for the record and preserve it in this deposition Any objections?

MR FIBICH: I would like to know when you first saw the production

MR. LeGOWER: I first saw the production when Brian McCormick delivered it to me on Tuesday night at 5:00 p.m.

MR FIBICH: And Janssen or -- Who do you represent, again?

MR. LeGOWER: I represent AstraZeneca.

MR. FIBICH: Okay. So prior to that time AstraZeneca didn't have any notice of what he had in his possession?

MR LeGOWER: Prior to that time I had no

documents and, as far as I know, no one else knew what he was going to produce I don't know what he had in his possession.

MR. FIBICH: Thank you.

MR. SPIVACK: And I have one more matter to put on the record. I talked to Ms. LaMacchia before the deposition. There are documents that we produced pursuant to the Court's order after the hearing that contain Dr Biederman's personal financial information; for example, his Social Security number, bank account information, home address, et cetera.

What we would like to do is replace those documents with redacted copies We had anticipated that the Court would entertain a protective order Since at least at this juncture it has indicated it's not, we make that request

MR. FIBICH: Well, that camera over there sure bothers me. I don't think we can agree to that request, mainly because I don't know of any privilege that he has to protect that information

MR. SPIVACK: I mean, in that case, then we'll go forward with the motion for the protective order if you're not agreeing to that. I mean, it seems entirely --

MR FIBICH: Tell me what privilege he has to protect that information Is there a privilege under New Jersey law or Massachusetts law which you think applies?

MR. SPIVACK: There are privacy rights There are privacy rights under New Jersey law, there are privacy rights under federal law So if you're not willing to agree, we'll ask the Court to entertain that.

MR FIBICH: Let me just say this. We have had a lot of difficulty getting these documents and I will look at whatever privileges that you can refer me to that may protect this information, and if I find that you've got an arguable position, then we'll try to agree with it

MR. SPIVACK: Fair enough

MR. TRAMMELL: Is that it?

MR. SPIVACK: I think so

MR TRAMMELL: Swear him in

(Brief pause while the videographers prepared to begin videotaping)

(Biederman Deposition Exhibit 1 marked for identification)

THE VIDEOGRAPHER: We are on the record at 9:18 a m

This is the videotaped deposition of Joseph Biederman, M.D in the matter of In re Risperdal/Seroquel/Zyprexa Litigation, Case Code 274, Alma Avila as next friend of Amber Avila versus Johnson & Johnson Company et al. in the Superior Court of New Jersey, Law Division, Middlesex County, Docket Number -- I'm getting BlackBerry noises -- Docket Number 8-6661-06

This deposition is being held at Dwyer & Collora at 600 Atlantic Avenue, Boston, Massachusetts on February 26, 2009

My name is Bill Slater I am the videographer and I am present on behalf of Stratos Legal. The court reporter is Ed Varallo, also present on behalf of Stratos Legal

Counsel will now state their appearances and firm affiliations for the record

MR TRAMMELL: Fletch Trammell, Bailey Perrin Bailey, plaintiffs

MR FIBICH: Tommy Fibich, Fibich Hampton Leebron & Garth, plaintiffs.

MR SMITH: Ken Smith, Sheller, P C , plaintiffs

MS. HO: Jennifer Ho, Bailey Perrin Bailey, plaintiffs.

MR LeGOWER: Don LeGower, Dechert, for AstraZeneca
MS KOLE: Deirdre Kole, Drinker Biddle & Reath, Janssen and Johnson & Johnson
MR ESSIG: William V Essig, Drinker Biddle, Johnson & Johnson and Janssen
MR PECK: Jeffrey Peck, Drinker Biddle, Johnson & Johnson and Janssen
MR BURNEY: Keith Burney, Hogan & Hartson, representing Dr Biederman
MR SPIVACK: Peter Spivack of Hogan & Hartson for Dr Biederman
THE VIDEOGRAPHER: The court reporter will please swear in the witness; then we may proceed
JOSEPH BIEDERMAN, M D ,
having been first duly sworn on oath,
was examined and testified as follows:
EXAMINATION
BY MR TRAMMELL:
Q Good morning
A Good morning
Q Please state your name for the record
A Joseph Biederman
Q And where do you live, Dr Biederman?
A You want my address?

Q Yes
A It's 523 Boylston Street, Brookline, Massachusetts 02445
Q Can you speak up a little bit? I'm not sure --
A I'm a little bit hoarse I can't But if you want me to say it again? 523 Boylston Street, B-o-y-l-s-t-o-n Street, Brookline, Massachusetts 02445
MR TRAMMELL: Are you able to hear him?
THE VIDEOGRAPHER: Yes
MR TRAMMELL: Good
BY MR TRAMMELL:
Q And where do you work?
A The Massachusetts General Hospital
Q Is that here in Boston?
A In Boston
Q Doctor, who is representing you here today?
A Mr Spivack and Mr Burney
Q From the firm of Hogan & Hartson?
A Correct
Q Are you paying these lawyers?
A The -- Yes
Q Do you have a malpractice insurer that's

paying them or are you paying them directly out of your pocket?
A Well, it's paid through the Massachusetts General Hospital
(Mr Fibich interrupted, holding up a BlackBerry speakerphone in his hand A voice, later identified to the court reporter as Judge Jamie Happas, was heard on the phone The following colloquy ensued.)
MR FIBICH: Excuse me Hello?
THE COURT: Do we have a line?
MR FIBICH: Well, you're on a BlackBerry speakerphone and you've got the entire number of people, approximately fifteen or so here in the deposition
THE COURT: Okay And what is the issue? Hello?
MR FIBICH: Hello Just a second
MR TRAMMELL: Your Honor, the issue is we're here at Dr Biederman's deposition --
THE COURT: Are we on the record now or off the record?
MR TRAMMELL: We're on the record right now Would you rather we go off?
THE COURT: No, we can go on the record

MR TRAMMELL: Okay So we're on the record right now, the video record We've just started
We noticed this deposition, as you know, under the New Jersey rules to be a videotaped deposition and complied with all the New Jersey rules required to take such a deposition We showed up here today and counsel for Dr Biederman, Hogan & Hartson, has arranged for a second videographer to videotape the questioner in the deposition
There is no notice of this second videographer It doesn't comply with the New Jersey rules We put all this on the record and asked Hogan & Hartson to desist with the second videographer and they have refused to do so And so I suppose what we would like is an order from the Court requiring them to desist in those operations It is unprecedented, as far as I know, to have this done I've never been in a deposition where it's happened They certainly didn't raise it with the Court when the issue came up just yesterday There's no notice under New Jersey rules It's an improper videotape operation and we would like it to stop so we can proceed with the deposition
THE COURT: Okay, let me ask you

something. You mean they want to videotape the lawyer when the lawyer is asking the question?

MR. TRAMMELL: Right. That's correct, your Honor.

THE COURT: I see. You're cutting out. Is that the issue, that the defendant wants to videotape the questioner?

MR. TRAMMELL: That's correct, your Honor.

THE COURT: Okay. For the record let's agree 4:14-9 is the rule in New Jersey which states "Videotaped depositions may be taken for discovery purposes or for use at trial in accordance with the applicable provisions of these discovery rules subject to the following further requirements and conditions: (a) Time for Taking Videotaped Depositions. The provisions of Rule 4:14-1 shall apply to videotaped depositions except that such a deposition of a treating physician or expert witness which is intended for use in lieu of trial testimony should not be noticed for taking until 30 days" -- well, that portion is not relevant here

"(b) Notice. A party intending to videotape a deposition shall serve the notice required by Rule 4:14-2(a) not less than ten days prior to the date therein fixed for the taking of

the deposition. The notice shall further state that the deposition is to be videotaped " And that was done here?

MR. TRAMMELL: No.

THE COURT: Was that done by plaintiff?

MR TRAMMELL: That was done by plaintiffs, not by Dr. Biederman's counsel.

THE COURT: Okay And then section (c) has to do with the transcript. Section (d) has to do with the filing of the copies. (e) has to do with the use. (f) is counsel's objections (g) is the cost of the videotaped dep. And (h), also the record on appeal

Bear with me. I'm just reading the notice here. (Pause)

I have never seen a videotaped deposition where the lawyers were actually shown to the jurors neither in my tenure as a judge or trial lawyer If the defendants want to do that, give me a rule or give me some case law and specifically cite me to a rule or some case law which says you can just use recording technology without giving your adversary notice of it so if there is an objection, it can be presented to the Court Because under our video rule 4:14-9(a), it's important pursuant to this rule

that the parties be given notice so obviously if there is some problem, the Court can deal with it.

Due to the fact that it is not customary at least in my experience either as a judge or trial lawyer to have the videographer actually taking a picture of the questioner, the fact that you didn't even give notice, I mean, flies in the face of the court rules. You can be heard.

MR. SPIVACK: Thank you, your Honor. This is Peter Spivack, Hogan & Hartson, for third-party deponent Joe Biederman. First of all, Mr. Biederman is not a party to this action. The rule specifically applies to parties. He is not a party.

THE COURT: Give me a rule that says you're allowed to -- Isn't that the point, the videotaped deposition, that this just applies to parties?

MR. SPIVACK: Well, your Honor, first of all, I'm reading the rule --

THE COURT: Please back up Show me in the rule. I think if you can open the court rules, where does it say that this rule just applies to parties? You said that, and I want to take this one step at a time

MR. SPIVACK: Okay.

MR PECK: Doesn't the rule specifically state parties? It says any --

THE COURT: Any party intending to videotape. Well, there's a party intending to videotape. But where does it state that this rule just deals with parties that are being deposed?

MR. SPIVACK: I'm --

THE COURT: Quite frankly, it doesn't deal with that because part (a) deals with experts and physicians when they are being deposed and they're not parties.

MR SPIVACK: All right Well, the second basis for that, your Honor, would be the rule itself does not state -- it states that "A party intending to videotape a deposition shall serve the notice." That notice was served by the plaintiffs. The notice does not state, or it just states a videotaped deposition will take place.

THE COURT: Well, how about the fact that -- Are you admitted in New Jersey, counsel, or are you pro hac?

MR. SPIVACK: I am pro hac

THE COURT: Okay. How about the fact we don't do this in New Jersey? It's not customary in any trial that I've sat on or any trial that I've

been involved in
MR. SPIVACK: Your Honor, respectfully, I don't think that custom and practice is what should dictate here. I think it's the rule. And respectfully, your Honor, I have been in cases where videotapes of the lawyers, the questioners, have been undertaken
THE COURT: What rule, counsel? What rule? We're talking New Jersey rules here. You said pursuant to the rule What rule are you referring to?
MR. SPIVACK: I'm referring to the rule that your Honor quoted
THE COURT: 4:14-9?
MR. SPIVACK: Yes
THE COURT: Well, tell me where it says that you can take the video of the questioner.
MR. SPIVACK: Well, your Honor, it doesn't exclude it.
THE COURT: You're not giving me -- Quite frankly, you're not giving me a good reason why it should be permitted.
MR. SPIVACK: All right Your Honor, for the record I certainly understand your ruling I disagree with it. I think that the rule provides

for such videotaping I think given that this is intended to replicate a courtroom setting, if it's introduced into evidence, I think that the jury should see both the questioner and the witness
THE COURT: Have you ever done that in New Jersey?
MR SPIVACK: Your Honor, it's --
MR PECK: Judge Happas, this is Jeffrey Peck for Janssen and Johnson & Johnson
I believe Judge Corodemus and I know Judge Garruto has permitted cameras for exactly that reason, two cameras: a videotape camera obviously on the witness and a videotape second camera on the questioner. And orders have been entered in either Janssen-Ortho or HRT, one of the other mass torts, on exactly the same issue; and the reason being that the dual cameras do replicate the courtroom if in fact the deposition --
THE COURT: You've got to come in closer to the phone because you're fading in and out Now I can't hear you at all
MR PECK: Okay, I'm coming around the table
I know that Judge Garruto and perhaps Judge Corodemus before him have ordered dual cameras

for depositions that are videotaped in instances where -- Well, the argument is to replicate the courtroom environment. And what's been done is that when these videotapes are shown at trial, it is done as a split screen. It shows the questioner and it shows the witness just as one would see in the courtroom. And that is the rationale for allowing it I don't see how it prejudices anybody at all. I don't understand the nature of the objection
THE COURT: Well, let me ask you something
MR. PECK: But it's been done before in New Jersey.
THE COURT: For these purposes, because I think it's important that you get started with this deposition, what would be the problem at least for today's purposes of letting the defendants proceed in that fashion and this is an issue that we'll bring up at the time of trial?
MR. TRAMMELL: Well, your Honor, I mean, obviously had they raised their intention to do this, we would have objected to it. As your Honor said, that's the purpose of complying with the New Jersey rule, which they haven't done Even if Mr Peck can give us an allegorical account of a

situation in which this occurred, we don't know what those orders said We don't know whether they relate to the circumstances here
THE COURT: And that could be the case But here we are. Okay? Here we are at the point where everybody, all fifteen lawyers are seated in that room, you have Dr Biederman, and everybody is ready to go So at this point I'm not going to put the deposition off That doesn't make a lot of sense
MR. TRAMMELL: No, and we don't want to do that I mean, as silly as it is, the purpose is to intimidate the questioner
THE COURT: No, it's not to intimidate Come on You're lawyers If you're going to be intimidated by a camera, which I doubt that you will be, that's not to intimidate And that I don't buy I mean, a lawyer is not going to be intimidated by a camera
MR TRAMMELL: Okay Well, I certainly can't imagine what the purpose would be. And I agree with you there's nobody that's going to be intimidated by that but I don't know what the purpose of it is They didn't comply with the rules

THE COURT: Well, this is what we're going to do I think there's no harm, they've got the video equipment there, it will give us time to review it and see whether or not it is appropriate. I'm not really happy, quite frankly, that you didn't at least give the courtesy to the other side. I think there's courtesy involved here If you were going to bring in a videographer, I don't know why you couldn't have picked up the phone and said, by the way, we're going to do this. Okay? To come in carting this equipment, I just think as a courtesy it should have been done And maybe even more.

But at this point we're past that. You have everything set up, everybody's ready for the deposition, and I think we'll save the argument for another day I'll look into some of those other situations that occurred. And let's get the deposition started. Everybody's been waiting a long time for this deposition to be completed and we'll deal with the issue when it comes up before trial as to whether or not you'll get to show both the questioner and the witness or just the witness. Okay?

MR. TRAMMELL: Yes Thank you, your Honor.

MR. SPIVACK: Thank you, your Honor

THE COURT: Have a good day Thank you.

(End of BlackBerry speakerphone conference with Judge Happas.)

BY MR. TRAMMELL:

Q. Dr. Biederman, you understand you're still under oath?

MR. FIBICH: Are we on the record?

MR TRAMMELL: I don't think we were ever off.

BY MR. TRAMMELL:

Q. You said the hospital you work for is paying for your lawyers here today. Is that right?

A. Correct.

Q. So no money is coming out of your pocket?

A. No.

Q. Do you know if the hospital has any arrangement with Janssen or any other drug company to reimburse the hospital for the cost of your lawyers?

A. I do not know.

MR. TRAMMELL: I guess this is 2 now, isn't it?

MR. PECK: What's marked?

MR BURNEY: This other document

(Biederman Deposition Exhibit 2 marked for identification.)

THE WITNESS: You want me to look at this?

BY MR TRAMMELL:

Q. That is Plaintiff's Exhibit 2. This is a copy of the subpoena pursuant to which you are appearing here today Have you ever seen this document?

A I believe that I saw it when it was served

Q. If you'll turn to, it's not paginated, but if you'll turn to the Massachusetts subpoena, which is Exhibit A to this document

MR. BURNEY: There are several Massachusetts subpoenas within that packet, I believe.

MR. TRAMMELL: Well, if you'd go to Exhibit A.

A Schedule A?

Q. No, Exhibit A There's a blank page that just says Exhibit A

A Exhibit A, yes

Q. Keep going. Okay. If we go to the section of this document called Schedule A, Documents Requested.

A. Yes

Q. Did you review this list of documents when you received the subpoena, Doctor?

A. Mm-hmm.

Q. Did you talk to your lawyers about it?

A. Yes.

Q. And what did you do to comply with this subpoena?

A. I provided whatever the subpoena says

Q. Where did you look for documents?

A. I searched all my computers, provided there was a C.V., and gave you everything I have.

Q Which computers did you search?

A. My laptop, my staff laptop, my desktop, and every computer I use.

Q Did you search your home computer?

A Yes, I searched my home computer.

Q. Did you search your Outlook?

A. Yes.

Q. Do you delete e-mail as a matter of course?

A. Yes

Q. How often?

A Often

Q. Just randomly?

A. All the time.
Q. Do you use your folders in your Outlook?
A. I use some folders for current things that are pending.
Q. Did you search any folders for documents responsive to this subpoena?
A Yes, I searched all the folders that I have.
Q So you searched your entire system?
A. I searched my entire system
Q Did you give all those documents to your lawyers?
A. Yes.
Q. Did you withhold any?
A. No.
Q Number 5 is all communications between you and Janssen. Have you provided all those?
A. Yes.
Q. Number 8 is all documents prepared by, prepared for, or received by you relating to Risperdal Have you provided all those?
A. Yes.
Q. Did you meet with your lawyers in preparation for your deposition today?
A Yes.

Q. How many times?
A Yesterday and the day -- and half of the day before.
Q. So today is Thursday. You met with them all day on Wednesday?
A. All day on Wednesday and half of the day on Tuesday.
Q. Where did you meet?
A. In my house
Q. Your house over there on Boylston Street?
A. Yes.
Q. How many hours did you meet?
A. Probably about two hours on Tuesday and about I would say four or five on Wednesday.
Q. Did you look at any documents?
A I looked at some documents, yes.
Q. Do you know which documents you looked at?
A. No. I don't remember.
Q You don't remember any of the documents that you looked at?
A. I don't remember
Q. I want to look at your C.V., but -- Well, I'll get it. We're done with that, with the subpoena, Doctor.
A Where do you want it to go?

Q. Put it right here for the court reporter.
A. Okay.
Q. And just one more question about the documents. Do you recall how many documents you looked at?
A. I would say a dozen.
Q. A dozen documents?
A. (Witness nodded.)
Q. Were they your documents or were they Janssen documents?
A A potpourri of e-mails and I actually don't remember exactly what I looked at.
Q. Was it the documents that were in the newspapers here not too long ago?
A. I don't know what was in the newspapers. I don't read the newspapers
Q. You don't read the newspapers?
A. No.
Q Exhibit Number 3 is the C V you produced in response to the subpoena
A. Mm-hmm.
Q Is this, as far as you know, a current version of your curriculum vitae?
A. The time it was revised is stated in the top right upper corner.

Q. Hasn't been revised since?
A Not that I know.
Q. You were born in Prague, Czechoslovakia?
A. Correct.
Q Where did you go to college?
A. I went to medical school in Buenos Aires, Argentina.
Q. Where did you go to undergraduate school?
A. There is no undergraduate school. It's medical school
Q. I don't understand How did you qualify for medical school?
A. You pass exams from high school. It's a straight medical school curriculum.
Q. So you went to high school in Prague?
A No.
Q. Okay. When did you leave Prague for Argentina?
A. When I was six months old.
MR SPIVACK: Excuse me, counsel
Dr Biederman, could you just make sure Mr Trammell finishes his question.
MR FIBICH: And if there's any way you can speak up. I know he's soft-spoken, but it's difficult to understand him.

MR SPIVACK: Right
BY MR TRAMMELL:
Q So when you were six months old you left Prague for Argentina. Right?
A Right.
Q Went to all your grade school and high school in Argentina?
A Correct.
Q Passed an entrance exam and went to medical school?
A Yes.
Q And how old were you at that point?
A I was 16.
Q And how old were you when you got out of medical school?
A 22
Q What did you do after that?
A I did my internship in Hadassah Medical Center, Hebrew University, Jerusalem.
Q Why did you go to Jerusalem?
A Because I wanted to
Q Why did you want to?
A Because I felt like it.
Q And why did you feel like it?
A That was my choice.

Q What was of interest to you in Jerusalem?
A I like their medical training and I wanted to have that experience
Q Did you apply to any other internship programs?
A No.
Q Just the Hadassah University in Jerusalem?
A Yes
Q What did you do after your internship?
A I did my residency in psychiatry.
Q Immediately after?
A Immediately after
Q Stayed in Jerusalem?
A Yes.
Q And after that?
A After that, I came to Boston to train in child psychiatry.
Q You weren't a research fellow at the Jerusalem Medical Health Center?
A Yes, that was part of the residency.
Q Then you came to Boston to do your clinical training?
A I came to Boston to train in child psychiatry.
Q Did you have any child psychiatry training

in Jerusalem?
A No.
Q What was the nature of the child psychiatry training?
A Child psychiatry training consist of experience, supervised work, lectures It's a program approved by the accrediting bodies that oversee training of doctors
Q So you would treat children who came to Massachusetts General Hospital for --
A No. My training was in the Children's Hospital in Boston
Q Which children's hospital?
A Children's Hospital in Boston.
Q Is that a part of Massachusetts General Hospital?
A No.
Q Other than your -- Well, did you have any sort of pediatric psychiatry education in medical school?
A We have pediatric training, not pediatric psychiatry training. You train after medical school Psychiatry is a specialty within medicine and child psychiatry is a subspecialty within psychiatry

Q But your first pediatric psychiatry training was at the Children's Hospital at Harvard. Right?
A Yes, in Boston
Q And what kind of patients would you treat?
A All kinds of patients
Q Children, though?
A Children
Q Suffering from what?
A From a variety Children are affected with behavioral problems, emotional problems, developmental problems, psychosocial problems The entire range of conditions afflicting children.
Q And from there you went to Mass. General. Right?
A Yes
Q You're not a pediatrician, are you?
A I am not.
Q Is there a pediatric psychiatry specialty within psychiatry?
A Yes
Q Are you a specialist in pediatric psychiatry?
A I am
Q Since when?

A. Since the mid '90s. Or, I don't remember, but it's listed in the C V., I think A few years after my training, so in the '80s I completed. You first need to pass the adult psychiatry board and then you are ready to go to the child psychiatry board. It's a lengthy process.
Q. Do you have any other kind of scientific training at school, any kind of training in epidemiology or biostatistics or anything like that?
A. Not specifically. But I published 650 articles in my career. I am very well-known in the field of child psychiatry.
Q. Despite being very well-known and prolifically published, do you have any training in epidemiology or biostatistics?
A. Not formal training
Q There is training that exists for purposes of specializing in epidemiology, though, isn't there?
A. I was specializing in child psychiatry, not in epidemiology
Q. Are you married, Doctor?
A I am.
Q How long have you been married?
A. Twenty-eight years.

Q. Just once?
A. No.
Q. You were married before?
A. Yes.
Q For how long?
A Seven years.
Q. How old were you when you first got married?
A 23
Q Was that in Israel?
A No, in Argentina.
Q How old were you when you got married the second time?
A. 31 or 32
Q And how old are you today?
A 61.
Q. How many articles did you say you've written over the course of your career, Doctor?
A. More than 600.
Q It says in your C.V. that during the decade of the '90s you were the fourth highest producer of high-impact papers in psychiatry as determined by the Institute of Scientific Medicine Is that correct?
A That's correct.

Q. What does that mean? What's a high-impact paper?
A. That is a formula that includes a citation and some other factor that I don't exactly remember, but has two components, a part of what's called the citation index
Q And why does the number of times a paper is cited make a paper a high-impact paper?
A Because the paper is cited when other people consider it important.
Q. And so it's because other authors, other people that write on similar subjects, are relying on your paper in making whatever points they're making in their paper Right?
A. You can say so. I think that the quotations are when you are trying to make a case of what is the evidence for a scientific factor. I only write scientific papers, so they are used, for example, if somebody does epidemiological research and says that depression affects 10 percent of the population, so a paper would start "And depression affects 10 percent of the population and I would like to cite this source " So if somebody does a paper on ADHD and says that ADHD is familial, I published a lot of papers documenting that ADHD is

familial, so that will be quoted
Q. Now, it is a way of saying that your papers are influential in the scientific community. Right?
A. The papers are quoted because the reader of the paper consider the paper as having scientific value
Q. You don't think your papers are influential?
A. I do not know what you mean by influential. But the papers are cited. When I cite a paper, it's because I consider the information of the paper that I am citing of scientific value and that's the reason I cite the paper.
Q Okay Your papers are considered to be of high scientific value to other people that write papers. Right?
A Yes.
Q What is your problem with agreeing that your papers influence other scientific authors?
A Because influence, as I understand the word, has a variety of meanings; and that is not appropriate to science. So in science you build on blocks, one step at a time So you want to go to the next step, so you say we know this so far;

I want to know the next
Q. So your papers serve as a building block for a lot of other papers out there. Is that right?
A. My papers are used for people that are writing scientific papers to expand the scientific knowledge
Q. But a lot of people who write papers on subjects similar to yours rely on your papers as building blocks. Right?
MR SPIVACK: Objection, asked and answered
BY MR TRAMMELL:
Q You have to answer.
A. I do not know what you mean, rely. Could you expand on that?
Q Well, what is the purpose of citing a paper?
A The purpose of citing a paper is to provide evidence that there is some factual information that somebody has done the work before. And the example I used perhaps is the simplest to illustrate my point. If somebody does work on, say, depression will cite a paper that says depression is prevalent. So that's not to influence; the paper is a fact.

Q. So in 2005 you were number one in terms of total citations to your papers on ADD and ADHD over the course of the past decade Is that right?
A. That is correct.
Q. You had a total of 6,866 cites -- Let me start over. Over the course of the decade between 1995 and 2005, there were a total of 6,866 cites to your papers on ADD and ADHD. Is that right?
A. That's correct
Q That means that among the articles that were written on the subjects of ADD and ADHD, your papers were cited more than any other papers?
A I would guess that's the interpretation.
Q. Do you know whether citations to your papers that disagree with what your papers say also count?
A. Yes. In science you are allowed to disagree. So a citation could be in a paper that failed to replicate what I found
Q Do you know of any studies where that occurred?
A. I do not know on top of my head, but there are many in science. There is always different opinions and different views; and when somebody is writing a scientific paper on a subject that I

address and they have different results, they will say that contrary to what I reported, they found differently.
Q. Why did you put this information in your C.V.?
A. Because it's an honor to have citations of this magnitude.
Q. Who do you send this C V to?
A To what?
Q To whom do you send this C V.? What do you use it for?
A The C.V s are largely used for academic promotions
Q. What does that mean?
A. To move in the ranks from one rank, for example at Harvard there is instructor, from instructor you move to assistant professor, from assistant professor you move to associate professor, and from associate professor you move to full professor
Q. Full professor?
A. Mm-hmm.
Q. What rank are you?
A. Full professor
Q What's after that?

A. God.
Q Did you say God?
A. Yeah.
Q. If you've achieved the highest rank you can achieve, what's the purpose of updating this C.V.?
A. Because a C.V. is a running notation of what is my work and what I'm doing.
Q. Do you send this to pharmaceutical companies?
A. Only if they ask me.
Q. When was the last time you sent it to a pharmaceutical company?
A. I don't remember.
Q. But you remember that you do or you have?
A. I remember that it is my practice if somebody asks for my C.V. for a reason, I send my C.V.
Q. Do you recall whether any pharmaceutical companies have asked you for your C V.?
A. Not specifically.
Q. Is this something that's well-known about you, that you are a prolific writer of high-impact papers?
MR. SPIVACK: Objection, calls for

speculation.
MR. FIBICH: The objection, I think, is "objection" only under the rules. So if you would please not suggest answers to your witness by going further than saying "objection."
MR. SPIVACK: I am stating my basis for the record; I'm not suggesting to the witness
MR. TRAMMELL: It's improper.
MR. FIBICH: Well, Mr Spivack, we have the right to ask you to state the basis for your objection, but in the absence of that, I think the proper way to object and preserve your objections for the record is to say one word, "objection."
MR. SPIVACK: Are you referring to the New Jersey rules or the Massachusetts rules?
MR. FIBICH: Yes, sir, New Jersey.
MR SPIVACK: And to which rule are you referring?
MR. FIBICH: I'll pull it out for you, if you'd like, at the break. I truly want to proceed in this deposition without any interruptions, but I find those to be speaking objections that are intended to suggest answers to the witness, and I would ask that you not do it
For the record, I am stipulating on behalf

of all the plaintiffs at this proceeding that your word "objection" preserves for the record any objection you want to raise as to the matter that you've just objected to
MR. SPIVACK: On any basis?
MR. TRAMMELL: As to the form of the question.
MR SPIVACK: All right. And there may be situations, for example if you ask a question that calls for privileged information --
MR. TRAMMELL: Sure. That's different.
MR SPIVACK: So on that, you're saying I can --
MR. FIBICH: Sure. Anything that you think is improper that we're inquiring into, you can instruct the witness not to answer on the basis of privilege.
MR. SPIVACK: All right.
BY MR TRAMMELL:
Q. Doctor, do you know whether you have a reputation for writing high-impact papers?
A. The high-impact paper is determined by others So the listed data that is in the C V is what others compiled about me, not me
Q. Okay But you recognize and the reason

you put this in here is you want people who read your C V to know you write papers that doctors read and rely on. Right?
A. I put it in the C V. because it's an honor to be recognized by my peers as my scientific work being of importance to them positively.
Q. I don't understand. Are you just bragging or is there some purpose for having this information in your C.V ?
A No The purpose of the information is factual This is stating the facts I am not saying that I'm great. I'm saying that this is the facts that were compiled about me.
Q. What's the practical use of that information for anybody that reads your C.V.?
A. There is no practical use
Q. So why have it in your C.V.?
A. Because I think -- I am very proud of that and I consider that it is a great honor to be recognized by your peers through my scientific work. Since I am a scientist, science has the peer-review process, which is a very critical part of the practice of science. To be recognized that the papers that I write have scientific utility to my peers is of great honor to me.

Q. So this is in there so that the people who read your C V know who they're dealing with, that you are a great scientist. Right?
MR. SPIVACK: Objection, argumentative.
MR. TRAMMELL: I'll object to your objection. It's improper under the rules.
MR. SPIVACK: Well, actually, my colleague here shows me the New Jersey rules, which say under 4:14 dash -- I think it was 3 -- 4:14-3 that if there is an objection to the form of the question, the objector shall state the basis for the objection so as to allow the questioner to amend the question. So that appears to be the reverse of what Mr. Fibich said.
MR FIBICH: No Under 4:14-3(c), "No objection shall be made during the taking of a deposition except those addressed to the form of a question or to assert a privilege, a right to confidentiality, or a limitation pursuant to a previously entered court order. The right to object on other grounds is reserved and may be asserted at the time the deposition testimony is proffered at trial."
MR. SPIVACK: Would you read the next sentence?

MR. FIBICH: "An objection to the form of a question shall include a statement by the objector as to why the form is objectionable so as to allow the interrogator to amend the question. No objection shall be expressed in language that suggests an answer to the deponent."
Well, I still think I interpret this to mean that you're supposed to say "objection" and not suggest an answer.
MR. SPIVACK: I am not suggesting the answer. Suggesting an answer would be improper. I know what a speaking objection is, Mr. Fibich. In order to allow Mr. Trammell to amend the form of his question, as the rule states, if it's an objection to the form of the question, I will state a short basis.
BY MR. TRAMMELL:
Q. Doctor, the reason you put this in your C.V. is so that everybody will know that you are an influential, important scientist. Right?
MR. SPIVACK: Objection, argumentative.
A. I put it in the C.V. because as a scientist I am very proud that my peers find the information that I write in my scientific papers useful.

Q. That's something that you know, though, isn't it, that your peers rely on your papers?
A. I do not know what my peers rely on. I publish only scientific papers, data, and the data speak by themself. If it's useful, people use it; if it's not useful, people refute it. That's the scientific process.
MR. FIBICH: Objection, nonresponsive.
BY MR. TRAMMELL:
Q. In other words, you undertake no efforts to ensure that people rely on your work. Right?
A. No.
Q. Doctor, with which drug companies do you have any sort of professional relationship?
A. I work with many firms and drug companies, probably dozens, that produce medicines that treat disorders that may have utility for the management of psychiatric disorders of children.
Q. So, for example, you have a consulting relationship with every manufacturer of atypical antipsychotic drugs. Right?
A. No.
Q. With which do you not have a consulting relationship?
A. Could you tell me what you mean by

consulting relationship?
Q. Well, okay. Do you have any kind of professional relationship with Janssen?
A. Yes, I do.
Q. And what is the nature of that relationship?
A. Janssen supported our scientific work.
Q. Do you have a professional relationship with Eli Lilly?
A. Yes.
Q. And what's the nature of that relationship?
A. Eli Lilly supported our scientific work.
Q. You acknowledge that you have a professional relationship with Janssen, Eli Lilly, Bristol-Myers Squibb, AstraZeneca and Pfizer. Right?
A. Yes.
Q. And those are the manufacturers of the atypicals. Right?
A. That's correct.
Q. Do you have relationships, professional relationships with the manufacturers of antidepressant drugs?
A. Well, some of the companies have more than

one drug. Some of the pharmaceutical companies have more than one product.
Q. Can you think of a manufacturer that makes a drug that you use in your practice with which you don't have a professional relationship of any kind?
A. I cannot tell you. There are multiple drugs. I don't have a relationship with every manufacturer of every drug that is produced in this country or in the world.
Q. But you do have a professional relationship with dozens of drug manufacturers. Right?
A. Yes, I do, I have a professional relationship with dozens of manufacturers. But my relationships are on the basis of advancing the knowledge and advancing clinical care.
MR. TRAMMELL: Object as nonresponsive.
BY MR. TRAMMELL:
Q. In the course of carrying out these relationships with all these drug manufacturers, does the relationship always involve them giving you money?
A. Most of the time.
Q. What are -- I want to talk about Janssen specifically first. What are all the capacities in

which you've worked with Janssen or any of the affiliated companies that are responsible for Risperdal?
A. I do essentially two things. I do medical education and consulting.
Q. What is medical education?
A Medical education are CME activities, talks.
Q. And what that means is that there is a continuing medical education event attended by doctors at which you will speak on Janssen's behalf. Right?
A. The CME activities are sometimes funded by different pharmaceutical companies. The content is not necessarily dictated by the pharmaceutical companies. For example, I may be invited to give grand rounds at the medical center and that program or that grand round series is supported by pharmaceuticals, but not necessarily a one-to-one correspondence.
Q. Well, okay When you talk about medical education, what are you talking about? Are you talking about CMEs or grand rounds or is that the same thing in your opinion?
A No. CME is a larger category of the way

that medical education is delivered It's delivered in the form of lectures, it's delivered in the form of seminars, it's delivered in the form of grand rounds.
Q So when you say medical education, you're talking about grand rounds, lectures, and seminars. Right?
A. Mm-hmm, correct
Q. Anything else?
A. That's the majority of it.
Q. What are grand rounds?
A. Grand rounds are academic talks that academic institutions organize to educate their faculty
Q Who pays for those?
A. I don't know who pays for that. Sometimes it's paid by funds that the institution has. Sometimes the institution solicits outside funding.
Q But if you go speak at grand rounds, somebody pays you for your time Right?
A. Yes
Q. And when you go to grand rounds to talk about Risperdal, who pays you for your time?
A. I never talk on Risperdal I talk on the diseases that risperidone may treat, like pediatric

bipolar illness in this case To my recollection, I talk on the diseases that risperidone may treat. I never talk of my knowledge on risperidone as a talk on risperidone
Q When you go talk about the diseases which you studied as possible diseases that Risperdal will treat, who pays you for your time?
A. I talk about pediatric bipolar illness That's the only condition that I talk about that may be treated by risperidone.
Q. When you go to grand rounds to talk about pediatric bipolar illness, who pays you for your time?
A I do not know who pays me for my time.
Q. Do you get a check?
A I get a check from the institution Who pays the institution is not known to me
Q. Okay You have no idea who pays them?
A. I usually have no idea. Sometimes I do.
Q. How do you hear about these grand rounds? I mean, how do you hear about the opportunity to speak at these?
A. They invite me.
Q The hospital does?
A The hospital invites me.

Q. What are lectures in the context of your medical education activities?
A. Could you explain the question? I'm not sure what are you asking?
Q. Sure I asked you what medical education meant You said it meant grand rounds, lectures and seminars
A. Yes. So, for example, a lecture could be a scientific symposium at the American Psychiatric Association.
Q So it's a speech?
A. It's a talk, yes.
Q And do you give talks about Risperdal or do you give talks about pediatric bipolar --
A. I only talk about pediatric bipolar
Q. And who pays you for your time when you go give speeches about pediatric bipolar?
A Depending on who invites me.
Q. And what are seminars?
A. Seminars are some smaller talks that are designed for subgroups For example, a larger meeting may have a breakout session that contains people with particular expertise. Like the American Academy of Child Psychiatry has a session on Ask the Expert or something like that, so there are ten or

twelve child psychiatrists kind of discussing cases
Q And this is all -- Your medical education is separate from your consulting relationship with Janssen. Right?
A Yes.
Q. Who pays you to go talk at seminars?
A Depending on who has invited me.
Q. When was the last time you did it?
A. About a year ago
Q. And who invited you?
A. I don't remember.
Q. Do you know where it was?
A. No.
Q Do you know what you talked about?
A Say again?
Q Do you know what you talked about?
A. I talk about two subjects, ADHD or pediatric bipolar illness
Q. Is your specialty limited to ADHD and pediatric bipolar disease?
A. Pretty much. I treat all conditions in child psychiatry, but those are the conditions that my scientific work has focused on.
Q So your study to the extent you've studied these diseases and drugs that treat them, your study

has been limited to ADHD and pediatric bipolar disease. Right?
A. That is the predominance of my scientific work, not the only. I have been interested in children that have psychopathology and I have done work on children at risk for bipolar disease. I have been interested in children with autism spectrum, children with anxiety. But the bulk of my papers have been on ADHD and pediatric bipolar illness.
Q. How many times a year do you think you participate in medical education events as a speaker?
A. It's hard to know. I think last year I have done much less than in the past. I would say a dozen times or so.
Q A dozen times a year?
A I really cannot tell you an exact number.
Q. Does that mean in the last year you've gotten fewer invitations to do these things?
A. Yes.
Q. Do you have any idea why that is?
A. There has been some accusation by Senator Grassley about issues of conflict of interest; and while the investigation is going on, I agreed not to

speak.
Q What is the nature of Senator Grassley's investigation of you?
A. Senator Grassley read, there was an article in The Boston Globe about a little girl in town that the parents are accused of first-degree murder. In fact, you may have seen it The accusation has been upgraded from second-degree to first-degree murder But because the child was diagnosed with bipolar illness, it captured the imagination of the media and there was an article in The Boston Globe that talked about the diagnosis and how controversial that is and particularly as it pertains to preschoolers
And in the article, the reporter got -- I sent my standard disclosure forms, so he wrote that I have extensive relationship with fifteen or so pharmaceutical companies. So Senator Grassley wrote a letter to the institution, to Harvard and Mass. General, asking for details. And that has been the cascade of events.
Q. So Senator Grassley became interested in you because of these people who were accused of killing their kid?
A. Senator Grassley claims to be interested

in issues of conflict of interest and is interested in making sure that the universities have tight conflict-of-interest rules I have no dispute with that.
Q. What have you done -- What interactions have you had with Senator Grassley or his staff?
A. None. Senator Grassley's interactions are with Mass. General and with Harvard, not with me directly.
Q. I didn't understand that at all. With who?
A. With Mass General and Harvard and not with me directly
Q. Have you spoken to Senator Grassley?
A. No.
Q. Have you testified before him?
A. No.
Q. Have you sent him any documents?
A. The documents were sent by the institution, not directly by me.
Q. Did the institution ask you for any documents?
A. The institution asked me for documents
Q. Did you give them to them?
A I gave all the documents that they asked

me.
Q. Did you destroy any?
A. No.
Q Were the documents you gave them produced to us here?
A. Say that again?
Q. Were the documents you gave to the school in response to Senator Grassley's investigation produced to us here?
A. I believe that anything that has to do with risperidone was produced.
MR. FIBICH: Objection, nonresponsive
BY MR. TRAMMELL:
Q Were the documents you gave --
MR. PECK: Excuse me, Mr. Trammell. I think at this point I ought to raise this for the record.
Both Mr. Fibich and yourself were admitted pro hac in the Foti case, and it is inappropriate for two lawyers to speak for or question or object for the same party. It's been going on for the first hour or so, and I just raise this for the record. Mr. Trammell is asking the questions Mr. Trammell has the right to object to answers that are nonresponsive

Mr Fibich, you are here representing the same party Under New Jersey rules and procedures, you are not permitted It's two lawyers for the same party
MR. TRAMMELL: I think, just to be clear, I think I'm also pro hac'd in the in re case, and so I represent all plaintiffs in addition to this plaintiff particularly
MR PECK: I think you're wrong I think the pro hac application was for the Avila case as well as for Mr Fibich Now, we can check easily
MR TRAMMELL: Sure Well, in any event, your objection is noted
BY MR TRAMMELL:
Q Did you send -- Did you produce to the plaintiffs in this litigation everything that you produced or that was produced by your school to Senator Grassley?
A The information that I produced, as I told you at the beginning, was sent to the lawyers and I assumed that my lawyers would produce whatever you need.
Q. That's not the question I was asking When you were requested to produce documents to Harvard and to MGH so that they could respond to

Senator Grassley, you produced certain documents to the school and to the hospital Right?
A That's correct
Q Were all those documents produced to us here?
A I do not know.
Q Do you have -- At what point did you retain Hogan & Hartson?
A Since the beginning of Senator Grassley's investigation
Q So since it came to your attention that Senator Grassley was investigating you, at that point Harvard and MGH or Harvard or MGH hired Hogan & Hartson for you?
A Yes
Q Do you know who hired Hogan & Hartson?
A I imagine it is the hospital counsel The hospital has an office of the general counsel that has legal responsibilities, so they probably did that
Q So the hospital you work for hired the Hogan & Hartson law firm to represent you in the Grassley matter, Senator Grassley's investigation, and for the purpose of this deposition Right?
A Correct

Q. Do you have any idea what they're charging the hospital?
A. I have no idea
Q. You have not seen any bills?
A I have not seen any bills.
Q. Nobody ever said "Doctor, we've got a bill here that says they met with you on this day Is that right?"
A. I have not seen any bills
Q. Well, that's not what I asked you. Did anybody ever ask you about the course of their representation of you?
A. No.
Q. Okay. You don't talk to general counsel of MGH about it?
A. No.
Q. Who is the general counsel of MGH?
A. His name is Christopher Clark.
Q. When was the last time you talked to him?
A. I would say about two months ago.
Q. Who have you told that you're at this deposition today?
A. Who I -- ? Sorry
Q. Who have you told that you were at this deposition today?

A. You want a list of people? I told my staff because I have been absent from taking care of my usual duties because of the time that you required from me, so I told them that I am in a deposition.
Q. And where does your wife think you are today?
A. My wife?
Q She know you're here?
A. My wife knows that I am here.
Q. Okay. Did you talk to anybody else about the deposition?
A. I do not know what you want from me What exactly -- ? Could you be specific about what information you're asking?
Q. Sure.
A. You want a complete list of people that I talked to, or what do you want?
Q. I want a complete list of people with whom you have spoken about this deposition.
A. My children know about this deposition Some of my friends know about this deposition.
Q. What did you and your friends --
A. My staff. Say that again?
Q. What did you and your friends talk about

with respect to this deposition?
A I just mentioned that I have this deposition
Q That's it?
A Yes
Q. Just said "By the way, I have a deposition this week"?
A Yeah. I cannot see them; I cannot partake in some social activity
Q What is Partners HealthCare?
A Partners HealthCare is the umbrella organization of several health care organizations such as Mass. General, Brigham and Women's, Faulkner Hospital, and some other institutions
Q Do you work for Partners HealthCare?
A Indirectly. I work for Mass General That is one of Partners HealthCare's institutions In fact, my ID badge says Partners
Q. Who is general counsel of Partners?
A I have no idea
Q Have you ever heard of Paul Cushing?
A. Paul Cushing? Paul Cushing is a lawyer in the office of the general counsel, yes
Q Okay Did you talk to him about the deposition?

A. This one?
Q. Yes.
A No. Not that I know of.
Q When you met with Hogan & Hartson yesterday and Tuesday, were Janssen lawyers there?
A No.
Q Who all was in the room?
A. Myself and the two gentlemen that are here to my left.
Q. And no one else?
A. No Well, it was my house. My housekeeper was around and my wife was around.
Q. And can you tell us who your lawyers are?
A. Yes. It's Peter Spivack and Keith Burney.
Q. Now, in addition to medical education activities, you said you do consulting work for Janssen Right?
A. Correct.
Q. And just so that we don't get confused, when I say Janssen, I'm referring to the Johnson & Johnson companies that make and market Risperdal. Do you understand that?
A. Yes. But Janssen is a company that makes and markets Risperdal.
Q Okay, just so we're not confused. What is

the nature of your consulting relationship with Janssen?
A. The nature is an ad hoc consulting arrangement that if they assemble, for example, an advisory board, I may partake if my time permits. That's the nature of the consulting. I don't have any formal title of consultant.
Q. Can you tell me all the types of consulting that you've done for Janssen?
A. My consultation has to do with the issues pertaining to the design of clinical trials, science, these type of things.
Q. Okay, I want to be a little more specific. Do you participate in ad boards, advisory boards?
A. Sometimes, yes.
Q So advisory boards is one thing you do as part of your consulting relationship. Right?
A. Yes.
Q. What else?
A. If there is a need to -- If Janssen wants to consult with me about anything that is important to them and they want to hear my opinion, they will call me and arrange for a time to meet
Q. They can call you anytime and talk to you about anything. Right?

A They can pick up the phone the same way that you can pick up the phone and talk to me.
Q. I'm not sure I can pick up the phone and talk to you. But Janssen can, right?
A. That's not true I think I am available --
MR. PECK: Object to the form.
A. I'm not sure what you will ask me, but I am available; and I return all my calls and I return all my e-mails
Q. So you participate on advisory boards for Janssen, they ask you to comment on clinical trials Right?
A. They ask me whatever is in their mind. Usually has to do with design of clinical trials, rate and scale, these type of things.
Q. When did your relationship with Janssen begin to the extent it affects or to the extent it involved consulting or medical education? Oh, and just to be clear, that's not the extent of your relationship with Janssen, is it?
A. I'm not sure. What are you asking?
Q. Okay. You do consulting, you do medical education speaking You also author papers. Right?
A I do not -- I author papers that I write

I do research that is funded by Janssen, if this is what you are asking.
Q. So they fund studies that you're going to do or that you're going to be involved in. Right?
A. Yes.
Q. That will result in some sort of publication. Right?
A. Yes.
Q. That'll be written by you. Right?
A. Yes
Q. Is that it? Just the research, the consulting, and the medical affairs speaking?
A. (Witness nodded)
Q. What kind of advisory boards have you participated in for Janssen?
A. Well, Janssen had a few years of something that they called the T&S Summit that brought together hundred or so psychiatrists, adult and child psychiatrists in the country, to interchange scientific information One year was focused on genetic, another year was focused on neuroimaging So those are kind of -- And during those meetings there were smaller groups For example, for me it was child psychiatry and things of that type.
Q. And where do those meetings take place?

A. In different parts of the country.
Q. Nice places usually?
MR BURNEY: Object to form.
A. I'm not sure what you call. . . Could you define "nice"?
Q. Yeah Can you name places where those advisory boards have taken place?
A. I remember one of them was in Arizona; I'm not sure which city Mostly because of weather issues.
Q. New York City?
A. I don't remember whether there was a T&S Summit in New York City.
Q. Hawaii?
A. No.
Q. Any advisory boards ever in New York City or Hawaii?
A. I don't remember.
Q. Janssen pay for you to go to the advisory boards?
A. Yes
Q. They pay for your hotel?
A. Yes.
Q. You stay in a nice hotel?
A. Could you define "nice"?

Q. Well, what kind of hotel did you stay at?
A It was a hotel that they made arrangements to stay
Q. Where did you stay in Arizona?
A. I don't remember. A hotel.
Q. They pay you for your time?
A. Yes.
Q. How much did they pay you an hour for an advisory board?
A. I believe the advisory board, I think the honorarium, I think it was two or three thousand dollars for the day.
Q. I'm sorry. Didn't mean to interrupt you So two or three thousand dollars per day for --
A. For one day. The meeting was one day only.
Q. Okay But your standard rate for participating in an advisory board for Janssen is two or three thousand dollars a day?
A. Yes, I would say so.
Q. Who came up with that number? Was that you or them?
A. Me.
Q. And will they just write you a check or how do they pay you?

A. Usually they write me a check.
Q. To you personally?
A. To me personally.
Q. And what do you do with that money?
A. I deposit the money in my account.
Q. Do you know how many times you've participated in advisory boards for Janssen?
A I don't remember.
Q. Do you think it's a hundred?
A. I don't think so
Q. Do you think it's fifty?
A I do not know.
Q. Could it be fifty?
A I don't think so.
Q. But you don't know?
A. I don't remember.
Q. Okay I asked you earlier, and just to be clear, just so that we've got -- just so we understand the nature of the relationship, they fund your research, you do consulting which consists only of advisory board activity or whatever other random questions they have for you, and you do speaking at medical education events, and that is the entire scope of your relationship with Janssen Is that right?

A. Yeah, that's correct
Q. When did your relationship with Janssen begin?
A I really don't remember. Janssen developed risperidone, was approved in the '90s, so we became interested in risperidone after observing that it's a useful treatment for our patients. So I think our paper was in the mid '90s, I would say in the late '90s or so. Mid to late '90s it would be.
Q Do you know when Risperdal was approved for marketing?
A. I don't remember exactly. I think it's in the early '90s, in the 1990s.
Q. '93?
A '93 sounds right.
Q. Okay After it was approved, you started using it in your patients Right?
A. Not immediately. In our clinical care of children with bipolar illness we observed that the traditional treatments, mainly lithium, Depakote, carbamazine, did not work very well. The treatment took months to unfold and was associated with very high rates of relapse So we noted that the second-best treatment that benefited these children were atypical neuroleptics. So at that time when we

finished doing analysis on this, the only atypical outside of Clozaril that was available was risperidone, so we began using risperidone in our practice And we noticed it was very helpful to our --
Q. You say the second-best treatment for children was atypicals?
A. No, not second-best What I said, the second outside Clozaril -- Let me go back. We did an analysis that we published on what helps children with bipolar illness So we noted that in the paper that was published in the Journal of Clinical Psychiatry, that this is about 100 children that had the diagnosis, treated by about a dozen doctors. So we noted that the traditional treatments that were mainly lithium, carbamazine, valproic acid was helpful selectively more than anything else, but the treatment took very long to unfold and was associated with very high rates of relapse. The second-best treatment after the traditional mood stabilizers were the typical first-generation antipsychotics
So at that time when we finished the analysis, it took several years to do, risperidone was available, so I would say it was mid 1990s And

in our clinic when we treated children with risperidone added on to other medicines, we noticed that children improved. So we were very interested in exploring the usefulness of risperidone further as monotherapy
MR FIBICH: Objection, nonresponsive
MR TRAMMELL: Objection, nonresponsive
BY MR. TRAMMELL:
Q. Do you recall whether you initiated the contact with Janssen to begin the professional relationship that you've described or they initiated the contact?
A. I approached Janssen in the mid 1990s after I noticed that risperidone worked for our patients in the paper that we published. We approached them -- I approached them to see if they would be interested to do a clinical trial.
Q. So you published on this subject before you approached Janssen?
A. I published on the subject before I approached Janssen
Q. And what paper is that?
A. It was a paper, a case series that we published that is in my C.V. that we added risperidone to I think two dozen children on top of

other treatments that they were receiving and we noted that it was very helpful.
Q. Where was that published?
A. I don't recall, but I can do a computer search and I can find the paper for you.
Q I think I have it
So you initiated contact with Janssen to let them know that you were studying the use of Risperdal in kids and you wanted to do what?
A. I approached them to seek funding to do a clinical trial of risperidone monotherapy
MR. TRAMMELL: Let's take a break.
THE VIDEOGRAPHER: The time is 10:32. We're off the record
(Short recess taken)
THE VIDEOGRAPHER: This is the beginning of tape number 2 We're back on the record. Time is 10:53.
BY MR. TRAMMELL:
Q. Dr. Biederman, you understand you're still under oath. Right?
A. Yes.
Q. Who is John Bruins?
A John Bruins was the medical liaison person for Janssen in the '90s

Q. And what's a medical liaison?
A. A medical liaison is a person that interacts on medical and scientific matters between Janssen or the pharmaceutical company and academia, doctors
Q But he works for the pharmaceutical company. Right?
A. Yes.
Q. Now, you testified earlier that you initiated a contact with Janssen in the late '90s asking them if they would be willing to fund a study of the use of Risperdal in kids Right?
A. I think it's in the --
MR PECK: Object, form.
A I think it's in the mid '90s I don't remember the dates, but somewhere in the '90s.
Q. Did Janssen ever -- Now, before that time did Janssen ever request that you put together a trial proposal for generally the same type of study?
A. All proposals came from me to Janssen, not the other way around.
Q. Okay. They never requested that you put together a study to evaluate the use of Risperdal in kids. Right?
A To my recollection, I submitted proposals

to them. They may have asked to expand on what I submitted, but the idea of doing a trial came from me.
Q Do you know approximately what year you first submitted a trial proposal to Janssen?
A. Somewhere in the '90s. I don't remember. In the mid '90s
Q. Any of those ten years?
A. Hmmm?
Q. Any of those ten years?
A. I don't remember the exact date. I would say somewhere in the middle of 1990s, I would guess. The answer is I don't remember the date.
Q The first record I've seen is 1998, correspondence between you, from you to Janssen. Does that sound right to you?
A Sounds right if you have it.
Q. Okay
Did Janssen ever refuse to pursue one of your proposals for studying Risperdal in kids?
A Pharmaceutical companies, they get a lot of proposals and most of them are refused.
Q Did Janssen ever -- Objection, nonresponsive. Did Janssen ever refuse to fund one of your research proposals for using Risperdal in

kids?
MR. PECK: Objection to form
A. I don't remember. I think that my first proposal was denied, so my guess that the answer is that they refused.
Q. So the first proposal you sent to them, they refused to fund the study?
A. Yes.
Q. Did that bother you?
A. Proposals are submitted to do a study. If the study is not done, it's disappointment.
Q. But it didn't bother you, did it?
A. Could you define bother?
Q. Sure. Were you upset?
A. I don't think I was upset. I was disappointed
Q. So not upset, just disappointed Right?
A. This happens a long time ago I cannot recall my response, but I think that disappointment is a more accurate description.
Q In any event, you send out a lot of proposals, some of them are accepted and some of them are denied Right?
A. Correct.
Q. Janssen happened to deny your first

proposal. Right?
A I think so
Q. And did that affect your prescribing practices of Risperdal?
A. Not at all.
Q. Did it affect your professional relationship with Janssen?
A Not at all.
Q. How long was it between the time that they rejected your first proposal to any suggestion on either side that you would do more research?
A. I don't remember. We got funding to do a study of risperidone in I believe 2002
Q. Did you ever try to get back at Janssen for denying your request to do a study?
A. No
Q I'm on 4 Handing you Biederman Exhibit 4, Doctor, what I want you to do is look at the e-mail that is the third e-mail on the first page from John Bruins, who is the Janssen medical science liaison, to a bunch of people at Janssen Do you see that?
A. Could you point out what you want me to -- ?
Q It's this one right here.

A This e-mail?
Q Yes
A Okay
Q You see that?
A. Yes
Q It's dated November 17, 1999; the subject is Dr Joseph Biederman payment. Do you see that?
A. Just one second. John Bruins, Wednesday, November -- What date you are talking about? November 17?
Q. November 17, 1999
A. Subject and payment, yes
Q Okay. And the subject is "Dr Joseph Biederman payment " Right?
A Correct.
Q If you go down and look at the second bullet point here, it says "Three or four years ago Janssen H O ," which I assume means home office, but maybe you know better, "requested that he put together a study to evaluate Risperdal in the child and adolescent population He submitted a thorough and lengthy proposal which amounted to approximately $280,000 We dragged our heels on his request, which we made, for over a year. He finally received a standard ding letter. By the time I found out

about it a week later I went to see him, his secretary advised me of his fury. The sales representative who called on him and I took an hour of verbal beating. I have never seen someone so angry." Did I read that reasonably correctly?
A. Yes. This is what the e-mail says.
Q. Right Does this refresh your recollection that Janssen requested that you put together a study proposal which you then submitted to them?
A. The way that I recall it happened, it was that I sent a letter; they responded -- that I'm interested to do a study. They responded that they wanted a detailed proposal and a budget. But the initiative was from me to them, so the budget -- they requested to follow up with a detailed proposal and a budget
Q. And they denied that proposal?
A. Yes
Q And you were furious. Right?
A. I don't recall being furious. I was disappointed.
Q Do you understand the difference between furious and disappointed?
A Maybe you can explain to me

Q Well, do you understand the difference?
A. I am telling you that I have no idea what he's talking about.
Q. You're a person of reasonable intelligence or maybe exceptional intelligence. Do you know what furious means?
A. Yes, I do
Q. Okay What does it mean to you?
A. Furious means that somebody is out of their usual modus operandi, in anger. I have never, never in my career been acting up. So rejection is the law of the land in science You get more often than not rejected than accepted. It's his interpretation of the state of affairs, not my state of mind.
Q You think he's wrong Right?
A. I think it's his recollection of what happened, not mine.
Q He misunderstood? To him your disappointment looked like fury. Right?
A. This is his interpretation of my ..
Q Or Mr Bruins is lying. Right?
MR. PECK: Object to form, foundation
A It's a free country; he can say whatever he wants. That's not -- I was never in any state of

fury in my career that I recall, so I have no idea what he is referring to
Q. You've never been in a state of fury in your career. Right?
A. I have always been respectful and collegial. Okay? I never had a temper tantrum with colleagues. Okay?
Q. Because it would be unprofessional to be furious with people like this and give them an hourlong verbal beating, wouldn't it?
A. I would never have done it.
Q It would be unprofessional, wouldn't it?
A. I would never have done it.
MR. FIBICH: Objection, nonresponsive
MR. TRAMMELL: Objection, nonresponsive.
BY MR. TRAMMELL:
Q Would it be unprofessional?
MR. SPIVACK: Objection, asked and answered
MR. TRAMMELL: He hasn't answered it.
BY MR. TRAMMELL:
Q Would it be unprofessional?
MR. SPIVACK: Objection, asked and answered.
A. I have never done it. I do not know what

he is talking about
Q. Do you consider this kind of reaction that he's describing to be unprofessional?
A I would describe it as as a behavior that is not applicable to me
Q. So either Mr. Bruins misunderstood your state of mind or he's lying in this document. Right?
MR. SPIVACK: Objection, asked and answered, misstates the witness's testimony.
A I have no idea what Mr Bruins is saying, what his state of mind is.
Q. Well, either he's wrong about how you felt about the rejection or he's lying to people at Janssen Right?
MR. PECK: Objection to form
A I have never --
MR. SPIVACK: Objection, asked and answered, calls for speculation, argumentative
MR. TRAMMELL: Can you wait for them to fill up the record before you answer?
(Pause)
BY MR. TRAMMELL:
Q. You see there where it says in that paragraph that the secretary advised Mr. Bruins of

your fury. So in fairness to you and Mr. Bruins, it may have been your secretary that was mistaken. But do you see that?
MR. SPIVACK: Objection, calls for speculation, foundation
A I have no idea, but --
MR. SPIVACK: Just a second
BY MR. TRAMMELL:
Q You don't understand what this document says?
MR. SPIVACK: Objection, no foundation.
A. I have no idea what he's talking about.
Q. Can you read the words that are on this document?
A. Yes, I can read the words.
Q. It says the secretary advised, your secretary advised Mr. Bruins of your fury. Do you see that?
A. I see that.
Q Do you have the same secretary you had then?
A. I don't remember.
Q You don't know who your secretary was?
A. I don't remember what the secretary was at that time and who he talked to. There are several

secretaries, receptionists and people in my staff.
Q. Who is your secretary now?
A Her name is Yvonne Woodward.
Q. And how long has she been your secretary?
A. Last year and a half.
Q. Who was your secretary before that?
A. There was a woman by the name of Julie Fiore.
Q. And how long was she your secretary?
A. Seven years.
Q. Who was your secretary before that?
A. I don't recall
Q. Why isn't Julie Fiore your secretary anymore?
A She decided to change jobs and to move on.
Q. Where is she now?
A. I do not know
Q. Did she quit or was she fired?
A She was not fired. She quitted.
Q It then says, after the secretary who we can't identify told Mr Bruins of your fury, Mr. Bruins, the medical science liaison, and the sales rep who was responsible for calling on you took an hour of verbal beating. That's pretty strong language, isn't it?

MR SPIVACK: Objection, calls for speculation, no foundation
BY MR TRAMMELL:
Q. Do you recall laying a verbal beating on John Bruins and the sales rep?
MR SPIVACK: Objection, asked and answered
A. I do not
Q. Certainly you would recall that if it happened, wouldn't you?
A. I cannot recall things that happened so long ago.
Q. Is it customary for you to administer verbal beatings to people?
A. Absolutely not.
Q. Okay. So it would be extraordinary if that happened, wouldn't it?
A It did not happen, to my recollection.
Q. Okay, it didn't happen. Nevertheless, it was his impression that he had never seen someone so angry. But you don't recall being angry about it Right?
MR SPIVACK: Objection, no foundation, calls for speculation.
BY MR. TRAMMELL:

Q. Right?
A. (Pause) So what was question? I don't --
Q You don't recall being angry?
A. No, I don't.
Q. The next bullet point says "Dr. Biederman is the head of adolescent psych at MGH. Since that time our business became nonexistent within his area of control." Do you have any idea what that's referring to?
A. No.
Q "He now has enough projects with Lilly to keep his entire group busy for years " Do you see that?
A. Yes.
Q. Now go up to the first bullet point: "Dr. Biederman is not someone to jerk around. He is a very powerful national figure in child psych and has a very short fuse." Did I read that reasonably correctly?
A. Yes.
Q. Do you remember telling Mr. Bruins that you're not somebody to jerk around?
A No
Q Did you have the impression that Janssen was jerking you around?

A. No.
Q. Did you tell Mr. Bruins that you're a powerful national figure in child psych?
A. Absolutely not.
Q. Did you do anything that would indicate that you have a short fuse?
A No.
Q And the truth is, Doctor, that after Janssen asked you for a proposal and you took your time, your valuable time to create this proposal and send it to them and they had not enough courtesy to give you what you considered to be a reasonable explanation of their decision, you decided that you were going to show them and your business was going to be nonexistent with them for the future. Right?
MR. SPIVACK: Objection, asked and answered, argumentative, no foundation.
A. I have no idea what you are asking.
MR PECK: Objection, form
MR FIBICH: Okay, would you instruct Mr. Biederman to let your objection get on so he can then answer the question?
MR. SPIVACK: Yes Thank you.
MR FIBICH: Because I don't know. Are you able to get all that?

THE REPORTER: I hope so.
MR. SPIVACK: Dr. Biederman, if you could, please just wait. The attorneys will interpose objections if the questions are believed to be objectionable. Can you just wait?
THE WITNESS: I will try again.
MR FIBICH: And for the record, an objection by one is good for everybody. I mean, we have that agreement, don't we?
MR. SPIVACK: Could you clarify?
MR. FIBICH: What I'm saying is if you make an objection as Mr. Biederman's attorney and Mr. Peck makes an objection on behalf of his client, your objection is good for him as well.
MR PECK: They may be different objections.
MR. FIBICH: I understand they may be different objections. This isn't my first deposition. What I'm saying is you don't need to make the same objections. Okay?
MR PECK: I hear you.
MR. FIBICH: Does that mean okay?
MR. PECK: It means I hear you.
MR. FIBICH: Well, I'm trying to understand Are you going to make repetitive

objections for the same objection?
MR. PECK: Let's proceed
MR. TRAMMELL: In any event, Doctor, as we go on, you've got to give them time to make their objections before you answer the question Otherwise we will have --
THE WITNESS: I apologize.
MR. TRAMMELL: -- a disastrous record
THE WITNESS: I apologize.
MR. SPIVACK: And just let Mr. Trammell finish That way it'll be easier for the court reporter and the videographer
BY MR. TRAMMELL:
Q. Now, the truth is you wanted to show Janssen you weren't somebody to jerk around and if they were going to deny your research proposals after they requested that you make the proposal, you were going to show them how powerful a national figure you are by ending your business with them. Right?
MR. SPIVACK: Objection, argumentative, no foundation, calls for speculation, asked and answered
A. I am actually not sure what is your question. Maybe you can do one question at a time,

not a multi-layered one
Q. I'll object as nonresponsive. And just answer my question the best you can.
A I submit -- I am a scientist. I submit applications all the time to various sources, foundations, pharmaceuticals, the Government. The most common state of affairs is rejection. Okay? So what happened with Janssen is a matter of fact of life in academia. Submit a proposal, they don't want it, that's part of life.
Q. Well, the truth is it's one thing to deny other people's requests for proposals. It's another thing to deny yours, because you're a powerful national figure in child psychiatry and you had the impression that they were jerking you around by denying your request for research funding Right?
MR. PECK: Object to form.
MR. SPIVACK: Objection.
A This is Mr. Bruins' state of mind and interpretation of the reality. I submit applications all the time and to all kind of agencies, and rejection is a very common state of affairs.
Q. How could Mr. Bruins be so mistaken?
MR. SPIVACK: Objection, no foundation

A I have no idea
Q. Did you find him to be a person who was not truthful?
A No
Q He was always honest with you, wasn't he?
A I do not -- My interactions were strictly professional I have no basis to think one way or another
Q The subject of this e-mail, though, is payment for a grand rounds you were going to do. It's not explicitly the subject but that's what the e-mail is about And the rest of this information looks like background to me. But if you go to the second page, it says, and it's the top bullet point there, it's saying generally that Dr Biederman was coming to UConn to give grand rounds in September of '99 According to him, some previous discussion had taken place between the Boston rep, the Janssen sales rep covering Dr Biederman, and the Hartford rep, who I'm assuming is a Janssen sales rep covering UConn The Boston rep was doing everything she could think of to get Dr Biederman back in our graces
Anyway, they had done some behind-the-scenes negotiating to schedule this program

Dr Huey informed me that Dr. Biederman received his commitment that Janssen would pay for this program, includes a promise of 2-1/2 thousand dollars honorarium and expenses. Dr. Huey and I were both surprised by the figure. We were not part of negotiating and stayed out of it." Have I read and summarized that bullet point reasonably correctly?
A Correct
Q And so this is the type of talk that you were referring to earlier when you were talking about your grand rounds duties with Janssen Right?
MR. SPIVACK: Objection, no foundation
A. To my recollection the invitation to give grand rounds came from the chairman of the department and I did not know who was supporting the grand rounds. When the matter of payment came to be, he told me that he cannot pay me because Janssen was supposed to support it and Janssen did not pay UConn But the agreement, my discussions were between me and the university, not with Janssen.
Q Did you get furious at Dr Huey?
A. Absolutely not. I was disappointed that the commitment to pay for my time was not honored for six months, so I asked him to make sure that his commitment is honored.

Q. Did you give Dr. Huey a verbal beating?
A. Absolutely not
Q. Now, did you know that there was behind-the-scenes negotiating among the Janssen reps to arrange for that grand rounds presentation?
A. I had no idea I was not involved in those negotiations.
Q. Did you know that's the way that these kind of things usually happen, that there are these behind-the-scenes negotiations by the sales rep?
MR. PECK: Object to form.
A. I don't.
Q. You don't know that?
A No
Q. At any rate, you were upset that Janssen hadn't paid your honorarium. Right?
A. I was asking Dr. Huey that invited me and committed to pay me to honor that commitment.
Q. Did you ask him when you were done giving your talk?
A Absolutely not This is six months later this was happening.
Q. Oh, okay So you went and gave your talk and then no money came and you said where's my money?

A. Yeah. I think after some time passed I asked if there is any problem with honoring his commitment to me.
Q. And he said Janssen is supposed to pay you?
A. I don't recall exactly the conversation, but something went to the extent that he cannot pay me because Janssen did not pay them. This is what I recall may have happened
Q. So you went to collect from Janssen. Right?
A. No. I wanted to collect from the University of Connecticut.
Q But you raised it with Janssen?
A. I may have asked Janssen to make sure that that payment is received or some variation thereof.
Q. Okay. You must have raised the issue with Mr Bruins, though. Right?
MR. SPIVACK: Objection, calls for speculation, asked and answered
A. I do not recall
Q. Do you know whether you did?
A. I don't recall
Q. The next bullet point says "I then filled out the grant request paperwork and sent it to you

for approval This was about three months ago and well before the program on September 20, 1999. You then returned the paperwork to me and requested me to get the sales force to pay for it."
Just skipping down, the fourth from the last bullet point says "One week ago" -- or "Over a week ago Dr Biederman was on his way back to tirade He was calling me and Dr. Huey's office and was starting to ruffle Dr Huey's feathers that we had not paid him I asked Dr Biederman for further documentation and committed to him that we would get his check to him by yesterday in exchange for documentation from him. In two lengthy voicemails to you I explained the situation and promised the documentation to pass in the mail with the check "
Do you have any idea what he means when he says you were on your way back to tirade?
A I have no idea
Q What does that mean to you?
MR SPIVACK: Objection, calls for speculation
A. I don't know
Q. You don't know what a tirade is?
A I know the meaning of the word. I don't know what he means by that.

Q. Did you give the impression that you were working up to a tirade with Mr. Bruins?
A. I don't recall the circumstances of what he's alluding to.
Q Nevertheless, you were calling Dr. Huey's office and Janssen to try to collect the payment Right?
A. I called Dr. Huey's office to ask him to honor his request and he told me that he was not -- did not receive the payment from Janssen. So this is what I recall. This happened a long time ago I do not know the exact details
Q. And what was it that bothered you so much? Is $2500 a lot of money to you, or was it just that a deal is a deal?
MR. SPIVACK: Objection, argumentative, misstates the witness's testimony.
A. A deal is a deal
Q. Is $2500 a lot of money to you?
A. $2500 is money.
Q. Is it a lot of money?
A. I don't know. Define "lot "
Q. Well, to you. Do you consider $2500 to be a lot of money?
A. 25 dollars is a reasonable amount of

money
Q. Then the next bullet point says you paged Mr Bruins and wanted to know where your check was; and then he says "I told him to call you," which I guess is reference to more of the behind-the-scenes arrangement for your payment. It says "Dr Biederman has done everything we have asked of him. Again we have jerked him around. I am truly afraid of the repercussions " And "truly" is misspelled, but have I read that reasonably correctly?
A Yes
Q. Do you have any idea of what he means when he says he's truly afraid of the repercussions of jerking you around?
A I have no idea
Q. Did you ever make any threats to him?
A. Absolutely not
Q Would that be unprofessional?
A. I would never do anything like that.
Q Because it would be unprofessional?
A. Because it's not part of my repertoire.
Q It's wrong, isn't it?
A "Wrong" is a moral statement.
Q Well, can you make a moral judgment?

A. No. This is not part of my repertoire; I am not a moral expert.
Q. Do you know the difference between right and wrong?
A. I do.
Q. Is that wrong or is it right?
A. This is not in that category.
Q. What do you mean by your repertoire? What are you talking about?
A. That I don't behave in that manner
Q. You don't believe in what?
A. I don't behave in --
Q You mean tirades and threats?
MR. SPIVACK: Objection, argumentative, misstates the witness's testimony, asked and answered.
MR. TRAMMELL: Well, now we're talking about his repertoire, which we haven't talked about before
BY MR. TRAMMELL:
Q. It's not part of your repertoire to be furious at people you work with and go on tirades and threaten them Right?
A Correct.
Q. Are you surprised by that e-mail?

A. Yes.
Q Does it make you angry?
A. No. I'm surprised.
Q. Are you disappointed that you gave that impression to someone?
MR SPIVACK: Objection, calls for speculation.
A I am surprised.
Q Do you still speak to Mr Bruins?
A. Mr Bruins is no longer with Janssen. I do speak with him when I meet him in places.
Q You do speak with him what?
A When he comes to meetings, say, when I see him I speak to him.
Q. What does he do now?
A. I have no idea.
Q. What meetings does he come to?
A Psychiatric meetings.
Q Oh, so he works for another pharmaceutical company, or you don't know?
A I have no idea where he works.
Q When you see him, are you going to apologize to him for giving that impression?
A. I did not know that I made that impression.

Q. You didn't do anything wrong. Right?
A. I did not do what he is saying here that I did.
Q So this is Exhibit 5; and we're done with the e-mail. Oh, and by the way, is that e-mail a document you reviewed to prepare for the deposition?
A. This one?
Q. Yes.
A. I saw this document.
Q. Okay. You reviewed this with your lawyers?
A. Yes

Q. Do you recognize this document?
A. I recognize this is a document that has my name on it.
Q. But you don't recognize it? You just recognize your name?
A. No, not specifically.
Q. Do you know whether you wrote this?
A. Most likely.

Q. Okay. Can you confirm or deny whether this is other than the -- Well, does this have anything to do with the subject of Mr Bruins' e-mail? Do you know?
A I have no idea

Q. And how did you come to put this document together? What motivated you to do this?
A I am a researcher and I need -- Research is costly and I need to seek funding to do research, so I apply to different sources of funding, pharmaceuticals, foundations, private donors, the NIH, for different ideas to see if we can advance the field

Q. None of the MSLs, none of the salespeople, nobody said, hey, you really ought to propose to do research on Risperdal here at your hospital?
A Proposals for research are submitted routinely to pharmaceutical companies, to the NIH, to foundations, to seek funding to advance the scientific foundations of the diseases that I treat

Q. So what you're saying here is that despite whatever effectiveness these drugs have, they're certainly, including Risperdal, associated with bad side effects including the side effects that are listed here. Right?
MR PECK: Objection. That's not what he said.
A. All medicines --
MR. TRAMMELL: That's more objection than you're allowed.
MR. PECK: I objected to form.
MR. TRAMMELL: Fine.
MR. PECK: And then you misquoted it.
MR TRAMMELL: Well, I understand. You don't get to instruct the witness what to do.
MR PECK: I am not instructing the witness.

MR. TRAMMELL: You sure are
MR. PECK: I'm making an objection.
MR TRAMMELL: Well, that's not a proper objection. We talked for thirty minutes about that this morning movement
BY MR. TRAMMELL:
Q. Doctor, what you're saying here is that, and you tell me if I'm wrong, despite the uses that they have, these atypical neuroleptics, including Risperdal, they're associated with side effects including weight gain, hyperprolactinemia, and disturbances of glycemic and lipid control. Right?
MR. PECK: Object to form.
A. All medicines have benefits and adverse effects. Physicians do a risk/benefit analysis when they prescribe medicines.
MR. FIBICH: Objection, nonresponsive.
MR TRAMMELL: Objection, nonresponsive.

A No, I'm explaining to you that there are side effects in every treatment. The treatments are not delivered to produce side effects; they are delivered to produce benefits

Q. Are these the side effects associated with Risperdal?
A. Yes.

Q. The next point -- And, by the way, the use of Risperdal in the pediatric population was off-label at this time, wasn't it?
A. Yes
Q And what does that mean?
A. Off-label means that the medicine is used by physicians that is not specifically approved by the FDA for that use
Q So it means a drug is being used for something that the FDA hasn't approved it for. Right?
A. Yes.
Q. Okay. And so you were proposing to do research on off-label uses of Risperdal Right?
A. I was proposing to do research on the efficacy and safety of risperidone relative to other

medicines.
Q. In an off-label population. Right?
A. The use in children at that time was off-label and two years ago has been approved.
MR. TRAMMELL: Objection, nonresponsive.

Q. One of the things you wanted to study was the efficacy of Risperdal in preschoolers Right?
A. Yes.
Q. And how old are preschool kids?
A. Could you repeat the question?
Q. How old are preschool kids?
A Four to six.
Q. And what age range was Risperdal approved for at that time?

A. It was approved, to my recollection, for individuals older than 18.

Q So what you're saying is there's evidence that is accumulating that kids or that pediatric bipolar disorder onsets in these preschool kids, who I assume are three and four years old?
A Usually four to six.
Q Okay. So pediatric bipolar disorder onsets in four- to six-year-old kids coupled with the fact that the drugs are widely used, despite that, there's not a lot of data on efficacy. Right?
MR. PECK: Object to form. It's a compound question.
A On efficacy and safety, yes.
Q. And so basically what you mean is, what you're trying to say is that we have kids suffering

from this disease or it's possible that they're suffering from this disease in the preschool years, the drug is used a lot in these kids, we ought to have some data to instruct doctors about whether it's safe and effective to be doing this?
A. Yes.

Q Who makes Wellbutrin?
A. Bupropion was initially made by Glaxo or Wellcome, Burroughs Wellcome, and then when they merged I don't know who owns Wellbutrin. I think GlaxoSmithKline, I think.

Q. Did Janssen fund any studies that you did to study other companies' drugs?

A. Not that I know
Q In the absence of Risperdal.
A. Not that I know of.
Q. So is this really kind of the origins of the J&J Center at MGH?
A. Well, not really This was a treatment program The J&J Center was centered on understanding the diseases, not the treatment of the diseases. This is a program to treat the condition, pediatric bipolar illness at different ages and to treat the components of the illness, depression and ADHD.
Q. And just so the record is clear, can you tell us what the J&J -- the Johnson & Johnson -- Center is at Massachusetts General Hospital?
A. The Johnson & Johnson Center was structured on the basis of an NIH center that has components, or we call them cores, and focused on studying the two conditions that we're interested: ADHD and bipolar illness The center had a core that was neuroimaging, a core that was focused on genetics, a core that was focused on data analysis of existing data, a core that we call assessment that had a core of trained psychometricians to do structured interviews, and a core that was in

product development. There was no treatment in the J&J Center.
Q When did the center start?
A. The center, to my recollection, started in 2002.
Q. Does it still exist?
A. No.
Q. When did it cease operations?
A. In 2005
Q. And why?
A. It was not refunded.
Q Janssen decided to stop?
A Yes
Q. Okay.
A. By the way, the center was funded by McNeil and Janssen, not just Janssen.
Q Because McNeil, the McNeil-Janssen group makes other drugs that you're studying for kids Right?
A McNeil makes Concerta. We study ADHD and bipolar illness
Q Did you say it was an NIH center before it was a --
A. No I said it was modeled after centers that the NIH funds.

Q. I see
A The structure of the center was modeled after NIH centers.
Q. I want to go back just quickly. We talked about all the ways, all the characteristics of your professional relationship with Janssen over the years. Do you have any idea how much money you've gotten from Janssen either to you personally or to fund your research?
A The center was funded at $500,000 a year and was funded for four years.
Q. Do you have any idea how much money either you personally or the center has received from Janssen over the course of your relationship?
A I never totaled it.
Q. Is it just too much to count or you just don't know?
MR. PECK: Object to form.
A. No, I do not know.
Q. Is it millions of dollars?
A. From Janssen?
Q Mm-hmm.
A. Well, the center alone had 2 million
Q. Okay But all in, it's millions of dollars. Right?

A I would not say millions of dollars That was the most substantial amount of funding that we received.
Q. You don't know whether you got over a million dollars from Janssen?
MR PECK: Object to form
A No.
Q. Do you have any idea -- Did Janssen, anybody from Janssen ever talk to you about the reasons they wanted to fund the study? Or fund the center. I'm sorry.
A. Nobody discussed reasons. I sent a proposal to Janssen to create such a center and it was finally funded.
Q. So you proposed the idea of the center to them?
A Yes
Q. They didn't propose it to you?
A Absolutely not.
Q And this was around 2002?
A. The center was funded in 2002.
Q How much money did they give you in 2002 to fund the center? Janssen I mean.
A The center budget was a half a million dollars per year

Q. And did that fund studies?
A No. The center was structured around infrastructure support. As I mentioned before, we had five cores. One was neuroimaging. The neuroimaging core dealt with the development of software that we can expedite the processing of MRI data from neuroimaging. The genetic core helped collect DNA data on subjects that were going through our assessment The paradigm development core we evaluated and developed is driving simulation and work simulation for ADHD.
Q. What specifically did Janssen get for its 500,000 in 2002?
A Well, it was not specific. It was a very different type of funding than pharmaceuticals do, that they fund a proposal very close to their commercial interest This was advancing the science of the diseases for which they have potential treatments
Q. You're saying Janssen's purpose in giving you that money was to advance science and not for their commercial interest?
A. To advance science. Our proposal was to advance science and not necessarily -- We thought about it as a win-win situation, that Janssen as a

commercial entity could help the advancement of the science of the diseases for which they could have effective treatments.
Q Janssen funded the study so they could make more money selling Risperdal. Right?
MR PECK: Objection, foundation.
A. Janssen funded the study to do the work that we proposed.
Q. Right. Their goal was to advance their commercial interests. Right?
MR. SPIVACK: Objection, calls for speculation.
A. They funded us to do the studies that we proposed to advance science. What was there for them is for them to decide
Q. Well, but you understand how this works I mean, Janssen is in the business to make money. Right?
A. Yes.
Q. They sell Risperdal to make money. Right?
A (Witness nodded.)
Q They're not a charity, are they?
A. They are not.
Q. Okay. The only reason that Janssen exists is to make money for its partners and shareholders.

Right?
MR. PECK: Objection, foundation.
A. We conceptualize the study. The center has the moral responsibility of a pharmaceutical company that has potentially helpful medicines to treat serious diseases affecting children to understand the diseases for which they can have medicines to treat them. Our goal to intersect between a commercial entity and our interest to advance science was that doing good science also could be profitable too.
MR. TRAMMELL: I'll object, nonresponsive.
BY MR. TRAMMELL:
Q. Are you trying to say that Janssen funded your center because of its moral responsibility to patients?
MR. SPIVACK: Objection, misstates the testimony.
A. We proposed to advance science I believe that advancing science could result -- is doing the right thing and could result in profitability too That's the intersect that we saw between the commercial entity and a scientific organization like mine.
Q. Was funding this center a growth

opportunity for Janssen in its off-label promotion of Risperdal for kids?
MR. SPIVACK: Objection, calls for speculation.
MR PECK: Objection, speculation.
A. I have no idea what you are asking me. Could you repeat the question?
Q. Sure. Did your center represent a growth opportunity for Janssen in its efforts to promote Risperdal off-label for kids?
MR PECK: Objection, foundation.
MR. SPIVACK: Same objections, speculation.
A. The center was focused on understanding whether the disease is a serious disease, pediatric bipolar illness Did not do any clinical trials So the condition if it's serious enough requires treatment. The efficacy and safety of the treatment needs to be established in separate studies, as has happened I mean, as you know, Janssen did conduct the pivotal studies that led to the approval of risperidone for pediatric bipolar illness
Q. Do you agree that articles that you publish or anyone else publishes for use of Risperdal in kids expanded market for Risperdal even

though it was off-label?
A. I have no influence or idea of that information. I publish scientific articles. I describe data, results from studies, and this is what I publish in the literature. What is the result of that is not for me to tell.
Q. Well, one of the results of your studies is to inform clinicians' practice. Right?
A. The results of my studies are to share with clinicians and scientists results of a systematic study that weighs efficacy and adverse effects.
Q. So they can take that into account when they're treating kids. Right?
A. They can take into account when they treat children, yes.
Q. Did anyone ever tell you from Janssen that the purpose of funding your center was to generate maximum revenue in 2002?
MR. PECK: Object to form.
A. No.
Q. Nobody ever told you that?
A. (Witness shook head.)
Q. Have you ever heard the phrase money on the table?

A. No.
Q. You never heard it in the context of your center?
A. No. The center did science only.
Q. Well, the truth is the center was just a marketing device for Janssen Right?
MR. SPIVACK: Objection.
MR. PECK: Objection, foundation.
MR. SPIVACK: Argumentative
A. The center was designed to advance the science of bipolar illness in children and ADHD across a large spectrum This is what the center did.
Q. Had nothing to do with making money Right?
A. No.
Q Okay There's Exhibit 6. I want you to turn with me to the second page This is an e-mail from Alex Gorsky You see this right here? Alex Gorsky is the president of Janssen Pharmaceutical at that time. He is writing to a bunch of other people at Janssen; he says "All," and the date is November 2, 2001, "All, As per some of my earlier discussions, please note the dates that Joe Scodari has requested." Do you have any idea who Joe

Scodari is?
A. No.
Q. "Specifically on January 21, we will review growth opportunities," in quotes, "with him. These are similar to the money on the table exercises we conducted last year. For these, we should look at investment opportunities that we did not include in 2002 plan due to budget constraints that we feel can generate top-line growth in the 2002-2003 time frame " He said "These should also include commercial and medical affairs activities." Did I read that reasonably correctly?
A. Yes.
Q. If you go back to the first page, the very top e-mail, it's an e-mail from Gahan Pandina to Georges Gharabawi dated November 9, 2001. It says "Georges, Would this be an appropriate forum to discuss the J&J Center idea with Dr Biederman?" Did I read that right?
A. Yes
Q So the truth is Janssen needed to make more money, they wanted to expand the pediatric market, they saw your center as a way to facilitate that Right?
MR PECK: Object to form, foundation.

MR SPIVACK: Objection, calls for speculation, argumentative
A. I had no idea -- At that time the use of risperidone was very widely used with unclear boundaries My work, I in fact tried to circumscribe the use of risperidone to children with bipolar illness, not to all children So the center, as I mentioned several times in this deposition before, focused on advancing the understanding of the diseases for which these companies had potential medicines, Janssen with risperidone and McNeil with Concerta.
MR. FIBICH: Excuse me. I didn't hear everything you said. Would you mind reading that answer back? Thank you
(The reporter read the answer.)
MR. FIBICH: Thank you very much.
BY MR. TRAMMELL:
Q. Doctor, you said one of your efforts was to circumscribe or limit the use of Risperdal in kids. Right?
A. My recommendation, my focus was on a subgroup of children that had bipolar illness, this minority of children Risperidone was widely used to treat all forms of aggression outside the context

of bipolar illness Aggression is a very common problem in child psychiatry.
Q. Can you identify any of your papers that can reasonably be interpreted to circumscribe the use of Risperdal in kids?
A. My papers address the use of risperidone in the context of bipolar illness.
Q. But your papers try to expand the use of Risperdal in this population. Right?
A My papers described the efficacy and safety of risperidone and other medicines for the management of children. It did not expand or retract or contract anything.
Q Do you think Janssen paid you millions of dollars to limit the use of Risperdal in kids?
MR. SPIVACK: Objection, calls for speculation.
MR. PECK: Objection, foundation.
A Janssen funded a center that was dedicated to the advancement of the science of the conditions for which they have effective treatments or potentially effective treatments
Q. And I understand that's your interpretation of Janssen's intentions However, having read this document that says we're looking

for money on the table and then a response to that statement saying this is an appropriate forum to discuss the J&J Center with Dr. Biederman, how can you interpret that any other way than to mean that Janssen was looking to you to help them develop this off-label marketing campaign?
MR. PECK: Objection form.
MR. SPIVACK: Objection, asked and answered, argumentative, no foundation, calls for speculation
A. I have no idea what is in the mind of Janssen executives
Q. Well, you just said what you thought was in the mind of Janssen.
MR. SPIVACK: Objection, argumentative.
A I'm sorry. I did not hear what you said.
Q. You said the purpose of Janssen's funding of the study was to promote science, didn't you?
A. The center -- The center's job and mission was to promote science
Q. That may have been your mission. Janssen's mission was to get the money on the table. Right?
MR. SPIVACK: Objection, argumentative, calls for speculation, no foundation.

MR PECK: Objection, form and foundation.
BY MR. TRAMMELL:
Q. You don't know. Is that what you're going to say?
A. (Witness nodded.)
Q. Yes?
A Yes.
Q Is there any other reasonable interpretation of this e-mail?
MR. SPIVACK: Objection, argumentative, calls for speculation --
A. I don't know.
MR. SPIVACK: -- no foundation.
Q. There is not another reasonable interpretation, is there?
MR. SPIVACK: Objection.
A. I don't know.
Q. Well, can you think of one?
MR. SPIVACK: Objection.
BY MR. TRAMMELL:
Q No? You can't, right?
A. No.
Q. Do you know whether from Janssen's perspective, whether an essential feature of your center was to move Janssen's commercial goals

forward?
A. I believe that there is an intersect, a synergy between a commercial entity like Janssen and our interest that was to advance the science of the diseases for which they could have effective treatments
Q But one of the things your center had to do to make sense for Janssen was to advance its commercial interests. Right?
A. I believe that doing good science is profitable.
MR. TRAMMELL: I'll object as nonresponsive
BY MR TRAMMELL:
Q Did you understand that it was an essential feature or an essential premise of Janssen's funding of your center that the work that your center did would advance its commercial interests?
A In the larger sense of the word, but not in a one-to-one correspondence So the steps as I saw, if we have diseases that are serious, disabling and important, and if there are medicines that can be tested to treat them and if they are shown to be safe and effective, in the case of risperidone has

been the case You need to keep in mind that at the time pediatric bipolar illness was not a well-known entity, so the notion is to understand what it is, to define it in the best way possible, to understand its seriousness, and if the illness is serious enough, may require treatment with serious medicines. And they need to establish the benefits by doing clinical trials, as they did. But it is a step-by-step approach, it is not a one-to-one correspondence

Q But taking that approach would ultimately advance the commercial interests of Johnson & Johnson Right?

MR. PECK: Objection, foundation, form

BY MR. TRAMMELL:

Q. Is that right?

A I believe that if the illness is prevalent and morbid and severe and disabling and if risperidone proves to be safe and effective, that they will benefit from that association between the treatment and the disease.

Q. Well, even if Risperdal wasn't proven to be safe and effective, just having your name attached to its promotion would advance their commercial interests. Isn't that right?

MR. SPIVACK: Object to form.

A. I have no idea what you are referring to.

Q. Doctor, this is Exhibit 7. We're done with 6. Oh, and, by the way, have you ever seen Number 6 before?

A I don't recall.

Q. Have you ever seen Number 5?

A. I don't think so. I have seen it --

Q. Except for when you might have read it.

A. Yes

Q. You didn't review it with your lawyers?

A I don't remember.

Q. Number 7 is called Annual Report 2002, The Johnson & Johnson Center for Pediatric Psychopathology at the Massachusetts General Hospital. This is your center Right?

A. Yes

Q Have you ever seen this document?

A. I have seen the document, yes.

Q. You have seen it?

A Yes, I have seen it.

Q When did you see it?

A. Around the time it was written.

Q. So this is an internal Janssen document that was circulated to you. Right?

MR. PECK: Objection, foundation.

A I don't know what it is.

Q. Well, you saw it. Right?

A. Actually, I thought that this was referring my report to them, not their internal reporting. I have not seen internal documents of reporting I thought that this document is a document that I reported to them, not that they reported internally.

Q Okay. Having looked at it, do you know whether you've seen it?

A. I don't think I've seen it.

Q. Okay If you go to the third page, which has a heading that says Executive Summary, go to the second paragraph; it says "An essential feature of the center is its ability to conduct research satisfying three criteria: A, it will lead to findings that improve the psychiatric care of children; B, it will meet high levels of scientific quality; and C, it will move forward the commercial goals of J&J." Did I read that right?

A. Yes.

Q. So there may have been multiple purposes for the center. One of the essential purposes was that it move forward the commercial goals of J&J.

Right?

A. We were talking to an interlocutor that was a commercial entity, so there has to be something for them So we saw that the intersect between advancing science is commercially viable. This is what we alluded to.

Q. Right Because they're not going to fund this kind of thing if they can't get anything out of it. Right?

MR. PECK: Object to form

A This, they will not fund this if theoretically it will not have anything to do with their possibilities. So what I explained to you before, the statement's approach is starting the diseases for which they have effective treatments, is the beginning of that road, not the end where the road finishes

Q The next sentence says "We strongly believe that the center's systematic scientific inquiry will enhance the clinical and research foundation of child psychiatry and lead to the safer, more appropriate and more widespread use of medications in general " Did I read that right?

A. "In children."

Q. In children, right

A Yes
Q. Did I read that correctly?
A. Yes, that's correct.
Q. So what they're saying here is that because of the work that you do at the center, there'll be more Risperdal used. Right?
MR. PECK: Object to form.
A. We believed that if the medicines -- if the disease is found to be morbid and disabling, if the medicines like risperidone are found to be safe and effective, clinicians will be more able to deploy them for the right patients with better knowledge about the spectrum of effects and adverse effects. This is what we meant
Q. And the result will be that more people will get Risperdal Right?
A The results will be that if this is a safe and effective treatment, our children will be appropriately treated. And so if this is a condition that affects a lot of children, then the consequence will be that more children will receive an effective treatment, an effective and safe treatment
Q The next paragraph, "Equally important to effective use of medications is the demonstration of

the validity of disorders " Did I read that right?
A Yes
Q What does that mean, the validity of disorders?
A. The meaning is not all temper tantrums are bipolar illness Not all lack of concentration is ADHD. So when we describe a condition, we need to do our best to make sure that this condition is valid.
Q. So you and Janssen were inventing disorders?
MR. PECK: Objection, form.
A. Absolutely not.
Q Is there something wrong with that, inventing disorders?
A Inventing disorders? Of course, the way that you say it and the choice of words has some pejorative conspiratorial component.
Q. You mean pejorative, you mean it has a bad connotation?
A. Yes
Q Why is it bad to be creating diseases or creating disorders or creating categories of disorders?
A. The diseases are not created The

conditions that we see in front of us are reconceptualized In other words, the child that was called before mentally retarded today may be called autism spectrum. So as we understand more these problems, we conceptualize in a different way Schizophrenia and bipolar illness were not considered separate entities in the past, so as progress and knowledge develop, clinicians and scientists understood that they are separate entities that required different treatment
Q That was an advancement, right, to make that distinction, wasn't it?
A It's an advancement to know what we have in front of us
Q. So what's wrong with what y'all were doing here, inventing disorders?
MR PECK: Object to form.
MR SPIVACK: Objection, misstates the witness's testimony, misstates the document.
A. I did not invent any condition
Q. Well, you certainly created the belief in the medical community that things that weren't thought of as psychiatric disorders in the past were actually psychiatric disorders, didn't you?
A. No

MR SPIVACK: Objection, calls for speculation.
A. I described that the children that were going under different names that were disturbed, some of these children may have a condition that is called bipolar illness. Not none of these children I did not grab anybody from their basement and brought them to the clinic. So these children existed but they were conceptually seen differently. They had other diagnoses, like conduct disorder, for instance.
Q. So you're trying to say you weren't preying on kids?
MR. SPIVACK: Objection, argumentative, misstates the testimony
MR PECK: Objection.
BY MR. TRAMMELL:
Q. Is that what you're trying to say?
MR. PECK: Object to form.
A. Are you seriously asking me this?
Q. Yes.
A. I'm preying on children?
Q. Are you trying to say that you weren't doing that?
A No, I never preyed on anybody.

Q. Do you know which disorders it's talking about, the validity of which disorders?
A. We were interested in bipolar illness and ADHD.
Q And were there multicenter placebo-controlled randomized double-blind clinical trials showing that Risperdal was safe and effective for pediatric bipolar illness or ADHD at that time?
A. No. Risperidone is not a treatment for ADHD, by the way.
Q And you've never recommended it be used to treat ADHD?
A. No.
Q Would that be inappropriate?
A. Depending on circumstances.
Q. What circumstances would make Risperdal a safe and effective treatment for ADHD?
A. There are children, 80 percent or so of children with bipolar disease with comorbid ADHD, and the stimulus can make them worse. So sometimes just using one medicine can correct some of the symptoms of ADHD It's not to treat ADHD but to help symptoms of ADHD in the context of bipolar illness.
Q. But if a kid doesn't have bipolar disorder

but does have ADHD Risperdal is not a safe and effective treatment. Right?
A. No.
Q. And it's wrong to promote it for that purpose, isn't it?
MR PECK: Objection, foundation
A. Yes.
Q. Now, in order to demonstrate, what kinds of science would need to be generated to demonstrate the validity of pediatric bipolar disorder?
A. We conceptually thought to do neuroimaging to see if the neuro-anatomy of the brain is different in people that have bipolar illness and ADHD using different imaging technologies. Our genetic research was interested in trying to identify genes that are associated with one or the other.
Q. So the work you wanted to do to demonstrate the validity of pediatric bipolar disorder was neuroimaging and genetic research?
A And associated. We also were interested in examining the course of the illness, to examine clinical correlates We examined familiality of ADHD and bipolar illness These are things that we did

Q And did that work demonstrate the validity of pediatric bipolar disorder?
A. Well, the classic understanding of validity rests on a disease that has a unique set of clinical features, that has a unique course, biological correlates such as neuroimaging, genetic and familiality and the therapeutic responsiveness to different treatments.
Q. It says validity of disorders. That's a plural. Do you know what other disorders it's talking about?
A. ADHD and bipolar illness.
Q. At this point was ADHD a valid disorder?
A ADHD in children was a valid diagnosis but still under attack ADHD in adults was emerging.
Q. Do you know whether the disorders it's referring to are bipolar disorder and ADHD alone?
A. I believe the center focuses on only those two.
Q Okay
You said, I think you said that adequately characterizing or accurately characterizing the clinical characteristics of a disease are essential for demonstrating its validity. Is that right?
A. It's one of the components that I

outlined. There are five.
Q. Is the reason for that so that it's possible to correctly diagnose it?
A. It is to have confidence that this is a separate disorder from something else. So an illness that is different from another illness should have different familial correlates, for example
Q. And one thing I think is important for the jury to understand and for me to understand, at some point Janssen conducted FDA-worthy double-blind multi-site placebo-controlled clinical trials in pediatric bipolar disorder, didn't they?
A. Yes.
Q. Did you participate in those trials?
A. No
Q. Did you ask to?
A. I was asked. I couldn't.
Q They asked you?
A. They asked me
Q And you refused?
A. I couldn't at that time.
Q. Why?
A. I don't remember We were very busy with other programs

Q Because you were too busy?
A Yes.
Q Do you know who did conduct that trial?
A These trials are usually conducted among many, many sites. Multi-site registration studies, FDA requires many studies, not just two or three but dozens.
Q Do you know who the lead investigator was?
A I don't know
Q Do you know when the trial happened?
A The trial happened probably around 2006 or so.
Q Do you know the number of the trial?
A No.
Q And you don't know where any of the sites were?
A No.
Q You weren't a site or your hospital wasn't?
A No.
Q Why didn't you put together a trial like that at the center?
A The center did not do any clinical trials. It supported infrastructure studying bipolar illness and ADHD.

Q What is the difference -- Why does the FDA require such rigorous standards for trials? Or, excuse me, that's not what I meant. Why does the FDA require certain procedures to be followed in trials that are submitted for getting a new indication?
MR. SPIVACK: Are you asking for his understanding?
MR. TRAMMELL: Yes.
A It's to establish the safety and efficacy of a compound.
Q And in your opinion is doing those trials relatively or is it the most reliable way to establish the safety and efficacy of the compound in the disease studied?
A It's the gold standard
Q And it is relatively more reliable than doing, for example, open label studies or retrospective chart reviews or studies like that. Right?
A The process in the evolution of thinking about a potentially useful medicine starts with observations in the clinic. These medicines work like we observed and we published case series. Followed with open studies. If the open study does

not work out, then it's not very smart to do a double-blind study at the extraordinary expense.
Q I understand.
A It ends with the gold standard which is a randomized clinical trial.
Q Now, here's something I don't understand. You dedicated years and years of your life to studying pediatric bipolar disorder and Risperdal's use to treat it and other drugs used to treat it. Right?
A Right.
Q And so when it came time for Janssen to do the clinical trial to finally get the indication on this disorder that you had talked about for so long, your testimony is you just didn't have time to participate in it?
A At that time it did not work out for us. We have a finite amount of clinical trial resources and we were not able to absorb another trial at that time
Q Were you disappointed by that?
A No
Q You didn't care?
A It's part of life
Q Did the papers that you wrote -- Oh, and,

by the way, we talked about the relative merits of different kinds of studies, the gold standard versus other types of studies like retrospective chart reviews and open label studies, which are relatively less reliable Right?
A Yes.
Q What kinds of studies did you do on Risperdal in kids?
A We did -- We published a chart review and open label study that was fully replicated in the double-blind study.
Q So the studies that you were doing were less reliable than the study that was submitted to the FDA Right?
A Could you define reliable?
Q Well, less reliable as a demonstration that Risperdal was safe and effective to treat the conditions that you were talking about.
A That's not the definition that I assign to reliability The open studies are open studies. They are not meant to be DNA discoveries
Q You mean FDA discovery, or DNA discovery? What do you mean?
A I mean the open study has limitations. It's an open study, it's not double-blind, it's not

meant to be the gold standard It was never meant to be the gold standard. That's kind of -- We think about that as proof of concept. Is there any signal there in an open study to warrant a double-blind study? That's the way -- That's the reason that open studies are done.

Q. It is hypothesis-generating. Right?

A. It is a pilot. It's to see if there is promise in their medicine.

Q. It is certainly not appropriate to take a hypothesis-generating study like an open label study and represent to people that that study is proof that Risperdal is safe and effective to treat the disorder that was studied. Right?

A. My paper never had any statement in that regard.

MR. FIBICH: Objection, nonresponsive.

MR. TRAMMELL: Yeah, objection, nonresponsive

BY MR. TRAMMELL:

Q If someone took your paper and used it as a basis for representing that Risperdal was safe and effective to treat pediatric bipolar disorder, any of your papers, would that be appropriate?

MR SPIVACK: Objection, calls for

speculation

A. I don't know how in what context my papers were used. My papers are data-driven and objective, so I only describe; I do not state or recommend All my papers had side effects listed in exhaustive detail. I do not make a sales speech of any type in my papers. It's a description. How is this used? I have no idea

MR. TRAMMELL: I'll object as nonresponsive

BY MR. TRAMMELL:

Q. I understand you're not a Janssen salesman. But if a Janssen salesman took one of your papers that you wrote about the use of Risperdal in pediatric bipolar disorder and represented to a doctor or any other type of prescriber that Risperdal was safe and effective to treat pediatric bipolar disorder based entirely on your papers, would that be appropriate?

MR. SPIVACK: Objection, calls for speculation

MR. PECK: Objection, calls for speculation

A Probably is.

Q. What?

A. Probably would be inappropriate

Q. And, again, why is that?

A. Because it's a very small open study So the efficacy data is limited to the sample size. That's the reason that we have large-scale studies.

Q. Right It's a limitation of your type of study Right?

A. Yes.

Q. What is an open label study?

A. Open label study is a study that there is no placebo. So patients receive only the active ingredients

Q And the person participating in the study knows what drug they're getting and the doctor prescribing it knows what drug they're giving?

A. Right

Q. Right?

A. Correct, correct

Q. And is one of the limitations of an open label study potential bias in the study results?

A Yes.

MR. TRAMMELL: Okay, let's take a break.

THE VIDEOGRAPHER: This is the end of tape number 2. Time is 12:14. We're off the record.

(Discussion off the record.)

MR SPIVACK: Shall we take a lunch break?

(Discussion off the record.)

(Luncheon recess at 12:15 p.m.)

AFTERNOON SESSION
1:23 p m.

THE VIDEOGRAPHER: This is the beginning of tape number 3 We're back on the record Time is 1:23.

BY MR. TRAMMELL:

Q. Doctor, we're back on the record And you understand you're still under oath?

A I understand

MR. TRAMMELL: Can you hear him as low as that is on his tie? Okay

BY MR. TRAMMELL:

Q. Now, Doctor, if you go back to Exhibit 7, I'm still on the executive summary page And again this sentence: "Equally important to effective use of medications is the demonstration of the validity of disorders." Now, doesn't that mean that -- Well, that has to do with creating a market for a drug, doesn't it?

MR. SPIVACK: Objection, calls for

speculation.
MR. PECK: Objection
A. Not really.
Q What is your impression of that statement?
A. Disorders, the meaning in medicine of validity is the distinguishing a disorder from other disorders
Q. Well, isn't it true and wasn't it your understanding that what Janssen was trying to do with the center and with your research was to look for markets for Risperdal any way they could and create a market, if they needed to, by inventing disorders?
MR. PECK: Objection, foundation.
MR. SPIVACK: Objection, argumentative
BY MR. TRAMMELL:
Q. Isn't that true?
A. The center focused on the evaluation of the correlates of biology and neuroimaging of pediatric bipolar illness and ADHD At the time bipolar illness was not fully recognized in children, was going by different names like ADHD or conduct disorders or things of that type. So what we were interested is to think about the possibility that children have bipolar illness and try to limit

the use of medicines like risperidone for a small subgroup of children that satisfied criteria for bipolar illness
Q. Got it. Your goal was to limit use of Risperdal?
A. No My goal was to argue that not all children that have aggressive symptoms have bipolar disorder My goal was to try to separate the children that have aggressive symptoms in the context of bipolar illness from other children that may be just aggressive without bipolar illness.
Q. And -- I'm sorry. I didn't mean to interrupt you. So your goal was to limit the use of Risperdal to children who were probably in the extreme minority of the children that would be seen for this type of problem, to limit the use of Risperdal to the kids who were truly sick?
A. How clinicians use the medicine is not on my hands. We were trying to describe a group of children that had a set of symptoms suggestive of bipolar illness, to try to distinguish those from other forms of aggression that is not part of bipolar illness. And we argued that the potential antimanic effects of medicines like risperidone, not only risperidone, we evaluated all of them, should

be directed at those children, not just every child with aggression that this spectrum covers
Q. What percentage of kids have bipolar disorder?
A. We estimated based on other calculations about 1 percent
Q. So the same percentage as in adults. Right?
A. Adults it's more than 1 percent. It's about 2 to 3 percent.
Q. Okay So for some people bipolar disorder manifests in childhood and for some people it manifests later on in life. Right?
A. 70 percent of adults onset in childhood or adolescence with bipolar illness.
Q. So 70 percent of people who are adults who have bipolar disorder, that disorder onset when they were kids?
A. Yes
Q. And what is your basis for that statement?
A There's a very large study done by several centers in the country, a comparison somewhere on the order of 5,000 adults with bipolar illness. It's the largest study ever done on bipolar adults. It's called the STEP study, Systematic Treatment --

I don't know. STEP, S-T-E-P program It's about four or five thousand adults with bipolar illness, in other words, systematically assessed and treated; and about close to 70 percent of those, a representative sample of bipolar adults in this country, had an onset in childhood or adolescence.
Q. Who conducted that study?
A. The study was funded by the National Institute of Mental Health
Q. What percentage of the 1 percent of kids that have bipolar disorder will respond to Risperdal treatment?
A. In our study, the open label study that we did was about 60, 65 percent.
Q. So 65 percent of that 1 percent are appropriate candidates for Risperdal. Right?
A. No. 65 percent of the 40 or so that we tested responded to risperidone.
Q. You weren't trying to make the point that 60 percent of all kids that have bipolar disorder are appropriate candidates for Risperdal, are you?
A. No.
Q. Now, one of the ways Janssen wanted to use your research was to train doctors in these novel ways of screening kids to identify bipolar disorder

Right?
MR. SPIVACK: Objection, calls for speculation, argumentative
MR. PECK: Objection, foundation.
A. I have no idea what are you talking about.
Q. Okay. Did you ever publish any articles or give any speeches the subject of which was discussing the diagnostic criteria for pediatric bipolar disorder?
A. In all my talks on pediatric bipolar I describe what are the features that describe these children.
Q. Right And the association of these features with bipolar disorder in these kids was a novel concept, wasn't it?
A. It was not so novel. It was novel to the extent that we focus on severe irritability as a distinguishing feature
Q. It certainly wasn't widely accepted that pediatric bipolar disorder was even a real disease, was it?
A. It was accepted that it was a real disease, but was considered to be a very infrequent.
Q. It was considered to be infrequent and irritability wasn't considered to be a significant

diagnostic criteria. Right?
A. Irritability was always an important part of the diagnosis. This is the way that it is described in the DSM.
Q. Was that your contribution to the diagnostic criteria, emphasizing the role of irritability in the onset of the disease?
A. Our contribution in my mind was to point out that this is a common, much more common condition than was previously thought of. It was not rare.
Q. Was the diagnosis of bipolar disorder and the use of medications to treat it in kids controversial when you began your research?
A. No. I think that the entire idea of using medication to treat any psychiatric disorders in children is at the outset controversial, not only risperidone. So there is a school of thought that argues that children are angels and don't have any disorders, and that is not necessarily restricted to risperidone
Q. But you don't agree with that?
A No, not only that I don't agree I think that the evidence that a sizeable number of children suffer from very serious emotional and behavioral

disorders is not disputed.
Q I suppose what is disputed is whether those disorders are a bipolar disorder and the proper manner for diagnosing what the disorder might be in the troubled kid. Right?
A. Bipolar disorder is one of many conditions that afflict children. It's one of the least common Children about, about 5 to 10 percent of children have ADHD, about 2 to 3 percent have conduct disorder, 5 percent have major depression. So if you aggregate those numbers, somewhere in the order of magnitude of I would say 15 percent of children may have emotional or behavioral difficulties.
Q What percentage of that 15 percent are appropriate candidates for Risperdal therapy?
A. I would say that I recommended to consider risperidone only for bipolar illness.
Q. So it's inappropriate to use Risperdal for non-bipolar kids?
MR. PECK: Object to form.
A There are in the clinical topography many circumstances that physicians may make a decision to use a particular compound outside the most restricted use of the medicine.

Q. Let me ask you this If Janssen promoted Risperdal to be used for non-bipolar kids, would that be appropriate in your mind?
MR SPIVACK: Objection, calls for speculation.
MR. PECK: Objection, foundation.
A. I don't know if they do it -- You are finished? I do not know what they did or did not do.
Q. If they did that, is that appropriate?
A. Depending on --
MR. SPIVACK: Objection
THE WITNESS: Sorry Are you finished?
MR. TRAMMELL: Just wait for your lawyer and then you can answer. So you can answer now
A. Depending on circumstances. You need to be more specific
Q Under what circumstances is off-label promotion appropriate?
MR. SPIVACK: Objection, calls for a legal conclusion.
A. Again, you are asking two separate questions Off-label use is legal, first of all.
Q. Right. I'm not asking about off-label --
A. Very commonly used in medicine, and we owe

a lot of gratitude to discoveries because of off-label use. Whether the pharmaceutical company is promoting or not, I have no idea.
MR. TRAMMELL: I'll object as nonresponsive.
BY MR. TRAMMELL:
Q. Is it appropriate for Janssen to promote Risperdal for off-label uses in kids?
MR. PECK: Objection, foundation.
MR. SPIVACK: Objection
A. I am not a lawyer.
Q. Well, as a clinician, do you think that's appropriate? Do you think it's appropriate for Janssen to be promoting a clinical practice that's not supported by the gold standard of scientific evidence?
MR. SPIVACK: Objection, calls for speculation, no foundation.
MR. PECK: Objection
A. There is a lengthy process before the gold standard that you are alluding to, the randomized multi-site clinical trial, occurs; that I would say ten, fifteen years from the time of the first reports on potential use of a medicine until that standard is met

MR. TRAMMELL: I'll object again as nonresponsive.
BY MR. TRAMMELL:
Q. And the reason the FDA requires rigorous testing is so that representations made about a drug are based on reasonably sound scientific evidence. Right?
A. Right
Q. And so to promote the use of the drug in the absence of that evidence is inappropriate, isn't it?
A. If the drug is promoted without evidence, yes
Q. Well, if a drug is promoted without the gold standard, that's inappropriate Right?
A. Yes.
Q. Did anyone at Janssen ever tell you that one of the purposes of your center was to help Janssen target pediatricians to use Risperdal?
A. No.
Q. Did anyone ever tell you that one of the purposes of your center was to create research that would help Janssen target general psychiatrists so that they would use Risperdal in kids?
A My center focused on the clinical

conditions for which Janssen and McNeil have medicines. The center did not do clinical trials, so they did not promote anything. We started neuroimaging, genetics, paradigm development, we analyzed data on the illness itself, ADHD and bipolar illness
Q. You don't consider yourself responsible for what Janssen did with your research, do you?
A I don't.
Q If Janssen -- Well, never mind.
If you'd go to the next page of this document, it's the third bullet point -- I'm sorry -- under the heading Resolving Complex and Controversial Diagnostic Issues, the third bullet point says "Implementing training programs for screening tools in continuing medical education programs targeting pediatricians and general psychiatrists." Did I read that right?
A. Yes.
Q. And so what they're saying is one of the specific goals of the research that you do, one of Janssen's specific goals of the research that you do will be to instruct doctors on how to diagnose bipolar disorder and use Risperdal to treat it. Is that what that means to you?

MR. PECK: Objection, foundation.
A What this means to me is that there is a scarcity of trained child psychiatrists with expertise in psychopharmacology for the population of affected children. So if the condition were to be found to be morbid and devastating and affect 1 percent of children, there is not enough resources in child psychiatry to treat all these children. So these children, there are several states that there is no child psychiatry to be found, so these children will require some kind of pharmacological support from their primary care physician or general psychiatrist
Q By the way, do you know how much Risperdal is used in kids?
A. No
Q. You have no idea?
A. No. Risperidone is used in adults as well, as you know.
Q. Sure Would it surprise you that over 20 percent of all the Risperdal that's used is used in kids?
A I have no idea how much risperidone is used in children.
Q. Do you consider yourself in any way

responsible for that?
A. No.
Q. Is it appropriate in your mind for Risperdal to target pediatricians to try to get them to use Risperdal in their patients?
MR PECK: Objection, form
MR. SPIVACK: Objection, no foundation, calls for speculation.
A. As I mentioned to you before, pediatricians are more abundant than child psychiatrists. So in many communities there is no access to child psychiatry. If the condition is found to be morbid, devastating and impairing and if medicines to treat it were to be found safe and effective, the deployment of the treatment could be done by primary care physicians
Q. Let me ask you this This is 2002. Who do pediatricians treat, what age groups?
A. Pediatricians treat children from birth to 18.
Q. Okay Pediatricians treat people for whom the use of Risperdal is off-label. Right?
MR SPIVACK: Objection
A. Not now
Q. What do you mean?

A. Now it's approved.
Q. I understand In 2002 pediatricians treated people for whom the use of Risperdal was off-label. Right?
A. The use of risperidone for children in 2002 was off-label.
Q So in your opinion, and you've testified to this already a few minutes ago, was it appropriate for Janssen to be doing this, to be targeting doctors who only treat patients for whom the use of Risperdal is off-label?
MR. SPIVACK: Objection, asked and answered, calls for speculation, no foundation.
MR. PECK: Objection.
MR. TRAMMELL: You can answer.
A. I would say yes.
Q. It's appropriate?
A. It is not appropriate.
Q. It's not appropriate, is it?
MR. SPIVACK: Objection, asked and answered
BY MR TRAMMELL:
Q So that I don't have to say gold standard or placebo-controlled, I'm going to say clinical trials to refer to clinical trials that would be

appropriate to submit to the FDA for an indication, so that we cannot confuse each other What clinical trials do you know of that have been conducted by Janssen to support the use of Risperdal in kids?
A. To my knowledge, there is a study that was not conducted by Janssen but included risperidone that was in autistic children with severe aggression. That led to the approval of risperidone I believe in 2006 for severe aggression in autistic children. And the other study is the randomized clinical trial that led to the approval of risperidone for pediatric bipolar illness
Q Are those Risperdal's only approved uses in kids?
A. No Abilify has received approval and I believe Zyprexa may be receiving The clinical trials have been conducted with Zyprexa, Abilify, and risperidone, to my knowledge.
Q. I'm sorry I was asking about Risperdal, so let me restate my question.
Are the agitation associated with autism and the mania associated with pediatric bipolar disorder the only indications that Risperdal has for kids?
A To my knowledge, yes.

Q. Does it have an adolescent schizophrenia indication?
A. Yes, that's true. I forgot. Thank you.
Q. And so there was a clinical trial that was done to support -- Obviously, there was a clinical trial that was done to support the autism indication Right?
A. Yes
Q. Did you participate in that?
A. No.
Q. You weren't a center?
A. I was not.
Q. Were you asked to participate in it?
A. No
Q. Did you ask to participate in it?
A. No.
Q. And do you know the number of that trial?
A. I do not, no.
Q. And there was a clinical trial to support the use of Risperdal in kids with mania associated with bipolar disorder. Right?
A. Correct.
Q Do you know the number of that trial?
A. No.
Q Did you participate in it in any way?

A. No
Q. You were asked but you weren't available. Right?
A. I don't remember exactly. I know I didn't participate I don't remember exactly the sequence of events
Q. I think you testified earlier they asked you; you didn't have the capacity to do it at the time
A. Yeah, that's my recollection.
Q. Okay. And I suppose all the same -- Well, for adolescent schizophrenia there was a clinical trial that was done to support that application Right?
A. Yes
Q. Do you know the number of it?
A. No
Q. And you didn't participate in it?
A No.
Q. And weren't asked and didn't ask them?
A. No, schizophrenia is not a disorder that we have a lot of patients
Q. Do you know of any other clinical trials that have -- Oh, you said earlier that Janssen didn't conduct the autism trial

A. To my knowledge, the autism trial was conducted in an NIH-funded multi-site entity that is called RUPP, R-U-P-P, research unit in psychopharmacology. That is my understanding, that it was conducted in that setting But I am not totally sure
Q At Ohio State?
A. The RUPP included multiple sites, not one.
Q. Who was the lead investigator at Ohio State?
A. I have no idea
Q. Do you know whether anyone associated with RUPP has a relationship with Janssen?
A. I have no idea
Q Have you ever met anyone associated with RUPP?
A. Yes, of course
Q. Who?
A. The person that oversees the RUPP at NIH is Benedetto Vitiello that is the head of the extramural program in pediatric psychopharmacology for the NIMH
Q. Have you ever heard of Trial 93?
A. No.
Q. Have you ever heard of Trial 97?

A. No
Q. How about a Canadian trial called 19?
A. I have no idea.
Q. How about a Canadian trial called 20?
A. I have no idea
Q. Have you ever heard of any clinical trials conducted involving Risperdal and children with conduct disorders?
A. Yes.
Q Which trials have you heard of?
A There is a paper published by Dr. Aman in the American Journal of Psychiatry on children with conduct disorder and mild mental retardation.
Q Do you know whether Aman relied on 93, Trial 93?
A. I have no idea.
Q Do you know whether Trial 93 or any of the other conduct disorder/disruptive behavior disorder trials were ever submitted to the FDA or Canadian authority to try to get an indication?
A I do not know
Q You have no idea about that, do you?
A No
Q And just to be clear, I mean, it has nothing to do with your relationship with Janssen,

their interactions with regulatory authorities Right?
A. Nothing to do
Q. So you don't perform clinical trials that are intended to be submitted to the regulatory authorities like the FDA. Is that right?
A I do perform. My site participated in several registration studies. I did not participate in the risperidone study.
Q. Okay, that's what I'm asking about You weren't a site for any registration studies for risperidone?
A. For risperidone? No, not that I know of, no.
Q. Do you interact with anyone at the FDA at all?
A. I sometimes attend meetings at the FDA
Q. Which meetings have you attended?
A. I attended a meeting when there was a discussion about the approval of Aldoril for adult ADHD I was at the FDA when there was a discussion about approving a Cephalon compound, modafinil, for ADHD
Q And I'm sure you know what I'm going to ask you Have you ever been at an FDA meeting or

had a discussion with FDA that involved Risperdal?
A. No
Q. You're a consultant for Cephalon. Right?
A. I consulted for Cephalon, yes.
Q Did you disclose that to the FDA when you were on the committee?
A. Absolutely
Q. Did anyone at Janssen ever tell you that they had submitted an application for approval of the use of Risperdal for conduct disorders in kids?
A. I don't remember.
Q. You don't know whether anyone ever told you that?
A. I don't remember
Q Well, did anyone ever tell you that they had submitted that application but it had been denied by regulatory authorities?
A. I don't remember I receive communications of all types all the time, so I don't remember.
Q. Did you rely in any way on the Aman paper?
A. If what?
Q The Aman paper
A If I was involved in the Aman paper?
Q. No, no Did you rely on it in any way in

any of your publications?
A. Yes, we did an analysis of the Aman result, a secondary analysis it's called, extracting from the rating scale that they used symptoms of mania and depression. So we were able to publish a paper and documenting that, in addition to conduct symptoms, risperidone also helped symptoms of euphoria, agitation, and depression
Q. Do you know whether the data on which Aman relied and I suppose indirectly you relied was ever submitted to a regulatory authority to try to get a new indication for Risperdal?
A. I do not know.
Q. If that data was submitted and you were relying on it and the application under which that data was submitted was denied, would you have liked to have known that?
MR. PECK: Objection.
A. I am not sure, what are you asking? The denial of an application has nothing to do with my work. Application sometimes could be denied because the FDA may not like the diagnosis Conduct order may be a diagnosis that FDA may not consider a good target for medicines But my work has nothing to do with the regulatory position on the application.

Q. And so I'm sure that's not a lucky guess, you know the FDA denied an indication for that, right, conduct disorder?
A Yeah, I guess -- I -- Yes. The answer is yes
Q. Okay Did you know that the basis for that application by Janssen was Trial 93, which is what Aman's paper is based on?
A No.
Q. Would it have been of interest to you while you were relying on this data and on Aman to know that the FDA had denied an application based on that data?
A No It's irrelevant.
Q. No matter why they denied it, it's irrelevant to you no matter what?
A. I am a scientist. I took data in the dataset of Aman and analyzed symptoms of depression, agitation, and mania So this is what I did. The application, whether denied or not, has no bearing into the fact that the data are the data.
Q. Does it matter when conducting a clinical trial the number of patients in the trial?
A. The number of patients usually is a function of the statistical power that the study

needs to show separation from placebo
Q You mean the statistical power is a function of the number of patients?
A. Yes
Q. And so the fewer the patients, the less statistical power you have Right?
A Correct.
Q. And so when you say the data is the data, that's not entirely true. There are qualitative differences in datasets. Right?
A. No, not really. I was saying to you that you don't understand data. The study that Aman reported showed striking separation from placebo The problem, if you cannot show separation from placebo, could be due to insufficient subjects. But it's not the other way around. If you have a relatively small number of subjects and you have separation from placebo, that is not debatable.
Q. Right. But it's a less powerful signal than if you have a lot of patients Right?
A. No. The signal is the signal. The statistical significance when the signal is weak cannot be rejected unless you have a large number of subjects. So some studies that expect a small separation from placebo and drug require a huge

number of patients to show that separation But if you have a relatively small number of patients and you have very robust separation from placebo, that means that the signal is very, very strong that the medicine is effective

Q This is Number 8

A We're done with this?

Q We're done with that one. Had you reviewed that document before, by the way?

A No.

Q Prior to your meeting with your lawyers?

A No

Q Okay

Have you ever seen this document?

A No

Q But it was in your area of study, wasn't it?

A Not really In the most general sense. I study children with emotional and behavioral disorders, but I don't study conduct disorders specifically And the category of disruptive behavior disorder is a very broad category and encompasses a huge number of disorders.

Q Right If I were to say to you, you know, how do you characterize a disruptive behavior disorder, you would have no idea how to do that, would you?

A No. There are three categories under that rubric: ADHD, oppositional defiant disorder, and conduct disorder. Together they may afflict 15 percent of children

Q But the phrase disruptive behavior disorder is too vague to be used as a diagnostic category?

A I am not the one to determine that Disruptive behavior disorders is a category

Q Did anyone at Janssen ever tell you there was a lot of concern among regulatory authorities about the high incidence of adverse events in kids with Risperdal?

MR PECK: Objection, foundation.

A Not really I don't remember having such discussion

Q. And why is that?
A. Because it is less of a concern for efficacy than it is for safety, because for safety if you have less common adverse events, you need more subjects to determine less common adverse events. You can show efficacy on a smaller number of subjects
Q. But for safety, this was an insufficient number of people in the trial. Right?
A. I would guess so Certainly the FDA considered it insufficient for regulatory purposes.

Q. Has that been your experience?

A. Yes. We in fact published a paper documenting or recommending or suggesting a treatment for elevation of prolactin.
Q. And, by the way, what is prolactin?
A. Prolactin is a hormone produced by the hypophysis that as its name indicates it's released when the mother gives birth, to permit lactation. Pro means promoting, lact means lactation.
Q. Does prolactin -- Does everyone's body produce prolactin?
A. Everybody produces prolactin at low levels And what we are talking about here is elevated levels.
Q. Is there any danger in low levels of prolactin in the body?
A. Low levels? Not not I know of.
Q Is there any danger of high levels of prolactin in the body?
A. It's unclear. In postmenstruating, postmenarchal women, elevated levels can produce secretion of milk from the breast and can disrupt the period.
Q Is there any difference in the danger of elevated prolactin levels in kids versus adults?
A. It's totally unknown. The children that

we treated were totally asymptomatic; they did not have any symptoms. I decided to offer treatment to reduce the level because of theoretical concerns that elevated levels may have some detrimental effects that had not been documented. But none of the children that we treated for elevations of prolactin had any symptoms of concern.
Q And of course that only has -- That has no scientific value, does it?
A. Which one?
Q. I mean just your historic impression that the kids you treat don't have symptoms of elevated prolactin. The issue of whether elevated prolactin is dangerous is a separate issue. Right?
A. Whether elevated prolactin is dangerous is not necessarily something that is absolutely known. I think the fact is that some people have elevated prolactin and have no symptoms of any kind, and others do.
Q What are the dangers of elevated prolactin in kids?
A They are unknown.
Q. You don't know what some of the potential dangers of elevated prolactin in kids are?
A. They are unknown. Scientifically my

speculation was it may interfere with the hormonal development, but has never been documented.
Q Is there anything about the chemical nature of Risperdal that makes it more likely that it will cause elevated levels of prolactin in kids?
A. Yes.
Q What is it?
A Risperidone has a strong effect on blocking dopamine 2 receptors The blockade of dopamine 2 receptors is responsible for the increase in prolactin.
Q. That's something that is common to all antipsychotic drugs Right?
A It is common to all first-generation antipsychotic drugs. Risperidone has stronger effects in elevation of prolactin than other drugs in the class of atypical neuroleptics.
Q. To the extent Risperdal elevates prolactin levels in people that take it, it does so to a greater degree than the other atypical antipsychotics. Right?
A. Well, now, these are average inferences. Not everybody has elevation of prolactin It is not a universal one-to-one phenomenon. Some people do, some people don't Relatively speaking, on average,

it is more likely to happen on risperidone than on other drugs in the class.
Q. Have you ever reviewed Risperdal's package insert?
A Yes, I did.
Q. Do you know whether it has any statement in the warning on prolactin that Risperdal poses a greater risk of elevated prolactin levels than other atypical antipsychotics?
A. I don't remember
Q. You don't know whether it says that or not?
A I do not know that that exact phrase you are asking me is in the package insert.
Q. Should the Risperdal label have information in its warning, information in the prolactin warning that makes clear to doctors who use it that it presents a unique risk for hyperprolactinemia among the atypical class?
MR. PECK: Object to form.
A. I believe that the package insert contains the elevation of prolactin. I do not know whether they have to have some kind of additional details. But the elevation of prolactin is noted in the package insert.

Q. You think that's something that would be important for doctors to know, that among the class of atypicals, Risperdal is the most likely or more likely than the others to produce hyperprolactinemia?
MR. PECK: Object to form.
A. I'm not sure that this is a clinical piece of information It's not that the elevation of prolactinemia is a lethal side effect. So I think it's noted I don't know what to tell you
Q You think it's known?
A. It is known, yes
Q. And it is not a lethal side effect so they don't have to warn about it?
MR PECK: Object to form.
THE WITNESS: Can I respond?
A. The side effects are described in the package insert
Q. Right.
A. For physicians to read.
Q I think you understand what I'm asking you.
A No, I don't
Q. Okay. You told me that Risperdal is unique among the atypicals in its elevated

propensity to cause hyperprolactinemia Right?
A Yes, it's a relative. It's a little bit more, so it's relative to others if you take group data. In the clinic we always have 100 percent of everything. The patients do not care, my patients do not care if they are medical oddities. So my patient has or does not have prolactin with any of the drugs. So it's something that I am always concerned when I treat people, because they may be less likely to develop prolactinemia but they can still develop it with any drug that I prescribe
Q In the general population Risperdal poses a greater risk of hyperprolactinemia than the other atypicals. Right?
A. Yes
Q Should that information be in the label, the relative risk of Risperdal?
A. I do not -- I am not a regulator and I do not know what to tell you. It is not something that I consider in my responsibility. I think it's noted that prolactinemia is a side effect.
Q. You're a clinician that looks at labels to understand what drugs do. Right?
A. Yes
Q Is it important when doctors are

conducting the risk/benefit analysis for their patients that they understand whether there are relatively greater risks among treatment alternatives?
MR. SPIVACK: Objection, calls for speculation.
A. Could be.
Q. That could be important?
A I do not know what to tell you I think in the clinic the issue is always doctors weigh risks and benefits in the individual patient So there are many considerations for selection of drugs. That's one of those The other one is how effective the drug is, what is the previous experience with other compounds and so on and so forth. So it's a very complex decision That is what the physicians are trained for, to weigh risks and benefits. You are describing one of many factors that go into this decision, and prolactinemia is a monitorable side effect. It's not deadly. So I do not know what is the right response to what you are asking me
Q Well, I'm trying to understand why you as a doctor are so resistant to the idea that doctors ought to be warned about relatively greater risks

among drugs that they might choose
MR SPIVACK: Objection, argumentative, misstates the witness's testimony
BY MR TRAMMELL:
Q I mean, and perhaps we're not communicating. I mean, can you explain to me why you think that's not a risk worth warning about?
A I think --
MR. SPIVACK: Objection, misstates the testimony
A. I think that it is a risk worth mentioning and it is listed in the PDR. You are asking me if there should be some particular black box or a particular warning, and I am not a regulator.
I think that the possibilities of prolactinemia are listed in the PDR.
Q. I'm asking you, should doctors know or be warned, regardless of how that warning looks on a label, should doctors be warned of a relatively greater risk among possible treatment alternatives?
MR. SPIVACK: Objection, asked and answered, calls for speculation
A. I believe that the warning that they have about this possibility of hyperprolactinemia is adequate.

Q. We talked about the relative risk, the relative potential harm of prolactinemia in kids versus adults To your mind, is there a relative difference in the potential harm for kids versus adults of hyperprolactinemia?
A. The word "harm" may not be the best description of what we are discussing here. The impact of elevated levels of prolactin in children is not well-known. It's not well-understood
Q. How do you treat hyperprolactinemia?
A. We published a paper in the late '90s using a D2 agonist in children with high levels of prolactin. These children were asymptomatic, did not have any symptoms visible to us in physical examination or clinical complaints; zero. But because the levels of prolactin were high, I preferred to try to bring it down. Another option is to remove the medicine and change it to another one
Q Are you trying to say that because you've never seen symptoms of hyperprolactinemia, that it doesn't exist?
A. No.
Q. Okay.
A. I am saying that the scientific evidence

of what does it mean clinically in children is not well-known.
Q Despite the fact that it's not -- What did you say?
A It's not a personal issue with me. The scientific literature on the subject is not clear
Q Okay. Despite the fact that it's not clear, should parents of kids who take Risperdal be told about the risks of elevated prolactin levels that are different in Risperdal than the other atypicals?
A. I think that parents should be told that elevation of prolactin is a possibility. And this is what I discuss with my patients, that I monitor the prolactin levels when I prescribe all the atypical antipsychotics.
Q. Should those parents be told that there is a greater risk of hyperprolactinemia with Risperdal versus the other atypicals?
A. They could be told I'm not sure that this is something that -- There has to be some kind of statistical study to show that that issue is a particular dangerous environment for risperidone. I am satisfied with the fact that it's described in the PDR. I warn the families that this can happen.

It is not the side effect that is associated with visible problems in premenarche, prepuberty children So it's not clear what symptoms people have
Q. Do you tell parents when you prescribe Risperdal that there is a greater chance of hyperprolactinemia in kids taking Risperdal versus other drugs?
A. No, I describe that they can have prolactinemia.
Q. You don't distinguish among the risks in the class?
A. I tell them when I describe that the medication can produce elevation of prolactin.
Q. But you withhold your knowledge that the risk is greater for patients taking Risperdal than other atypicals?
MR SPIVACK: Objection, argumentative, misstates the witness's testimony.
A. I don't do that kind of discussion As I told you before, when I am with a patient, it's a one-to-one interaction, so I tell the patient the risk that applies to the particular compound that I am selecting to use.
Q And just to clear this up, you said one of

the reasons you don't think it's a serious risk or that it's unknown is because there's no clinical trial showing it Right?
A. I said that the clinical impact of elevation of prolactin is not well-documented.
Q. Okay. But it is based on the chemical compound Risperdal. Right?
A. Based what?
Q The notion or Risperdal's effect on prolactin and understanding of that is based on Risperdal's chemical compound and its interaction with neuroreceptors Right?
A. Yes.
Q. And so because you can tell that Risperdal elevates, has the potential to elevate prolactin levels simply based on its chemical compound, what do you need a clinical trial for?
A. You need to actually document that's the case You need to show that it is in fact more than Zyprexa or Geodon or other medications on the class.
Q Did you ever do any research on the relative levels of prolactin in kids taking Risperdal versus other atypicals?
A. We measure prolactin in every study of an atypical that we conduct.

Q. But you never did a study to determine whether Risperdal caused greater hyperprolactinemia than other atypicals?
A. We measured the levels of prolactin and the percent of children that have elevations in every one of the studies and we tested them all.
Q. I understand
A. And we published in our papers the levels of prolactin.
MR TRAMMELL: I object as nonresponsive.
BY MR. TRAMMELL:
Q. I'm sure you know what I'm asking you.
A No, I don't
Q Okay. Every study that you conduct has a purpose. Right?
A. Yes.
Q You're trying to prove or disprove a hypothesis. Right?
A Right, yes, correct.
Q Did you ever try to prove or disprove that Risperdal has a greater effect on prolactin levels than other atypical antipsychotics?
A. No
Q. Did you ever propose to Janssen that that kind of study be done?

A. I don't recall.
Q. Did they ever ask you to do that kind of study?
A. No
Q. Nobody from Janssen ever said "Hey, we are concerned based on the nature of our chemical compound that we may pose a greater risk to kids that take our drug because of hyperprolactinemia. We need to study this so we can get the truth out there." Nobody ever said that to you, did they?
MR PECK: Objection, form
A. I don't recall. I always discuss the issue of prolactinemia associated with risperidone in my transactions with the interlocutors, including Janssen
MR. TRAMMELL: I'll object to everything after "I don't recall."
BY MR TRAMMELL:
Q. Now, we have talked about this some, but all these studies that you did at the center --
A The studies were not done at the center. The studies were done in my program
Q. Can you explain that distinction?
A The center did not do any clinical trials.
Q. Well, you didn't do any clinical trials.

You did studies Right?
A. Clinical pharmacological interventions were not done as part of the center activities
Q. Where were they done?
A. They were done in my program
Q. And what is the name of your program?
A Pediatric psychopharmacology.
Q. That's different? That's not the same thing as the Johnson & Johnson Center?
A. No.
Q. What does the Johnson & Johnson Center do? What did it do?
A. The Johnson & Johnson Center was an entity within my program following the NIH center definitions that had five cores. The core on neuroimaging evaluated better ways to read anatomical data from MRI. The core focused on genetics allowed us to have a repository of DNA on the studies that we are conducting in our center. And a study of paradigm development that we evaluated and developed driving simulation for adults with ADHD and a work simulation for adults with ADHD. The center had a core of data analysis in which we were able to devote statistical resources to analyze data of studies that we

completed in the past.
Q. And you published on all that work Right?
A Yes.
Q. What is the basis or where was the work done that served as the basis for your studies, your Risperdal studies?
A. We had the contract to do an open label study of risperidone in children and adolescents with pediatric bipolar illness.
Q. You're making a distinction between your center and something else
A. Yes The study that we did doing risperidone was done with a separate contract to do that study with Janssen It was not part of the center's focus
Q I understand. So Janssen gave you money every year to fund the center which had the cores which you keep talking about and then they would separately give you money to fund studies?
A. Yes
Q. And where did those studies take place?
A. The studies took place in my program at Mass. General
Q What's the name of your program?

A. The clinical and research program in pediatric psychopharmacology.
Q. Which is different from the J&J Center?
A Yes
Q. And, by the way, the J&J Center, did it have a physical address?
A. No.
Q It's just an entity. Right?
A It's a concept.
Q. Okay, it's a concept. There's no J&J building sign anywhere your building?
A. A building, no.
Q. Can you tell me one more time, there's the J&J Center and what was the full title of it? Do you remember?
A The J&J Center for the Study of Pediatric Psychopathology.
Q And your program is called what?
A The clinical and research program in pediatric psychopharmacology
Q. Is that a concept too?
A. What do you mean, a concept?
Q Well, it's a way you characterize different aspects of your business. Right?
A. I am a physician and not a businessman.

We see patients My program has about 3,000 children with severe mental illness that myself and my colleagues care for. The center carries a dozen of scientists that explore the underlying scientific foundations of all disorders that afflict children.
Q. Does the center have any employees?
A. No
Q Does your program have any employees?
A. Yes.
Q And who are they?
A You want me to name all of them?
Q. Yes. How many are there?
A Depending on funding, there are as many as one hundred.
Q. No, I don't want you to name them all. All those people that work at your program, is that their only job?
A. For some people that work part time, they have other jobs
Q. Is there someone who works at your program that's their only job?
A. Yes.
Q. And you employ up to a hundred people?
A. Yes
Q. And you run it?

A. Say that again?
Q. You run it?
A. Yes
Q. Do you get a salary from the program?
A. Which program?
Q. The program you just described
A. You have to be specific. J&J pays less than 10 percent of my institutional salary
Q. Okay. Did you write it down? Did you get a salary from the J&J Center for pediatric psychopathology at MGH?
A. Yes. That salary was about, it's less than 10 percent of my total income. It's 5 or 7 thousand dollars a year.
Q And what is your total income?
A. My total income varies depending on sources of funding, but it's somewhere about 250
Q. What percentage of your income comes from Massachusetts General Hospital?
A. The entire income comes from Massachusetts General Hospital.
Q Are you paid for giving talks on behalf of the pharmaceutical companies?
A Those are not salaries Those are outside activities

Q. I understand Do you know what income means?
A If I know the word income? Yes
Q Okay. What is your income?
A Could you define what are you asking?
Q. How much money was paid to you in 2008?
A. In 2008? The salary portion is about 250 or 260.
Q Any other income that you have?
A. Yes I have some private practice and I have consultation and talks that I give.
Q. And what was the total of that compensation?
A In 2008 the consultation and talks were about 50 or 60 thousand and the private practice, about 100,000
Q So about $400,000 in 2008?
A. Roughly
Q That was your total income?
A. (Witness nodded.)
Q. That's what you'll report to the Government?
A Yes.
Q. Was it more or less in 2007?
A. It was a little bit more. I did more

consultation in 2007.
Q Do you know how much you made through your consultations in 2007?
A I don't remember exactly But it was about, I would say, all around consultation I think was 170 or something like that
Q. 170? And how much did you make from your private practice in '07?
A The same thing. The private practice is about 100,000
Q And was your salary at MGH the same?
A. I think in 2007 may have been a little bit less I think was maybe 230 or something like that.
Q So income that you get from the drug companies is more than half of your income or it was in 2007 Right?
A No I think that the income of outside activities is not only from drug companies, it's from CME activities and other sources, not from drug companies
Q Okay Do you know whether drug companies paid that?
A Drug companies support some of the CME activities Some are other type of consultations
Q More than half of your income has nothing

to do with teaching at Harvard or seeing patients at MGH. Right?
A. Those are outside activities.
Q. More than half of your income is not derived from teaching at MGH or treating patients, or teaching at Harvard, treating patients at MGH. Right?
A. Correct
Q. And most of your outside income comes from pharmaceutical companies. Right?
A. Some of the outside income comes from pharmaceutical companies.
Q. And who is -- Over the course of the last ten years, where has the majority of your pharmaceutical company income come from, which company?
A For outside activities, you are talking about? Oh, I don't know. I think I have a -- I consult with all of them. Probably there is -- I don't know which one is the most representative, but I consult with dozens.
BY MR FIBICH:
Q. Consult with thousands?
A. Consult with dozens of pharmaceutical companies.

Q Thousands?
A No; dozens, dozens
BY MR. TRAMMELL:
Q. You don't know whether you made more money from Janssen than any other pharmaceutical company over the last decade?
A Well, I don't think so.
Q. Now, in addition to the J&J Center for pediatric psychopathology at MGH, what is the full name of your program?
A. It is a clinical and research program in pediatric psychopharmacology and adult ADHD
Q. You said which program earlier What other programs do you have?
A. That's what I have.
Q. Do you get a salary from that program?
A. The salary is a package of different components from clinical care to grants. The salary is largely self-made
Q Through consultations or private practice Right?
A. Consultations, private practice, outside activities, not inside salary No salary
Q This is Number 9 Now, this is a paper called Risperidone Treatment for Juvenile Bipolar

Disorder - A Retrospective Chart Review. You're listed as an author
A. Yes.
Q. Did you write this?
A. Yes.
Q. You wrote it?
A. I wrote it with my colleagues.
Q. Did you actually put pen to paper and write the words that are in this study?
A Yes.
Q Did you write the first draft of this study?
A. I don't remember who wrote the first draft, but the case series came from my patients in the clinic.
MR. SMITH: Objection as nonresponsive.
MR. TRAMMELL: Objection, nonresponsive.
BY MR. TRAMMELL:
Q Do you know who wrote the first draft?
A. I believe that I did the first draft, but I am not -- I cannot tell you with certainty.
Q. And when you say you wrote the first draft, does that mean you actually sat at a keyboard and generated a document or does that mean somebody sent you the first draft and you were the first to

review it?
A No, I actually typed in the words.
Q Did you have a consulting relationship with Janssen at this time?
A. I am not aware that I had a consulting relationship.
Q. Do you know of anybody else that's listed as an author that had a relationship with Janssen at the time?
A. I am not aware of
Q Do you know whether this study was funded by Janssen?
A. No, this study was not funded by anybody
Q Who funded it?
A. It was not funded by anybody. We just collected data from our records, tabulated it and reported it
Q. Now, it says it was published August of 1999.
A. Mm-hmm
Q. And the conclusion of this study is, "Although limited by its retrospective nature, this study suggests that risperidone may be effective in the treatment of manic young people and indicates the need for controlled clinical trials of

risperidone and other atypical neuroleptics in juvenile mania." Did I read that right?
A. Yes
Q. So it's saying that this study is limited by its retrospective nature. What does that mean?
A This is a chart review in which risperidone was added to other treatments, so the children were receiving other treatments, not only risperidone. And by being retrospective means that a study that is more evaluative has to be prospective, so you start -- You cannot say much from a retrospective study; it's just a signal. The process starts with clinical observation. This was a clinical observation with our patients, my patients
Q And this is a hypothesis-generating study. Right?
A. It's an observation.
Q. This study doesn't prove that Risperdal is safe and effective for the treatment of manic young people, does it?
A. No.
Q. And it would be inappropriate for anyone to represent to a doctor that a study like that proves that Risperdal is safe and effective for the

treatment of manic young people, wouldn't it?
A. It would not --
MR. SPIVACK: Objection, calls for speculation, no foundation.
A. It would not be appropriate.
Q. This is 10. 10 is a case report published in the Journal of Child and Adolescent Psychopharmacology, November 4, 2001. You and Louise Glassner Cohen are the authors. Right?
A Correct
Q What is a case report?
A. It's a group of children that have very elevated levels of prolactin that we treated with a selective D2 agonist called cabergoline.
Q. Why were you studying this? Why did you write this case report?
A. Because I was concerned about elevation of prolactin, particularly very high elevations that these children had, and I was looking for ways to normalize them
Q. Were you a consultant with Janssen at this time?
A. I don't remember.
Q. Is it your practice to disclose your relationships with these pharmaceutical companies

when you write articles about their drugs?
A Yes.
Q Why is that?
A. It's a requirement of the institution.
Q. Is it important for people reading the article to know that the author may be affiliated with the drug, with the company that makes the drug he's writing about?
A Yes
Q. Why is that important?
A. Because the reader may be better able to evaluate the findings on the study. This study did not evaluate risperidone It evaluated cabergoline.
Q. I understand I'm asking you generally what's the reason that readers ought to know whether the author of a study on a drug that's made by a manufacturer with whom he has a consulting relationship, what's the reason readers need to know that?
A. To be able to evaluate or at least consider whether there is any bias in their report.
Q. The conclusion here is "Cabergoline may be useful for the treatment of risperidone-induced hyperprolactinemia in youth. However, further research is needed " This study doesn't prove that

the dangers of Risperdal, whatever they are, the dangers of Risperdal-induced hyperprolactinemia are alleviated by cabergoline, does it?
MR. PECK: Object to form
A The study shows that levels of, elevated levels of prolactin can be normalized with this particular compound
Q Does it prove that?
A Well, it's not proof. It's a case report
Q That's 11. 11 is called No Seizure Exacerbation from Risperidone in Youth with Comorbid Epilepsy and Psychiatric Disorders, a Case Series It's published November 2, 2004, in the Journal of Child and Adolescent Psychopharmacology What is a case series?
A A case series is a group of children afflicted with a particular problem
Q What is the limitation of a case series type paper in drawing conclusions about safety and efficacy?
A Case series are by design the first signal that you have on a particular medical story They always start with clinical observations
Q This is a very limited type of analysis, is it not?

A. It's a small study, yes. It's a case series
Q. You're listed as an author here, the last author. Do you know whether you had a -- Well, you did. You had a consulting relationship with Janssen at this time, didn't you?
A. 2004? Yes
Q The other authors are, well, one of the other authors is Gahan Pandina. Who is that?
A Gahan Pandina is a scientist at Janssen.
Q. He is employed by Janssen. Right?
A. Yes
Q. Do you recognize any other Janssen employees among the authors here?
A. No
Q Do you know any of these other people?
A. I know Dr. Gonzalez. He was my mentee
Q. The authors of this case series never got together to exchange drafts and talk about ideas for the paper, did they?
A. I cannot talk about the other authors, but Dr. Gonzalez sent me a draft of this paper for my review.
Q You didn't write this?
A No

Q Is the purpose of this study to encourage doctors to use Risperdal to treat epilepsy?
A. The purpose of this study is to discuss the fact that children with epilepsy have psychiatric illnesses the same way as children without epilepsy and doctors in practice need to treat them, so Dr. Gonzalez specialized in children with epilepsy and was very interested to examine the question whether can you treat a child with severe epilepsy with a particular psychiatric drug, in this case risperidone.
Q. And risperidone according to this case series may be, is a relatively safe treatment for these kids because it doesn't have the propensity to cause seizures. Right?
A. In the context of a limited number of subjects with severe epilepsy as this one is discussed here, risperidone did not exacerbate their seizures. That's all what the study says.
Q And what use can doctors make of this information?
A. The use is limited to only knowing that somebody looked at the issue. Knowledge is better than ignorance. So limited or not limited, knowledge is better than not knowing.

So even though these are just case series, doctors know epilepsy affects at least 1 to 2 percent of the population, so doctors are likely to meet an epileptic child that has psychiatric illnesses that require psychiatric treatment. So having some idea that the drug is not exacerbating seizure is an important piece of information, not definitive or divine, but at least gives some kind of information in the absence of nothing

Q. Knowledge is better than nothing and it's important for doctors to have this knowledge in their risk/benefit analysis Right?

A. Yes

Q. And knowing is better than ignorance, except when it comes to relatively greater levels of hyperprolactinemia. Right?

MR. SPIVACK: Objection, argumentative

MR PECK: Objection.

A. I have no idea what you want from me, but I am discussing that prolactinemia was an issue I was always very concerned about prolactinemia. I treated prolactinemia I don't know what is the basis for your attack.

Q. It's not an attack I mean, I want to understand the distinction you make I mean, you

were perfectly happy to make a safety distinction when you're saying Risperdal is not associated with a risk but you disavow any obligation by Janssen to make a distinction when Risperdal is associated with a risk And is the reason that you do that because they've paid you so much money?

MR. SPIVACK: Objection, compound, misstates the testimony, argumentative.

A. The paper on prolactin -- Sorry.

MR. SPIVACK: Go ahead.

A. The paper on prolactin described the prolactinemia as associated with risperidone and I tried to treat it by using a medicine. This paper discusses the fact that children that require psychiatric intervention, in this case with risperidone, their seizures did not exacerbate Both are important issues.

Q. Right While you're being paid by Janssen, you are minimalizing side effects associated with Risperdal Right?

MR PECK: Object to form

MR. SPIVACK: Objection, no foundation.

A. I am not minimalizing anything

Q. Did Janssen -- There's a Janssen author on that paper Right?

A. Yes.

MR TRAMMELL: We've got to change tapes.

THE VIDEOGRAPHER: This is the end of tape number 3 The time is 2:39 We're off the record

(Short recess taken)

THE VIDEOGRAPHER: We're back on the record This is the beginning of tape number 4 The time is 2:55

BY MR TRAMMELL:

Q Doctor, we're back on the record. You understand you're still under oath. Right?

A. Yes

Q. Okay Now, when you would go give these talks that Janssen hired you to give, what kinds of things would you talk about?

A. First of all, Janssen did not hire me to give talks

Q. Okay Does that mean that you never were paid by Janssen to speak to anybody?

A No That means the talks that I give is on the diseases and some may or may not be funded by Janssen Not always I know who funds a particular program

Q. Well, maybe you misunderstood me Janssen paid you to give talks Right?

A. On occasion.

Q. And what did you talk about?

A. I only talk about the diseases for which a condition -- I talk on pediatric bipolar illness or ADHD

Q. Do you talk about the use of Risperdal to treat those conditions?

A. I talk on the disease and I would say 90 percent of my talk on pediatric bipolar is on the disease, its clinical manifestations, and I mention among the treatments available our results of risperidone.

Q So you talk about Risperdal, even if it's just for a small part of the time You talk about Risperdal when you give your talks about the diseases. Right?

A. I talk about the disease and I talk about treatments, and one of the treatments is risperidone.

Q Right. And the disease is pediatric bipolar disorder. Right?

A. Yes.

Q. And ADHD with comorbid pediatric bipolar disorder?

A. I talk on ADHD separately from bipolar

illness. When I talk on bipolar illness, I describe a sizeable number of children with bipolar illness have comorbid ADHD.
Q. When you're speaking at CME events, do you talk about Risperdal?
A I talk about pediatric bipolar disease, and when I talk about treatments I describe the treatments available to treat pediatric bipolar illness based on the evidence available to me at that time, and that includes risperidone.
Q. Sure. Do you talk about the side effects of Risperdal at those talks?
A. The talks have a finite amount of time, so I can only spend a few seconds per slide. Out of a slide set of about 100 slides, I may have one or two slides for risperidone
Q In your risperidone slides, are you discussing side effects?
A. The risperidone slides are mainly reporting on the efficacy part.
Q. So you're talking about the disease and then you say "This is my understanding of the treatments available This is Risperdal. I have studied it and found it to be effective in treating this disease"?

A. I talk about the disease, I talk about the treatments, and I describe what we know about the different treatments.
Q. But you don't talk about side effects generally?
A. I talk about side effects if somebody asks me
Q. But it's not part of your slide deck. Right?
A. Not necessarily. Depending on time available, I describe in some of the talks the weight gain being associated with atypical neuroleptics.
Q You mean you tell everybody that Zyprexa is the worst offender for weight gain and that the others are not as bad?
A. No I tell that the average weight gain in our studies with Zyprexa were 5 kilos over eight weeks and risperidone was 2-1/2 kilos over eight weeks.
Q. Why do you tell people about weight gain?
A Because weight gain is one of the most significant liabilities of the atypical neuroleptics.
Q. Because it can lead to diabetes and a

number of other health complications. Right?
A Weight gain is a problem in medicine, not only for diabetes It's a problem in its own right.
Q. But it is a problem for diabetes. Right?
A. Weight gain is one of the risk factors for diabetes.
Q. And so when you're talking about weight gain and Risperdal, it is to say that in your studies or in your experience weight gain with Zyprexa is twice as bad. Right?
A. Weight gain with Zyprexa is twice as bad, yes.
Q. And so if a doctor is differentiating between treatments and making a treatment decision for a patient based on weight gain, the impression you give is Zyprexa is more dangerous than Risperdal. Right?
MR. PECK: Object to form.
A. You could say so.
Q. Who writes the contents of your talks? Who writes your slides?
A. Me.
Q Even the ones paid for by Janssen?
A I write all my slides Janssen does not. As I mentioned to you before, I talk on the disease

and I frequently do not know who pays for the talk in the form of grand rounds or a scientific symposia. I never talk on risperidone.
Q. You don't know who pays for those talks?
A. Pardon?
Q. You don't know who pays for those talks?
A. Not always I know who pays for the talk I get an invitation to speak at an academic institution or a congress I frequently do not know who pays the congress or the institution for that talk.
Q. But some of your talks are directly paid for by Janssen Right? For some talks you give, they just pay you a check. Right?
A. Sometimes
Q Who writes the content of those talks?
A. I write the content of all my slides
Q. They don't give you any material at all?
A No. Sometimes I may ask if they have data from them that is not mine, just to be accurate and not need to reproduce a particular slide. So, for example, if a company does a clinical trial and the results are available in the form of slides, I will ask to have the original slides
Q Do they review your slides before the

talks that you give for them?
A. No.
Q. Why don't you let them do that?
A. Because it's my talk.
Q. You don't want any idea that they're influencing the content of your talk. Right?
A. Absolutely not.
Q. Do you think it would be inappropriate for Janssen -- Never mind.
Is childhood mania or was it ever a disease about which the clinical community was skeptical?
A. Yes.
Q. And why?
A. It was considered a very uncommon disease
Q. And because of that, there was a reluctance to treat it Right?
A. No. I think children went under different names and they were treated the same way So does not matter what you call it, so some clinicians felt more comfortable with the label of conduct disorder or severe ADHD or oppositional-defiant disorder. The treatment may be the same.
Q. But it was never thought of as potentially a psychotic disorder Right?

A. Sorry. Define that for me.
Q. Well, the way you characterized pediatric bipolar disorder, your contribution is characterizing something that used to be thought of as something else as pediatric bipolar disorder. Right?
A. I define the set of symptoms that characterize the disorder as fulfilling all structured diagnostic interviews criteria for bipolar disorder So instead of calling an animal with four legs and a tail an animal with four legs and a tail, I said maybe this should be called a dog.
Q What are affective storms?
A. The term "affective storms" allude to a very severe agitated, aggressive state
Q. Is there a scientific definition for it?
A What do you mean?
Q Well, is it a subjective phrase or is there some sort of objective criteria for affective storms?
A. An affective storm is subjective All our nosology is subjective, is based on signs and symptoms "Affective storms" is a term that was used I believe by Dr Davis many years ago before my

time to describe a prolonged state of temper outbursts.
Q Have you ever had an affective storm?
MR. SPIVACK: Objection, argumentative.
BY MR TRAMMELL:
Q. Is there a distinction in an affective storm and its clinical significance in children versus adults?
A. The term affective storm was described, was used to describe a prolonged state of a temper dysregulation
Q. I understand. Did you hear my part of the question about the distinction between children and adults?
A. I think that adults may have affective storms too.
Q. Does it have the same clinical significance in children as it does in adults?
A Yeah Adults get hospitalized when they are in one of these states They can be very dangerous and do things that are not compatible with living in society
Q. In either population, children or adults, it's a sign of potential mania. Right?
A. It's one of the symptoms that leads to the

suspicion that somebody may be suffering from --
Q. Okay. Does pediatric bipolar disorder present in the same way that adult onset bipolar disorder presents?
A In many ways, yes. They have the same symptomatic characteristics. There is a developmental variability For example, a child does not have credit cards and cannot go on buying sprees The child's hypersexuality may not necessarily be manifested by multiple sexual partners or manifested by downloading pornography from the Web So there is a difference in manifestation but not necessarily in content.
Q. Is downloading pornography a symptom of bipolar disorder?
A. In children that are hypersexual at a very young age, they are extremely preoccupied with sexual matters not compatible with the activities on sexual matters of peers of the same age.
Q. What age are you talking about?
A Children as young as four, six.
Q. What are the criteria for -- What are the diagnostic criteria for pediatric bipolar disorder?
A The symptoms defined in the DSM consist of a period of abnormal mood lasting a week or more

that can be either euphoric or irritable, associated with additional symptoms such as distractibility, hypersexuality, agitation, difficulties in concentration, difficulties in functioning.
Q. Those are not the criteria for kids, though?
A. The same criteria are used for kids as are used for adults.
Q. Are those criteria useful for kids?
A Yes.
Q. Does someone have to satisfy those criteria to be accurately diagnosed as bipolar?
A. Yes.
Q. Okay, this is 12
Doctor, is this a set of slides from a talk you gave?
A I think so.
Q. Do you know when?
A. No.
Q. You can't tell just from looking at it?
A. No
Q. Do you know what kind of audience you would have given this talk to?
A. No
Q. It would either have been at a CME or a

Janssen-sponsored event or an event sponsored by some other drug company?
A. Could be anywhere.
Q Well, it would be one of those two. Right?
A. I participate in congresses, so it's not -- Maybe more than two or three.
Q It would have been a talk to other doctors, though, probably Right?
A. Most likely.

Q. Why was it important to you to make those your first two bullet points?
A Because the issue of not diagnosing and choosing another name may be an important error in

clinical judgment, so the problem of controversy leads to funding agencies not funding the necessary research to establish It's a vicious circle that if I send a paper on pediatric mania, the paper is likely to be rejected because pediatric mania does not exist because there are no papers on the subject, something like that.
Q. And did you say earlier, did you testify that kids have an atypical expression of bipolar disorder compared to adults?
A. Atypical only in the developmental variability of the clinical picture, not in the items that define it.
Q. Okay

Q Irritability is one of the criteria. Right?

A. Yes. The abnormal mood has two components, either euphoria or irritability, or both.
Q. You certainly can't diagnose pediatric bipolar disorder just based on irritability. Right?
A. No. I said that irritability is not enough; has to be severe, persistent, and it has to be accompanied by additional symptoms.

Q. Does this mean fighting with your brothers and sisters?
A. No. This includes things like taking a baseball bat and attempting to murder your sibling.
Q It has to be that kind of action Right?
A. It has to be very severe, yes.
Q. Why didn't you explain that in this slide?
A. Because the irritability that we see in manic children is not fighting with your sibling

like you are asking me and it's not having a temper tantrum either.
Q. Attacking behavior towards others including family members, I mean, that's a vague description. Isn't it?
A. I don't think so
Q. That means murderous attack. Right?
A. No. I think it's severe, severe attack Can be something like a child can unbuckle himself or herself from the car seat and attacking the driving parent in the highway, for no apparent reason; opening the door of the car, a moving car on the highway, and attempting to jump. Okay?
Q Do you tell doctors when you talk on this that the type of irritability that is necessary to diagnose pediatric bipolar disorder is the type that involves some sort of excessively violent attack like trying to kill a parent or family member?
A. No. I say that the type of irritability that we see in children is extremely severe. Not all are murderous.
Q. What types of activity in between fighting with your brothers and sisters and trying to kill your parent satisfy the criteria for irritability?
A Well, for example, spending five hours

demolishing your room after you were not allowed to watch your TV show; taking a baseball bat and demolishing every furniture in the house.
Q. It has to be that extreme?
A. It has to be way out there in the decibels of aggression.
Q What is the scientific criteria for evaluating whether irritability rises to a level sufficient to be indicative of bipolar disorder?
A. We don't have an aggressometer. It is a subjective judgment. We wrote an article describing that there are different levels of irritability like there are different levels of fever or different levels of seizures
Q And that's why it's vague, right, because it's a subjective judgment and --
A. It's not vague at all
Q. Okay. Can you tell me exactly what kinds of behaviors are included and are not included in your definition of irritability necessary to be diagnosed with bipolar disorder?
A Yes It is a protracted state of very severe agitation, explosiveness and dyscontrol lasting totally different than normal human experience. And that's something that physicians

are trained to understand and diagnose If you were to have one of those children in your household, you would have no difficulty recognizing that the behavior is totally abnormal These are the children that the police needs to be called in -- okay? -- or the ambulance to take the child to the emergency room. This is the kind of behaviors I'm talking about
Q. I think that's the point, that I'm not qualified to diagnose bipolar disorder. I might agree with you that a child is a terror and is not much fun to have around, but that doesn't mean that that child is bipolar.
A No.
Q. So the problem with these criteria are that they are completely vague, that doctors who are not trained at diagnosing bipolar disorder or doctors who have not studied this population are unable to evaluate whether kids who're just angry or kids who are just acting out actually have a psychotic illness Isn't that right?
A. No I think that the kind of behaviors that I am describing are very, very severe These children have been called in the past conduct disorder, oppositional-defiant disorder. It's not

that these children did not exist, they were just under different names
Q. How long does the irritability have to protract? How long does it have to last?
A Usually more often than not for at least a week to qualify.
Q Is that included in your explanation here? Or do you give that explanation when you talk to doctors about it?
A Yes, I do. I think that there's a limited amount of material that I can hit in a talk. It's not necessarily that I'm covering every niche of the disorder, so I'm trying to hit on the highlights. And the irritability part, the same question that you are asking me about, as you say, fighting with your siblings is not part of it.
Q. So in order to be irritability -- And I'm just trying to understand this, because it's not clear to me. In order to qualify as irritability that can substantiate a diagnosis of bipolar disorder, a child has to be in a murderous rage persistently for a week?
A. I did not say murderous That's not a requirement for diagnosis It has to be severe, persistent, incapacitating, for a period of a week

A child goes to sleep at night
Q. What if a child is just irritable for a week?
A. That may not be enough. The irritability that we see in children that have oppositional-defiant disorder is a mild problem. It's kind of like a bad hair day. The irritability that we see in depression does not rise to the irritability of extreme proportions that we see in mania. So being irritable is not enough
Q. How does a doctor who reads your paper or hears your talk know how much irritability is enough when they're making subjective judgments about kids who are acting up?
A All the diagnostic criteria are subjective. People that treat children know what I'm talking about because these children come to our offices with desperate parents that do not know what to do with them
Q. Did Janssen ever tell you the true opportunity in bipolar disorder in kids is that the meaning of these diagnostic criteria is so vague, it's so hard to understand what would qualify as bipolar disorder, that we can convince doctors who are just confused and dealing with frustrated

parents to use Risperdal where they probably shouldn't?
MR. PECK: Object to form, foundation
BY MR. TRAMMELL:
Q. Did anybody ever tell you that?
A No.
Q. Anybody ever say that to you, "That's our plan here with Risperdal"?
A. Not at all.
Q. And, again, what's the scientific definition of irritable?
A. I think that you are using the wrong words. The scientific definition, irritability is a clinical symptom. Clinical symptoms are descriptive, not scientific What is the scientific definition of a headache? There's no scientific. You have a headache.
Q. Is it as easy to diagnose pediatric bipolar disorder as a headache?
A. No. But in the headaches, the way that the headache is afflicting the patient alerts the physician as to whether you have a tumor, you have migraine headaches, or tension headaches. So the clinical topography of the symptom tells the trained clinician what could be the underlying cause of the

problem So headaches are very different and there are very many reasons in medicine to have a headache.
Q. How do you tell whether someone who has mania according to your criteria doesn't actually have ADHD?
A My definition of mania is based on the Diagnostic and Statistical Manual of Mental Disorders, not on my inspiration.
Q Isn't it consistent with children's normal conduct to be irritable?
A No.
Q. It isn't?
A. No.
Q Do you have any children?
A. Yes.
Q Were you around when they were young?
A. Where do you think I was?
Q. I don't know.
A Okay Of course I was around.
Q. Were you around?
A Yes.
Q. Were you ever in the house when they would act up?
A. I am a child psychiatrist. I find it

offensive that you will think that I would not know the difference between a temper tantrum and this condition
Q. But maybe you can educate me and the jury
A. I would be happy to
Q Were you around when the kids would cry for no reason?
A. Yes
Q. Were you around when they would yell and scream at each other?
A. This is not what I am talking here.
Q. Were you around when that stuff happened?
A. Yeah.
Q. And which antipsychotic drug did you treat them with?
A The problems that families consult with me are extraordinarily debilitating, severe and devastating. Many of these children require institutionalization or placement outside the home. I am not talking about normal occurrence of everyday living.
Q. So, in other words, when your kids were irritable or crying, they weren't antipsychotic, but when other people's kids are irritable and crying, they are?

A. The problems --
MR SPIVACK: Objection, argumentative, misstates the testimony.
A. The problems that I consult on and treat are orders of magnitude different than normal childhood experiences.
Q. But the differences in magnitude and judging those differences is entirely subjective, isn't it?
A. All psychiatric diagnoses are subjective in children and in adults.
Q. And doesn't that create a tremendous amount of danger of misdiagnosis?
A. I think that subjectivity requires more clinical training than when you have objective parameters that anybody can determine. So there is training to be able to secure that the diagnosis is actually accurate, and that is what doctors are trained to do for many years
Q. Right Psychiatrists?
A. Psychiatrists, yes
Q. So the dangers of misdiagnosis are less in psychiatrists than they are in nonpsychiatrists?
A. Not only psychiatrists, depending on what we are talking about There is a discipline within

pediatrics that is called behavioral pediatrics that you have a reasonable amount of mental health training And as I explained to you before, there is a capacity problem in our field that there are not enough trained child psychiatrists to evaluate and treat all the children that require assessment and treatment.
Q. Does that mean that children should get substandard care just because there aren't enough doctors?
A. No. I am only stating the reality, that there are not enough child psychiatrists in the world, in this country, to attend to the many children that require care It's not something that I developed; it's a reality of our society.
Q. And so children get substandard care?
MR SPIVACK: Objection, argumentative, misstates the testimony, asked and answered.
MR TRAMMELL: What about speculation?
MR SPIVACK: Are you objecting to your own question?
BY MR. TRAMMELL:
Q. Doctor, if you'll go to Bates range, you'll see on the bottom or the side of your exhibit there's a JJRE stamp? You see that?

A. Yes.
Q. It's right here on the side of the document.
A. Mm-hmm.
Q. If you'll go to JJRE, the last three numbers are 891, the DSM Criteria. I think this is for bipolar disorder Is that right?
A. Yes
Q. Okay "A distinctive period" -- or "A distinct period of abnormally and persistently elevated, expansive, or irritable mood." Can be any one of the three. Right?
A. Yes
Q. Just has to be a distinct period?
A. (Witness nodded)
Q. Then B, at least three out of seven of the following but four out of seven if the mood is irritable. Right?
A. Right
Q. "Number 1, D, distractibility; number 2, I, increased activity or psychomotor agitation; number 3, G, grandiosity or inflated self-esteem; number 4, F, flight of ideas or racing thoughts; number 5, A, activities with painful consequences; number 6, S, sleep decreased; number 7, T, talkative

or pressured speech." And you've created an acronym or you've listed an acronym that says Dig Fast
A. It was not created by me.
Q. Okay. But the acronym exists and you used it?
A. Yes
Q. Did I read those right?
A Yes
Q. What is distractibility as a criteria for bipolar disorder?
A. Distractibility refers to a situation in which the person does not stick to the task at hand and is attracted to extraneous activities like being more interested in what's going on in the next room instead of doing their activities
Q. So distractibility in kids, is that like when you're trying to get their attention when they're watching their favorite TV show and they won't pay any attention to you?
A No Distractibility is a serious problem that occurs in many psychiatric units, including ADHD, where the child cannot stay on task That includes schoolwork or activities that require sustained attention.
Q. Is that like when you tell your kid to go

clean their room and they stop cleaning their room and start playing with their toys?
A. No. Distractibility refers to the inability to stay on task. So usually for children, the inability to stay on task is around schoolwork.
Q. I'm giving you examples of not staying on task and you're telling me that those are not criteria for bipolar disorder How is anybody supposed to know that from the word distractibility?
A That's the reason that you have training and you go to medical school and you go to residency for many years and you see a million people and then you understand the difference. If I ask you to evaluate the site of somebody's prostate, you will also not know. There are many things that you do not know, not only this
Q That's certainly true.
MR SPIVACK: So stipulated.
BY MR TRAMMELL:
Q. So if a doctor goes to medical school, goes through a residency and sees millions of people, he understands what distractibility means --
A. Yes
Q. -- in the context of pediatric bipolar disorder?

A. In the context of any. Distractibility is one item; it occurs in other conditions. If you have an attack of asthma, you also will be distractible. If you are febrile with influenza, you may not be able to concentrate. So distractibility is one. That's the reason that there are many symptoms, not just one.
Q. Right But it is the most common symptom?
A No, it's not the most common.
Q. Okay, we'll get to that in a minute. And just so we're all clear, this is the type of talk you would give when you were hired by Janssen to give talks. Right?
A. This is the type of talk --
MR PECK: Object to form
A -- that I give when I talk on pediatric bipolar illness.
Q. Including when Janssen hires you Right?
A. This is a talk that I give when I talk about pediatric bipolar illness; I define the illness By the way, these are not my definitions; this is something that is accepted in our nosology for children and adults
Q. But you talk about this subject matter when you give talks that Janssen has paid you to

give Right?
A This is the talk that I give when I talk about pediatric mania with or without Janssen.
Q. Okay, but with Janssen Right?
A. Sometimes with Janssen.
Q. Now, can you give me an example of distractibility that would satisfy the criteria for bipolar disorder?
A I gave you those examples.
Q. Well, give me --
A. It is a person that is unable to stay on task when required to do so. So in childhood, usually it's around school tasks. The person cannot engage in homework or cannot pay attention to the school activities deployed by the teacher.
Q So a kid that doesn't do his homework satisfies one of the criteria for bipolar disorder?
A. No. The child that is unable to do the homework all the time, not once. Okay?
Q So a kid who repeatedly fails to do his homework satisfies one of the criteria for bipolar disorder?
A If he is persistent and it's there all the time, that's one of the criteria, yes.
Q. What does "all the time" mean? What does

"persistent" mean?
A. Well, persistent is more often than not; it's lasting weeks, not minutes
Q. Number 2, "I, increased activity or psychomotor agitation," is that the same thing as hyperactivity?
A. No. Psychomotor agitation is a state of acute restlessness, has the feel of somebody that cannot stop moving, like a caged animal.
Q. What is increased activity?
A. Increased activity is somebody that is engaging in more activities than usual in the sense of doing projects that they had not been interested or able to do before, that they are trying to do activities outside their abilities, things of that type.
Q. Do you ever have increased activity at the same time as distractibility?
A. Increased activity refers as a choice of activities that people engage For example, a person may decide to do a wide range of activities way beyond the time of the day Has nothing to do with distractibility
Q. So how about a kid that doesn't want to do his homework for a whole semester and just wants to

play videogames or just wants to play the piano? Has he met two criteria?
A. No, because the psychomotor agitation is a very severe state that the person cannot stop moving and it's a frantic state of going from door to door or room to room or wall to wall. It has the feeling, as I said before, of a caged animal.
Q. I understand And you're trying to evade me, but there's an "or" there
MR. SPIVACK: Objection, argumentative.
BY MR. TRAMMELL:
Q. It says "increased activity or psychomotor agitation."
A. Yeah I did not invent the criteria.
Q I understand. So increased activity is -- Well, we've talked about that.
So a kid that doesn't do his homework for a semester and that just wants to play the piano all the time or draw pictures, has he met two criteria?
A Not doing the homework -- No. I'm not sure where you're going with this But not being able to attend to task or being distractible is different than refusing to do your homework.
Q Well, that was the example you gave.
A. You asked me for an example, I gave an

example.
Q. Okay. So if --
A. But not doing your homework would be somebody that is just oppositional or unable to do the homework. Distractibility is a clinical phenomenon in which a person can't attend to task and looks to other areas for interest
Q How do you tell the difference?
A. This is the reason that you go to school
Q. So it's just doctors in their subjective judgment are supposed to decide?
A. Yes
Q. "Grandiosity or inflated self-esteem," is that like little girls that say they're princesses? Is that what that means?
A. No.
Q. What does that mean?
A. It means like thinking that you are Superman and you can fly, so you go to the window and trying to fly.
Q. So a little boy who puts on his Superman costume and runs around the house is grandiose?
A No A little boy that puts the costume on, opens a window and try to jump is
Q. So it has to be some sort of suicidal

action?
A. No, has to be something out of the ordinary
Q. Well, isn't everybody that jumps out of the window out of the ordinary, I mean?
A. No This is not a suicidal act when children feel that they have flying abilities of Superman and that's the reason they want to fly out the window, not because they want to kill themselves
Q How do you distinguish between the detachment from reality in a small child who wears the Superman cape versus the small child that thinks he can fly?
A. Usually by the intensity and the bizarreness of the problem. So children have active fantasies; usually they don't act on those fantasies
Q. So even if a kid thinks he can fly, it's not grandiosity unless he jumps out the window?
A. The children that play Superman or house or firefighters don't act on those fantasies. If a child goes to join a firefighter brigade, it's a little bit different than playing house
Q. But it is impossible for you to draw a

line or --
A. Not for me or even for you.
Q. Well, why don't you tell me how you draw the line
A That is part of the training that physicians go through by -- As I said before, a physician that is trained to listen to murmurs of the heart can distinguish if it's your upper valve or right valve is affected and so on and so forth. So it's all part of training
Q. You see, it's not an answer to say "I'm a doctor and you're not," because you can't explain it. Can you explain where you draw the line without saying "I'm a doctor"?
A. Usually by the severity and the disability associated with the symptom The patients that come to see me come to see me; I am not going to recruit them. Okay? So a patient is in my office because there are certain symptoms that the patient is suffering from that the family is asking for help. And I'm not going to somebody's house and taking a child that dresses as Superman and tell him you need to be treated.
MR. TRAMMELL: I'll object as nonresponsive

BY MR TRAMMELL:
Q. It is a perfectly appropriate answer for you to say "I can't draw the line, I have no idea."
A. No, that's not true. I have an idea
Q Okay. Well, tell me where you draw the line.
A. The idea is if the symptoms are disabling, persistent, associated with distress and disability, those symptoms are abnormal
Q. Give me an explicit example of where you can draw the line in all cases.
A. You never draw the line in all cases; you draw the line in individual cases. So if somebody engages in an activity that is totally out of their purview, they want to do something that they have no skills of any kind and they think that they have and they actually engage in those activities So those are things that are not necessarily just regular play of children.
Q. Do you understand that doctors hearing this who aren't trained in psychiatry might get the misimpression that that means things that don't rise to the level of psychotic grandiosity or bipolar grandiosity? Do you understand that they might get that misimpression?

MR. SPIVACK: Objection, no foundation.
A. I do not know what doctors understand. But the kind of things that I am talking about, a doctor hearing of the behaviors that I am describing will not see that as normative behavior
Q. "Flight of ideas or racing thoughts," what does that mean?
A. That the thoughts are flooding your head; that the child has ideas that are changing very rapidly in his or her head.
Q. How about, can you give me an example of that?
A Well, ideas, I don't know what example to give A person that is talking about three or four subjects at a rapid clip. The patients sometimes complain that the head is flooded with thoughts and ideas and they cannot stop it
Q So the patient, the kid, has to come in and say "My head is flooded with racing thoughts"?
A No The children will say "I have ideas that I cannot stop" and "My brain is racing" is what children say The parents complain that the child talks about five subjects at the same time.
Q So when a kid talks about multiple subjects at the same time, they meet one of the

criteria for bipolar disorder?
A If it's disabling and severe and does not make any sense, yes.
Q Next is "Activities with painful consequences " Now, isn't that so vague that it's absurd? I mean, that is a useless criteria, isn't it? Because kids hurt themselves all the time.
MR. SPIVACK: Objection, argumentative
A I think that you should write a letter to American Psychiatric Association. I did not invent these criteria This usually reflects things like buying sprees, reflects things like engaging in extramarital affairs. Those are the things. So going on drinking binges beyond recognition or traveling across the world without having money to travel across the world These are the things that this is alluding to
Q How would this manifest in a kid?
A In kids it will manifest as doing like I told you before A patient of mine, for example, went through the ducts of the air-conditioning to watch, a seven-year-old, to watch his mother undress in the shower, for example. Or downloading pornography or touching the genitalia of a classmate, or touching the breast of their teacher

if he's a boy.
Q. That's what activities with painful consequences mean?
A. These are the childhood -- You asked me about the childhood equivalent. In adults is hypersexuality, is buying sprees, is inappropriate behavior. These are not just little things that people do
Q. Aren't there things that kids do that would be extraordinary for adults but are just part of normal childhood behavior?
A. No.
Q No?
A. I think that the children that engage in these activities do things that other children of the same age don't.
Q. Children are just little adults and they act the exact same way?
A. No They have equivalent abnormal behaviors A child may not have a credit card but may be insisting on buying things all the time, for example.
Q. But it is extraordinary for an adult to cry for no reason It's not extraordinary for a kid, is it?

A Children cry for reasons.
Q Well, to cry for nonapparent reasons.
A No, children cry for a reason: when they are frustrated, when they're sad, when they're reprimanded. Adults with depression sometimes cry continuously.
Q. Okay, well, how about this? And this doesn't seem to be a controversial point and I can't imagine why you're disputing it But my son wears a Superman costume sometimes and he's four. That would be an extraordinary thing for me to do, wouldn't it?
A. No, you can dress as Superman on Halloween.
Q. And this may be funny to you but it's not funny to me. And just so we're clear, you're saying that there are no distinctions between the types of extraordinary behavior that kids engage in versus adults, and so I just want the jury to understand exactly what you're telling doctors are the diagnostic criteria for treating these kids for bipolar disorder.
MR. SPIVACK: Objection, misstates the testimony, argumentative.
A. The symptoms that children have in content

may not be different but they have developmental variability because they are children. And as I said before, a child may not have a credit card but has other manifestation of excessive buying
Q. If you'll go to, the last three numbers are 895.
A. Say again?
Q. The last three numbers on the side are 895
A. Mm-hmm.
Q Says Frequency of Bipolar Symptoms It references a Wozniak and Biederman study, which I assume is you? You're Biederman?
A. Yes, I'm Biederman
Q. It says 97 percent of -- Well, I assume what this means, and you can tell me if I'm wrong, is that in the kids who met the diagnostic criteria for a pediatric bipolar disorder, 97 of them satisfied the D criteria?
A. 97 percent had distractibility, yes.
Q. 97 percent, okay. Was that the most common characteristic?
A. One of the most common ones, yes
Q And, again, it's tied with increased activity. Right?

A. 97 percent also had increased activity.
Q. And those are the two highest, aren't they?
A. Increased activity is one, yes.
Q. And the third highest is irritability Right?
A. Yes.
Q. So the distracted irritable child with increased activity is the most common bipolar child. Right?
A They have to meet criteria That means you have to have criterion A, euphoria or severe irritability of at least a week. If they have that, if they have irritability, they have to have four additional symptoms. If they have euphoria, they have to have three additional symptoms to qualify for a diagnosis.
Q. Well, that's not right.
MR. SPIVACK: Objection, argumentative
BY MR. TRAMMELL:
Q The criteria are elevated, expansive, or irritable mood. Right?
A Correct.
Q. And then if you have one of those three, you have to satisfy a certain number of these

criteria --
A. Yes
Q. -- and it's three if it's elevated or expansive mood and it's four if it's irritable?
A This is what I said
Q. Okay. I didn't ask you; I guess I should have: What's the difference between elevated and expansive mood?
A Elevated is euphoric, people that feel on top of the world Expansive is more refers to the behavior, kind of being looking happy inappropriately
Q. Looking happy inappropriately?
A. In circumstances that does not warrant that.
Q. Go to number 899 or -- excuse me, I'm sorry -- 900.
A. Yes
Q. What that says is Prepubertal Bipolar Disorder, which I suppose means bipolar disorder that onsets before puberty What does the big block with ADHD on top mean?
A That 42 of the 43 children in this study met criteria for ADHD
Q Did they have ADHD or did they have

bipolar or did they have both?
A They had both
Q But you're sure they had both?
A Yes
Q Is it possible that you have imprecise diagnostic criteria and you're calling kids that have one or the other the same?
A The diagnosis of bipolar illness requires an abnormal mood and additional symptoms There is nothing in the defining features of ADHD that speaks to abnormal mood
Q I want to go through these individually, the criteria If you go to 903, these are -- What I think this is is the percentage of kids who hit distractibility as one of their criteria, how that manifests in the kid Right?
A No This is a different module and the module on ADHD asks the symptoms that define ADHD
Q This is only ADHD?
A Yes In order to qualify for ADHD, you have to have a certain number of symptoms, a particular age of onset and associated impairment and disability
Q Are the criteria for ADHD more or less rigid than bipolar disorder for kids?

A. The criteria are the criteria They are equally --
Q What are they for ADHD? I'm sorry
A. The criteria for ADHD, depending on the nosology at the time, today the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition requires you to have six out of nine symptoms of either distractibility -- either inattention or hyperactivity and passivity When we did this study, the criteria required eight out of fourteen symptoms of inattention, distractibility, and hyperactivity.
Q. Was one of the points of your talk, talks like this that you gave, to get doctors who were comfortable with ADHD to see those patients as bipolar?
A. No My point was to highlight the fact that children with bipolar disorder frequently also have ADHD.
Q Which DSM was it you quoted from a second ago?
A. The DSM-III-R
Q. What is the average age of onset of bipolar disorder in kids?
A. In our study it was around five

Q. If you go to page 914, it says 4 55
A Yeah, around five. Where do you want me to go? Sorry.
Q What's that?
A. Where do you want me to go?
Q. Go to page 914
A. Mm-hmm
Q. So the average age of kids that met the diagnostic criteria in your study was four and a half?
A. Yes.
Q And how many kids was it?
A This study had -- what was the number? It was a small number. I remember it was 16 percent of our referral pool I think one of the slides has the number of children, fifty or so, in our first study.
Q. How many kids?
A. I don't remember exactly the numbers, but I would say around fifty. I don't remember exactly.
Q. There were fifty kids you evaluated to determine whether they met the criteria?
A. No. We conducted an audit of all the referral pool to our clinic So what we did is we looked at all the children that came up to the time

that we conducted the analysis. We looked at children that met criteria in structured diagnostic interviews for bipolar disorder and we looked at what characteristics these children had.
Q. So every one in your study met the criteria. Right?
A. The study started with children under the age of twelve that met diagnostic criteria on structured diagnostic interview for bipolar disorder.
Q. And among those kids the average age of onset was four and a half?
A. Yes.
Q. And so at four and a half you were applying the adult criteria for bipolar disorder and determining that these kids met the adult criteria?
A. The average age of the children that we described in this study was around eight. The age of onset is not the age of referral; it is when the parents described the onset of their symptoms
Q. Okay. But based on the parents' description of the symptoms, you determined that they met the criteria for diagnosis on average at four and a half?
A. Yes.

Q. And so there are these five psychological disorders here on page 914 and all of them onset under the age of five in your study?
A. Yes.
Q. Was that an extraordinary finding to you?
A. No.
Q. Why not?
A. Because conditions that afflict children very often emerge in the preschool years.
Q. And what do you base that on, by the way?
A. On the structured diagnostic interviews that we conducted.
Q. This study and your experience. Right?
A. This is information from a study, not from experience
Q. Now, was one of the reasons you were talking to doctors about early onset of bipolar disorder to validate the disorder?
A The purpose of talking about a condition or any talk is to educate, not to validate Validate is a statistical psychometric approach The purpose of a talk is to educate.
Q. The purpose was to convince doctors that bipolar disorder in kids is real and it can be diagnosed Right?

A The purpose is to describe what we had found in our research.
Q. Which is that bipolar disorder in kids is real and it can be diagnosed. Right?
A Yes
Q But moreover, it's real, it can be diagnosed, and it can be treated. Right?
A. The diagnosis -- If the diagnosis is correct, it can be treated, yes.
Q. And one of those treatments is Risperdal Right?
A. Right
Q. Is the structured diagnostic interview K-SADS?
A. The one that we used is the K, for child It is a structured interview that has modules for all psychiatric conditions that afflict children.
Q. Did you modify the criteria in any way?
A. We only modified to accommodate to the DSM-IV from the DSM-III-R
MR. TRAMMELL: Let's take a break.
THE VIDEOGRAPHER: The time is 3:35 We are off the record.
(Short recess taken.)
THE VIDEOGRAPHER: Back on the record

This is the beginning of tape number 5. The time is 4:09.
BY MR. TRAMMELL:
Q. Now, Doctor, we just finished talking about the substance of the kind of talk that you would give when you would talk about bipolar disorder, including the times when you would talk on Janssen's behalf. Do you remember that discussion?
A. (Witness nodded.)
Q Now, your role, your role or your relationship with Janssen was based on you helping them sell Risperdal or market Risperdal. Right?
MR. PECK: Objection, foundation.
A That was not my role
Q Well, certainly you knew the reason they had any association with you at all was that you would help in their sales and marketing efforts for Risperdal Right?
A. I never helped them on the marketing or sales effort.
Q Did they ever tell you "Doctor, this research you're doing, this work that you're doing, is very helpful for us in our effort to make a lot of money selling Risperdal"?
A No.

Q. And as far as you know, you weren't part of the sales and marketing operation at Janssen for Risperdal. Right?
A. I was not.
Q. Certainly nobody ever told you that?
A. No
Q. You would have objected had they told you that. Right?
A. Yes.
Q. You would have said "I don't sell drugs, I talk to doctors about science, I'm a doctor, I talk about patients." Right?
A. Right.
Q Something like that?
A. Mm-hmm.
Q. This is Biederman 13. It says Key Points From 2003 Child & Adolescent Business Planning Session 2, dated June 12, 2002. Then it says Sales & Marketing Do you see that?
A. Yes
Q. If you go down below Current Projects, it says key: "Need to train KOLs" -- which I think means key opinion leaders -- "to handle the media; need a proactive media plan." The first bullet point, "J&J Center for the Study of Pediatric

Psychopathology " Which is your center, right?
A Yes
Q "Joint effort by Janssen, OMP, and McNeil Consumer, in Boston with Joe Biederman " Do you see that?
A Yes
Q And that's you Right?
A Yes
Q So the truth is, whether they ever told you or not, Janssen thought of you as kind of like a paid spokesman, somebody that could help them sell Risperdal Right?
MR. PECK: Objection to form, foundation
MR. SPIVACK: And calls for speculation
BY MR TRAMMELL:
Q Do you know?
A No I consider my role as a scientist, and the intersect between my science and my research and the business partner is that it should be something for them as well But it's predicated on the idea that the science is the primary concern as far as I was concerned
Q What is your reaction to seeing reference to you on a sales and marketing planning document?
A I had no idea that I was in this document

Q Do you have any reaction other than that?
A. I am not a marketing, I never did any marketing; I produce data.
Q. Does it bother you that one of their motivations was to exploit your work for sales purposes?
MR. SPIVACK: Objection.
MR. PECK: Objection, foundation.
MR SPIVACK: And assumes facts not in evidence
A. I do not know what their intention is, but I know my work My work never had any advertising in it. The vast majority of my work had to do with the disease, not with the treatment There are many more papers on risperidone than my papers.
Q. Well, and you weren't the only KOL, were you?
A. No.
Q. And so whatever your intentions were, you had no idea or did you know that one of your purposes to Janssen was to facilitate sales and marketing efforts?
MR. PECK: Objection, foundation.
A. I saw an intersect between a commercial entity like J&J and the science that we produced

that at the end, if the illness is a serious illness, if the treatments that they have available are safe and effective, then they could benefit from their product, not before.
Q. So just so we understand what everybody was getting out of the deal, you got to do research on the population that you studied and you got to research possible therapies. Janssen, if your research turned out to support the use of Risperdal in the diseases you studied, would make more money?
A. My research through the J&J Center was not associated with therapeutics, it was on the disease. If the disease is a serious illness, it should be treated. And if their treatment, in this case for Janssen's risperidone, is safe and effective, it's predicated on that --
Q. Of course.
A -- then they would make money.
Q. Of course, Joseph Biederman also does studies that are funded by Janssen, or did studies. Right?
A. Yes.
Q So aside from your activities at the center, you were doing Janssen-funded studies?
A. I did a study of risperidone.

Q. Right. You did several and what you got out of those studies is you got the opportunity to study the use of Risperdal in diseases you were curious about or were the subject of your practice. What Janssen got out of it is the ability to expand the use of Risperdal and make more money because of your findings. Right?
MR. SPIVACK: Objection, calls for speculation, misstates the witness's testimony.
MR. PECK: Objection, foundation
A. My studies were designed to clarify the effectiveness and tolerability of the drug They were not designed to market anything. It's to see if the drug has efficacy in the diseases of interest, in this case bipolar illness, and it was safe and tolerable
Q. That's what you intended. But based on this document, it's clear that Janssen intended to use your research to increase Risperdal sales. Right?
MR. SPIVACK: Objection, calls for speculation.
MR. PECK: Objection, argumentative
BY MR. TRAMMELL:
Q You can't tell? You just don't know?

A. I don't know.
Q. Did you ever have any meetings with Janssen marketing people?
A. I met with marketing people on occasion.
Q. At Janssen?
A. The meetings that we have twice a year, one of those meetings occurred at Janssen and I'm not sure exactly. There are people from Janssen and people from McNeil in which we produced a kind of report of what has transpired with the center in the previous year.
Q. So y'all would have a meeting about the center twice a year with Janssen, you and people from the center and people from Janssen?
A. Yes
Q. And among those people that would be at the meeting on Janssen's behalf were the marketing people. Right?
A. I am not sure who was there, but there were people from Janssen and McNeil
Q. Did you ever say why are the marketing people here?
A I think that they have the choice of bringing whoever they see fit.
Q. Well, did you think it was odd that the

marketing people were at your meeting about the research and science?
MR. PECK: Objection, foundation.
A. I am not sure that I knew their positions in the company.
Q. Did you or did you not know that they were not scientists, they were from the marketing department?
A. My primary relationship with Janssen and McNeil were the scientists, not other executives
Q. I understand. And I'll object as nonresponsive. Despite the fact that your primary relationship was with the medical affairs people and the science people, at some of these meetings there were marketing people present Right?
A. Right.
Q. Did you ever wonder why they were there?
A I did not ask why they were there
Q. Did it occur to you at that time, well, wait a minute, they're just getting me to do this research so they can sell more Risperdal?
A. I always assume that there is an intersect. I saw it as a win-win situation between me advancing science and the commercial entity having some benefit They are not a philanthropical

organization
Q. I wish I could have said it that well. That's exactly my point You understood that what Janssen was getting out of it was advancing their commercial interest in selling more Risperdal Right?
A. The way that I understood it is like I would understand a venture capitalist that is investing in a venture. The success of the venture is predicated on several components and forces that are unforeseen So the process of expanding or using or whatever words you choose to use is predicated on the understanding of the disease and establishing that the treatment is safe and effective. Those conditions have to be met for risperidone to be more widely used.
Q. So they were making an investment in the center and in you in the hopes that research would come out of the center that would expand the use of Risperdal and pay off for them in the form of more Risperdal sales and more money Right?
MR PECK: Object to form.
A. I always thought that my interest was to advance science and their interest, if they have an effective and safe compound to treat a serious

illness, could intersect.
Q. Well, their interest was in selling more drugs. Right?
MR. SPIVACK: Objection, calls for speculation.
MR. PECK: Objection.
A. Their interest in selling more drugs is predicated on the idea that the disease is a serious disease and the drug is safe and effective. Those things have to be met for the drug to be better used.
Q Right. And so if your research proved that the disease was a serious disease and that Risperdal was effective to treat it, they could make more money. Right?
A. They have still to do the critical trial that they did, the randomized FDA type of registration study to show safety and efficacy. Only then the medicine will be considered safe and effective.
Q. And I think you said this earlier; I just want to make sure. You're not naive enough to testify that Janssen was funding your research because it didn't care about making money Right?
A No I never said that. I thought it was

an intersect between science and a commercial entity. In fact, they were funding activities that were not directly related to their commercial interest.

Q. Let me ask you this: How many studies did Janssen pay you to do on Risperdal?

MR SPIVACK: Objection, form, argumentative.

A. To my recollection, we did two studies One was an open label study of risperidone and we did an imaging study using a technology that is called spectroscopy that is based on MRI to examine the effect of risperidone on the brain.

Q How many papers have you written since you began your consulting relationship with Janssen about Risperdal?

A I have written papers before any consulting relationship with Janssen. I believe that I have written somewhere like nine papers of the fifty or sixty that have been written on risperidone in children

Q. So nine papers plus the two studies that you did?

A No, that includes the studies.

Q Okay, includes the results of those

studies?

A. (Witness nodded.)

Q. In any of those nine papers, did you determine that Risperdal wasn't safe or effective to treat the disease you were studying?

A. In the papers I described what I saw. I reported in detail what were the rate of response and I detailed all the side effects that we noted

Q. In all of those studies Risperdal was effective at treating whatever you were studying. Right?

A. Was effective in about 60 to 70 percent of the children that received treatment with risperidone

Q In any study where you compared Risperdal to another drug, Risperdal was more effective Right?

A No Abilify was more effective than risperidone

Q. When was that? When did that paper come out?

A. I think 2007 or --

Q. After the center closed?

A The center closed in 2005 Abilify came around that time, so I think it's an issue. I

cannot study medicines that are not available to me, so I tried to study each of the atypical neuroleptics as they came to market.

Q. And in 2007 when you wrote the paper where Abilify beat Risperdal, did you have a consulting relationship with Bristol-Myers Squibb, who makes Abilify?

A I had funding, relatively modest funding from Bristol-Myers Squibb Parenthetically I not only studied the atypical neuroleptics, I studied carbamazine as well.

Q. So in the study Bristol-Myers Squibb funded, their drug beat Risperdal Right?

A It was not a head-to-head comparison Using the same protocol that we used to treat children with risperidone, we noted that the rate of response was about 80 or 90 percent compared with 60 to 70 percent We did not do a head-to-head comparison.

Q. But the rate of response for Abilify was higher than for Risperdal. Right?

A. Yes

Q And that was a study that was funded by Abilify's manufacturer. Right?

A. Correct.

Q. Have you ever done a study where the sponsor's drug wasn't better?

A Many. We did a study for one of the companies of Johnson & Johnson examining galantamine that is a cholinergic drug showing that it has no efficacy in ADHD We did two studies on Depakote also by Abbott that showed it had very limited applicability in pediatric bipolar illness We did a study with carbamazine funded by Shire showing it has very modest effect, an effect the response was about 30 percent. The response of Zyprexa, for example, was much more modest, and funded by Lilly, was much more modest than the response to risperidone and Abilify.

Q Were these studies all published?

A Yes

Q Did you ever do a Risperdal study that was funded by Janssen that was not positive for Risperdal?

A. I did only one study on risperidone I did a study that was funded by Janssen. I did another study in preschoolers that was funded by the Stanley Foundation in children four to six that we compared risperidone and Zyprexa The studies that we did, say, with Geodon showed modest -- funded by

Pfizer -- showed modest effects
So the fact that we received funding does not mean that the results are positive And I would like to state for the record that our modest results with open label technology were fully replicated ten years later with a randomized clinical trial that is the gold standard of the industry.
MR TRAMMELL: I'll object as nonresponsive.
BY MR. TRAMMELL:
Q That's Exhibit 14 in front of you Have you ever seen that document before?
A Not that I know.
Q Have you ever seen 13 before, the sales and marketing document?
A No
Q. 14 is a set of slides It says on the front page New Initiative, exclamation point, J&J Pediatric Research Center at Mass. General Hospital, authored by Gahan J. Pandina, Ph.D., who works at Janssen Right?
A. (Witness nodded)
Q. Go to the second page, please.
A Second?
Q. Yes, sir, Pharmacologic Treatment of

Children and Adolescents. It says "Pharmacologic treatment of children and adolescent psychiatric disorders is widespread" and it says "Most use is off-label with limited data to guide treatment." Do you see that?
A. Yes
Q. At the bottom bullet point says "Strong needs for expert collaboration to inform pediatric initiatives " Do you see that?
A Yes.
Q. And when they say expert collaboration, they're talking about you and the center Right?
MR SPIVACK: Objection, calls for speculation, no foundation
BY MR. TRAMMELL:
Q. Well, it's in the document entitled J&J Pediatric Research Center at Mass General.
MR. SPIVACK: Same objection.
A. This is a general statement, not only with me. I am not the only pediatric psychiatrist interested in pediatric bipolar illness and psychopharmacology
Q One of the reasons they collaborated with you was to inform their pediatric marketing campaign. Right?

MR SPIVACK: Objection, calls for speculation, no foundation.
A. I think a serious responsible pharmaceutical company that knows that their drug is used off-label without any knowledge should support the expansion of the knowledge base about what to treat, who to treat, and how safe and effective is the treatment
Q. What should they do?
A. They should do studies to --
Q. Clinical trials?
A They should examine the disease as they were doing with me and they should conduct clinical trials as they did.
Q The moment they knew it was used widely in kids, they should have conducted clinical trials. Right?
MR. SPIVACK: Objection, misstates the testimony.
A. Risperidone was used very widely without clear boundaries for indications So the absence of knowledge is at the heart of my discussions with Janssen. I argue that the responsible pharmaceutical company has the ethical, moral, scientific responsibility to understand the diseases

for which doctors are using their drugs. So knowledge about the disease and about the safety and efficacy of the treatment is very critical.
Q. And it's important when they study the drug to tell doctors the truth about what they find. Right?
A Studies are descriptive and objective. This is what was done, this is what the results were. They are not philosophical data papers Things that I wrote are descriptive and factual
Q. When you say they're not philosophical, are you trying to say there's no objective truth?
A. We can have this discussion --
MR. PECK: Object to form.
A. -- at another time in another place
Q Well, what this means, "Strong need for expert collaboration to inform pediatric initiatives," what that means is they needed the credibility of someone like you who writes high-impact papers and who, according to you, is a leader in diagnosing and treating bipolar disorder to help them get the word out about this off-label use. Right?
MR. PECK: Objection to form, foundation
MR. SPIVACK: Objection, argumentative,

calls for speculation.
BY MR. TRAMMELL:
Q. Isn't that how you understand that?
A. I don't understand it the way you understand it It's your interpretation of a sentence. My understanding is that they need more information, that the fact that the drug is used is not enough; that they need to know more about when to use it, how to use it, and how safe and effective it is
Q Well, whether or not you and I understand it, we're going to see how Janssen understood it here in a second But if you go to the next page, Risperidone Treatment in Children and Adolescents, "Risperdal is widely used to treat psychiatric disorders in children and adolescents" and "Children and adolescents approximate 21 percent of the Risperdal market " Do you see that?
A Yes
Q. Did you know the number was that high?
A No.
MR. SPIVACK: Objection, calls for speculation, no foundation.
BY MR. TRAMMELL:
Q Did anybody at Janssen ever say "21

percent of our market is kids" to you?
A Not specifically I knew that it was widely used.
Q. But you didn't know it was that high?
A. I did not know it was 21 or 22 or 18 percent.
Q. Certainly because it's that high, it increases the need for a responsible pharmaceutical company to fully understand the possible efficacy and the possible risks associated with treatment of that population Right?
A. Correct
Q. The fourth bullet point says "Treatment with Risperdal in this population continues despite lack of well-controlled clinical research. Limited available data results in potential for medical misuse " Do you see that?
A. Yes.
Q. I think this is more of what you were talking about. The reason you have to get the true information out there about a condition for which your drug is widely used is to prevent misuse Right?
A. In the absence of information, there is danger of inappropriate use. So the fact that this

is the reality on the ground, that clinicians are using this medication widely, is a strong impetus for a responsible pharmaceutical company to understand the enemy a little bit better. The enemy: the disease.
Q. Is the impression that you've gotten so far from this document that Dr Pandina is saying the drug is widely used in this population but its use is poorly understood? Is that the impression you've gotten so far?
A The way that I read this document is that he's saying that there is very important need to do more research on the subject.
Q. Right, and collaborate with experts to fill the knowledge gap. Right?
A. Yes.
Q. Go to the next page, J&J Pediatric Research Center at MGH - Background. "Dr. Joseph Biederman is recognized as a global expert in the diagnosis and treatment of bipolar disorder and ADHD." Do you see that?
A. Yes
Q. Is that true?
A. Yes
Q. Do you agree with that?

A. I agree with that.
Q. You are a global expert, people around the world know that you are an expert in diagnosis and treatment of bipolar disorder and ADHD?
A. Yes.
Q. "Dr. Biederman has a large research team, with multiple collaborations at MGH, McLean Hospital, and Harvard University. This group was identified as one of the most important international scientific research centers by JPI " Did I read that right?
A. Yes, you read it correctly.
Q What is JPI?
A JPI I think is Johnson-something I don't know what JPI is.
Q. Okay. Nobody ever told you that you were identified by JPI as an important scientific research center Right?
A. No. I think that my read of this sentence means that because my center is one of the premier centers of research in childhood and adolescent psychology, that doing research in our center could be an important scientific work.
Q. And the point of this is to have the marketing people at Janssen collaborate with you on

creating information that doctors could rely on to prescribe more Risperdal and treat kids who otherwise wouldn't be diagnosed as bipolar. Right?
MR. PECK: Objection to form, foundation.
A. That's absolutely not my reading of this document. This document says that we have a scarcity of information on an important subject; that our medicine is widely used; that we need more research on where to use it, when to use it, for whom to use it, and how safe and effective it is. This is what I read here What you are telling me is a free interpretation of the same sentence.
Q. And maybe I'm wrong But it's got nothing to do with marketing. Right?
A. This is not a marketing statement.
Q. Okay, go to the next page. First bullet point, "With marketing, held initial discussions with MGH to discuss collaboration re specific extramural research with risperidone." Did I read that right?
A. Yes.
Q. Do you remember that meeting?
A. No.
Q. Does that refresh your recollection that the purpose of creating the center was to help

marketing Risperdal?
MR PECK: Objection, foundation.
A. The purpose of the center was to advance science in childhood psychopathology, to illuminate some of the conditions that clinicians are using risperidone for So I think that the issue of funding for marketing is not necessarily synonymous with marketing efforts
If you look at the second bullet, "reviewing specific scientific questions," what we wanted to do with the center was to advance knowledge.
Q. I understand And then if you keep reading that, it says "related to key business areas " Do you see that?
A My understanding, I'm not a corporate lawyer, but my understanding is that pediatric bipolar illness is a target for a company like Janssen to launch a clinical trial So the eventuality that they actually did the clinical trial many years later was the conclusion of research that was done before documenting that this is a serious illness, that risperidone may have a role to play; therefore they should conduct a randomized clinical trial, as they did, that led to

approval of the drug.
Q I understand.
A. So this is a marketing. If that happens, that will benefit Janssen
Q. Where does it say anything about clinical trials in this document? Have you seen that?
A. No, I do not see that, but that's what I understand from this document.
Q. It just says review scientific -- This is the bullet point you pointed out, "reviewing specific scientific questions related to key business areas." And I'm not a corporate lawyer either, but I understand what that means Are you saying that you don't?
A. That's not --
MR. SPIVACK: Asked and answered. He just testified as to his understanding
BY MR TRAMMELL:
Q. We don't interpret that the same way. Is that what you're saying?
MR PECK: Objection, argumentative.
BY MR. TRAMMELL:
Q Go to the second-to-last page, please. Go to the last bullet point.
A Which one? Sorry. I'm not sure.

Q I'm sorry. The second-to-last page of the document.
MR. SPIVACK: What's the Bates number?
MR TRAMMELL: It's 478
THE WITNESS: Yes.
BY MR. TRAMMELL:
Q. The last bullet point says "Coordinate data and messaging related to compounds from sister companies " What role did you play in messaging for Janssen drugs and what role did Janssen play in shaping the message of your papers?
MR. PECK: Objection, form, foundation.
A. My papers were written by me The content was my content; it was descriptive and factual.
Q. That's what I meant to ask you You actually wrote your papers?
A I wrote all my papers, yes.
Q. None of your papers were written by third-party contract research organizations?
A. No.
Q. None of your papers were written by people at Janssen?
A In the bipolar risperidone arena, no.
Q. The last page, Company Partners & Key Contributors, the first one is, well, under "Janssen

key contributors" the first one is Kent Bockes. Do you know who Mr. Bockes is?
A. No.
Q. Do you know what his job was at this time?
A No.
Q. Would it surprise you that he was the national sales director for Risperdal?
A. I don't know who he is
Q Well, at any rate, he's a key contributor in the formation of your center and he's the national sales director. Does that surprise you?
MR. PECK: Objection, form, foundation
A. I do not know how Janssen planned to fund my center I know what the center proposed to do.
Q. Does this help illuminate for you that Janssen's purpose in creating and funding your center was to help it sell more Risperdal?
MR. SPIVACK: Objection, calls for speculation
MR. PECK: Objection, form and foundation
A It illuminates only that different pharmaceutical companies use different pots of money to fund certain activities.
Q. This is Biederman 15. And, again, you've never seen that slide set before, have you?

A. No.
Q. Kind of makes me feel like I chose the wrong document. This is an e-mail from Gahan Pandina, March 22, 2002, to several people within Janssen; the subject is "Feedback regarding MGH pediatric seminar." And an MGH pediatric seminar would have been a pediatric seminar for doctors that you held at MGH. Right?
A. This is a postgraduate course that we run every other year.
Q And the audience is doctors. Right?
A. Not only doctors There are social workers and educators in attendance as well.
Q. But they are people who might use Risperdal in the course of their practice?
A. Yes.
Q. It says "Christine, Ramy and Carmen: Georges and I wanted to share some information as a follow-up to the meeting with Dr. Biederman This feedback came from an attendee of the large three-day educational seminar, over 1,000 physicians, $700 CME course, in child psychopharmacology and pediatric bipolar disorder that Dr. Biederman and his group conducted. This meeting began the day" -- First of all, did I read that first sentence right,

or these first two sentences right? Did I read them right?
A. Yes
Q Correctly?
A. The only incorrect statement here is that the postgraduate course was on child psychopharmacology. One of dozens of talks was on pediatric bipolar disorder.
Q So Gahan is wrong but I read it right?
MR. PECK: Objection
A You read it right, yes.
Q. You did a lot of these seminars. Right?
A. No. This seminar on pediatric psychopharmacology is given as a three-day postgraduate course and that is by subscription People pay fees to attend; it's not funded by anybody.
Q. But this isn't the only one you ever spoke at?
A. No, no, no. This talk on pediatric bipolar illness was not my talk, it was Dr. Wozniak's talk that he's alluding to. The course is given every other year, our postgraduate course.
Q. Well, well, maybe Dr. Pandina is mistaken

It says "This meeting began the day immediately after our meeting with him," meaning you, Dr. Biederman, "at Janssen last week. Dr Biederman was very well-received by the group. The validity of his diagnosis of pediatric mania was completely accepted and his diagnostic techniques deemed to be excellent. He was very balanced in his approaches to treatment and not perceived to be aligned with any company in particular. Evidently, he made quite a point regarding the metabolic issues related to olanzapine, to the extent of stating that this drug should not be used in the treatment of children and adolescents, highlighting the issues with published data." Did I read that correctly?
A. The reading is correct. One more time I want to emphasize that the talk on pediatric mania was given by Dr Wozniak and not by me as one of thirty talks that we deliver over a long weekend.
Q. But she was talking about your or your and her work on diagnosing pediatric mania. Right?
A. Correct.
Q. But they're attributing the diagnostic techniques to you Is that inappropriate?
A. No, because I am the more senior -- I am the director of the course and my work on pediatric

mania is well-known. But this particular talk, we're talking about our joint work.
Q. And they point out that you're not perceived to be aligned with any company in particular. Either that's because you work with almost every company or that they think it's an advantage that doctors don't see you as a salesman, they see you as Dr Biederman, the best pediatric psychiatrist in the world. Right?
MR. SPIVACK: Objection, foundation, calls for speculation
A. I am not aligned with any pharmaceutical company When I describe treatments, I describe all treatments as the data show
Q. And that perceived objectivity is what makes you so credible. Right?
A. It's not a perceived objectivity; it is an objectivity When I talk on the subject, the slide that you showed, I talk about all treatments available, not just one
Q. In talking about all the treatments, you made sure to make a point the day after your meeting with Janssen talking about Risperdal how their chief competitor, olanzapine, should not be used in the population you were hired by Janssen to promote for.

Right?
A I was never hired --
MR. PECK: Objection to form
MR. SPIVACK: Objection, calls for speculation, misstates the testimony, argumentative.
A. I was never hired by Janssen to promote risperidone. That's absolutely not true. The meeting, we met with them twice a year The meeting happened by chance to have been in the week preceding our course, not by design.
Q So it's a complete coincidence that the day after you meet with Janssen, you were telling a thousand doctors to not use their chief competitor in the population that you're studying for Risperdal?
MR. PECK: Objection, form.
MR. SPIVACK: Objection, argumentative.
BY MR TRAMMELL:
Q. Is that a coincidence, Doctor?
MR. SPIVACK: Objection, argumentative.
A. We met with Janssen on a regular basis throughout the duration of the J&J Center at times that were convenient to them and us, yes, not related to our course. Second, I did not remember that we made any strong recommendations. What we

may have done, what Dr Wozniak may have described is what I said before: that the weight gain associated with olanzapine was twice as large as the weight associated with risperidone. But we included in that information the fact that risperidone still produced a substantial weight gain of 2-1/2 kilos over eight weeks That is not minor. So we never said use or do not use that. This is the interpretation of the writer, not my interpretation I never said to use or not to use this or that drug
Q. I understand that Risperdal also causes dangerous weight gain in kids. But are you saying that when they say "Evidently he made quite a point regarding the metabolic issues related to olanzapine," that they are confusing you for Dr. Wozniak?
MR PECK: Object to the form and the foundation and the editorializing.
A. I am not responsible for an internal e-mail and interpretation of the writer. I can only tell you that we never say do or do not do We describe -- I do not know, because I may not have been in the room when Dr Wozniak delivered the talk. The only information that we deliver for clinicians to consider is the weight gain in the

same type of study that we did for each of the neuroleptics and anticonvulsants that we tested. Each one of those, we measure weight So we said olanzapine produced a 5-kilo weight gain, risperidone produced a 2-1/2-kilo weight over eight weeks. This is what we said The conclusions of what to do in your risk/benefit analysis is in the hands of the practitioners, not that we proscribe the use of olanzapine because it was a competitor to Janssen.
Q. And this was at the outset of your activities with Janssen and the center Right? This was at the beginning?
A. I believe that the center may not have been even operational at that time because we started in early 2002. We assembled the personnel, we thought about our projects, et cetera, et cetera. So at that time we did not have anything going.
Q. Had they paid you the 500,000 by this point?
A They paid an advancement. I think the 500,000 was for the year, not necessarily at the outset. I do not know when the money came, but we were planning to do the activities. We had a budget, we had a proposal, we had activities that we

were planning to do But March is very early 2002 when we started
Q Can you say with any certainty whether they paid you the 500,000 the day before you gave the talk telling doctors not to use their biggest competitor?
A I did not tell doctors not to use their biggest competitor and I do not remember any exchange of moneys in the meeting with Janssen The moneys came to Mass General, not to me This is not personal money And the moneys may have come, I do not remember when the moneys arrived, the day they arrived, and I do not know what amount arrived first either
Q. Well, the money came to Mass General to pay for the concept that was the center from which you drew a salary. Right?
A I drew a small salary as the director of the center, yes
Q And how small was that salary?
A The salary was about 5 or 7 thousand dollars a year
Q And is that an insignificant amount of money to you?
A It's 5 or 7 thousand dollars a year.

Q. Is that an insignificant amount of money to you?
A. No. It's a small amount relative to half a million budget and directing multiple scientific activities
Q. Well, the next paragraph says "I think this is a clear example of the utility of partnering with a group such as MGH, who has the potential of reaching and having a significant impact on the field of child and adolescent psychiatry with these types of professional activities in non-sponsored venues " Did I read that correctly?
A. You are a very good reader.
Q. Okay, thank you.
And so my understanding of this, and you tell me how you interpret it, but my understanding is what they're saying is using Dr Biederman and his group who have this perceived objectivity will help us convince doctors who treat kids to use Risperdal and the benefit is enhanced because he speaks at so many of these venues that aren't sponsored by us.
MR. PECK: Objection to form, foundation.
BY MR. TRAMMELL:
Q Is that how you interpret that?

A. No.
Q Okay. I'm curious to hear how you could possibly interpret it any other way.
MR. PECK: Objection to the editorializing
MR SPIVACK: Objection, argumentative.
BY MR. TRAMMELL:
Q Please tell me how you interpret it.
A. My interpretation is that we are a premier clinical and scientific group. Our reputation is not via propaganda Our reputation is because of the quality of our work. Talking about risperidone in this context was one of dozens of talks that we delivered over the weekend The audiences asked, we talked about ADHD, obsessive/compulsive disorder, anxiety disorders. So among thousands of slides that we showed, maybe two slides of risperidone.
So the comment is to consider us as a premier organization. And, again, they're a commercial entity, so being associated with a premier research and clinical center like ours is a good thing
Q. Right, it's a good thing Because you're not known as a propagandist and because people don't see you as aligned with any pharmaceutical company,

your Risperdal pitch will be that much more credible when you deliver it to doctors who treat the patients in the market they are trying to target Right?
MR PECK: Objection, foundation.
MR SPIVACK: Objection, argumentative, calls for speculation
BY MR. TRAMMELL:
Q. Isn't that right?
A. No
Q Well, I think the document speaks for itself.
MR. PECK: Objection, argumentative.
BY MR. TRAMMELL:
Q. Now, you also said one of the things you do for Janssen is participate in advisory boards. Right?
A. Yes.
Q. What happens at an advisory board meeting?
A The advisory boards in general are designed to address a particular question, most often has to do with either the design of a planned clinical trial or the interpretation of findings from a clinical trial.
Q. Do people from the marketing departments

attend these advisory boards?
A I guess that they do
Q Why?
A I don't know why
Q Is it so that they can use whatever information you give them to help them sell Risperdal better?
MR SPIVACK: Objection, argumentative, asked and answered, calls for speculation
BY MR TRAMMELL:
Q If you don't know, you don't know
A I do not know
Q Okay
Now, we talked earlier about whether mania in children presents different from adults and you said it doesn't Right?
A I did not say that
Q Okay Can you clarify that for me?
A I said that the items are the same We use the same criteria as we use in adults, but we have developmental understanding of how the symptom can manifest itself in children I gave you the example of buying with credit cards Since children don't have credit cards, they cannot go on buying binges

Q. What's the earliest that bipolar disorder can present in a person?
A. Some parents describe their children as never having been well from infancy. Not that this means we diagnose it in infants. But when asked a question when things started, they say they were never well
Q You would never suggest to a doctor that they could diagnose bipolar disorder in an infant, would you?
A. No
Q. And it's impossible because you can't tell whether it's onset as an infant. Right?
MR PECK: Objection.
A. No, I did not say that. I said that the description that parents provide us is that a child was dysregulated affectively since birth, cried all the time, was difficult to soothe, was a horrendous toddler, had massive temper tantrums, et cetera, et cetera
Q I just want to make this really clear for the jury. Dr Biederman, as the global authority, according to you, on diagnosing bipolar disorder, can you diagnose bipolar disorder in an infant?
A. You probably would have a lot of

difficulties making the diagnosis in an infant. What I was alluding to was the fact that many of these children, as many as 30 percent in our studies, the parents describe the onset of affective symptoms at the beginning of life
Q. Under the right circumstances do you think you could diagnose bipolar disorder in an infant?
A I don't do infant psychiatry. The children that come to my office usually come around age of four, not earlier than that.
MR. TRAMMELL: Objection, nonresponsive.
BY MR. TRAMMELL:
Q. Under the right circumstances, if the right infant was brought to you to treat, do you think you could diagnose an infant with bipolar disorder?
MR. SPIVACK: Objection, asked and answered.
MR. TRAMMELL: He hasn't answered it.
MR. SPIVACK: He has. You may not like the answer, but he has answered it.
MR. TRAMMELL: Well, no, he's told me about his practice.
BY MR. TRAMMELL:
Q Do you think you could diagnose an infant

under the right circumstances that was brought to you as bipolar?
MR. SPIVACK: Same objection.
A. I don't think so.
Q You can't do it?
A It's not that I cannot do it There are several obstacles. One is that children don't have -- Infants don't have a large repertoire of symptoms They cannot run around, they cannot express their emotions. They can cry So I think that it would be very difficult to make a diagnosis in the absence of some of the descriptions that you went through with me before
The other component is that usually infants with dysregulated mood and difficulties go to a subspecialty within child psychiatry that is called infant psychiatry, so they will not have access to clinicians like myself that tend to see children a little bit older than infants
Q. If those obstacles were alleviated, could you diagnose bipolar disorder in an infant?
A. With the armamentarium of today, without additional information, it would be very difficult to make a diagnosis in an infant
Q. What additional information would you

need?
A. Well, if there are biomarkers, for example. If our imaging technology or our genetic technology will alert us to a particular mutation that aggregates in children with bipolar illness, so a child that is expressing very abnormal behaviors in infancy with that mutation, the suspicion would be higher.
Q. So if you were able to use the techniques you just mentioned, could you diagnose an infant with bipolar disorder?
A. Again, it's a totally speculative. What I am telling you, when the imaging technology, biomarkers, genetic research will be advanced, the field will be able to make younger and younger diagnosis You will be able to know that you are going to end up demented when you are an infant We can say today that Huntington's disease is going to affect you when you are 50 at birth
Q I should have asked you this first Is it possible to diagnose an infant with bipolar disorder?
A. Today we have -- No, we don't have adequate tools to make the diagnosis in an infant.
Q And so it is impossible to determine

whether bipolar disorder has onset in an infant. Right?
A. What we are determining is that the onset of symptoms, not of the diagnosis, were early enough. Not the diagnosis per se but the symptoms. The parents were not able to tell us that the child has ever been mood-well
Q. Does the condition onset in infancy?
A. The condition can onset in infancy
Q. It can?
A. Yes
Q. Can the condition onset in utero?
A. It could
Q. So it's possible that people, that babies still in the womb could be diagnosed with bipolar disorder. Right?
A. I cannot do that today Nobody is suggesting that I'm not sure what is your purpose. But, for example, descriptions of children with ADHD, there's a very famous paper published in Science by a researcher by the name of Gabrielle Weiss from Canada She described that mothers of ADHD children described very hyperactive fetuses in utero. So the children were kicking all the time, they're moving all the time, things of that

type.
That does not mean that we make a diagnosis in utero But those are historical accounts to stress the point that some of these conditions emerge at the beginning of life; and of course people have life before they are born, as you know.
Q. Does bipolar disorder onset in utero?
A. I do not know.
Q You don't know?
A. No.
Q. Can you think of any reason that you would have discussed the onset of bipolar disorder in utero with Janssen marketing people?
A No
Q. Were you ever a part of any effort to promote Risperdal for mothers with bipolar children in utero?
MR PECK: Objection, form and foundation.
A. No
Q Would such an effort be appropriate?
A I never participate in anything like that.

Q. I'm sorry Do you know whether you were paid to be at the meeting?
A Most likely, yes
Q. And they would have paid for your hotel at the Plaza, your hotel room?
A. Yes.
Q. Paid for your plane ticket?
A. Yes.

A. I don't know where you are reading.
Q The last paragraph.
A The last paragraph on the page?

A. Just a second I want to make sure that I know where you are reading. Will you show me?
Q. Right there
A. Okay

MR TRAMMELL: I'm done for the day. Thank you, Doctor.
THE VIDEOGRAPHER: This is the end of tape number 5 and the deposition for today. The time is 5:06 We're off the record.

MR. PECK: No, we're on the record
MR. SPIVACK: Yes. Before we go off the record, what time are we starting tomorrow?
MR. FIBICH: 9:00.
MR. SPIVACK: And who is questioning tomorrow?
MR FIBICH: I am.
MR. SPIVACK: And who do you represent?
MR. FIBICH: Avila
MR. SPIVACK: The same party as Mr. Trammell?
MR TRAMMELL: No
MS LaMACCHIA: Mr Fibich has been pro hac'd in and paid his fees in the In re Risperdal/ Seroquel/Zyprexa.
MR PECK: Mr. Trammell was pro hac'd in to do depositions in the Avila case and corporate representatives of Janssen That's what he was pro hac'd in for That's what you asked my consent for and that's what I consented to
MS LaMACCHIA: The fact that Mr. Trammell was pro hac'd in to the Mabel Adams matter in In re Risperdal/Seroquel/Zyprexa means that he is entitled to take a deposition of a corporate or a nonparty witness

MR PECK: No. You asked my consent, which I gave to Mr. Trammell, to be pro hac'd in in the Avila case, which he is here questioning the witness, and for Janssen corporate rep depositions.
MR. TRAMMELL: I don't understand your point
MR PECK: Well, you may not understand the point, but she does
MR. FIBICH: Let me ask you this. Do we have an order? Do we have the pro hac order? Wouldn't that define what his right is?
MR PECK: Ask your counsel. Ask your sponsor.
MR FIBICH: No, I'm asking you with respect to Mr Trammell There is an order entered by the Court allowing him to appear since he's not licensed in your state. Wouldn't that order limit, if it was intended to limit, his participation as you want to limit it?
MR. PECK: The limitation was not placed by me, Mr Fibich; it was placed by Ms. LaMacchia.
MR. FIBICH: Well, what I'm suggesting to you is that if it's not in the order, then you don't have a limitation.
MR. PECK: Well, I don't have what's in

the order because I don't have it before me I consented to her request, which was the admission of Mr. Trammell to the Avila case and to --
MR. FIBICH: Are you objecting to him asking questions?
MR. PECK: Let me finish, please.
MR FIBICH: Please.
MR. PECK: And to depose Janssen corporate witnesses, whose depositions have been ongoing for the last couple months. That's what I consented to. I also consented to your admission in the Avila case for whatever the purpose was.
Since both of you are here on the Avila case and both sponsored by Ms. LaMacchia of Bailey Perrin, it seems to me that only one of you can question the witness and make objections. It is as if I being here on behalf of Drinker Biddle and Johnson & Johnson cross-examined Dr. Biederman and then my partner, Mr Essig, decided that he too had questions for Dr. Biederman and Ms Kole had questions for Dr. Biederman. That's not appropriate, nor permitted
MR. FIBICH: So that I understand you, you're objecting to me asking questions tomorrow, right?

MR. PECK: Counsel for Dr. Biederman has raised the point and he's raised a valid point Mr. Trammell I have no objection to asking questions because he is here representing the Avila plaintiffs sponsored by Bailey Perrin; he can continue the questions

MR. FIBICH: My question to you is --

MR. PECK: But I would have an objection to you and to Ms LaMacchia, for example, because she's from Bailey Perrin.

MR. FIBICH: I'm not asking you for your reasons. I'm asking you, do you object to me asking questions tomorrow?

MR. PECK: I object to you asking questions for the same reason you objected to the fact that --

MR. FIBICH: No, no, I'm not asking for your reason; I'm just trying to understand what you're saying

Mr. Spivack, are you going to object to me asking questions tomorrow?

MR. SPIVACK: I am if the pro hac motion, the order is limited to Avila I mean, the way I understand it --

MR. FIBICH: No, let me just first

understand what your position is Your position --

MR SPIVACK: Well, I'm telling you my position

MR FIBICH: Do you object? That's all I want to know

MR. SPIVACK: Well, it may be all you want to know, but let me go ahead and tell you why I'm objecting

MR FIBICH: Tell you what Let me take a short break, unless you object, and then we can come back on the record

MR SPIVACK: No, I don't object if you think it might help us settle this

MR FIBICH: Well, it might/it might not. Let's take a short break

MR. PECK: Before we take a short break, because you're going to want to talk about this, a reminder to all present that you are bound by the stipulated protective order that was entered in the New Jersey litigation and the Foti litigation, anybody here that's involved in other litigations, in the sense that you cannot disseminate Janssen documents that were produced during discovery in New Jersey.

I noticed that a number of the exhibits

have Janssen Bates numbers on them. A few of the documents were declassified; most of them were not And those documents which were not declassified are subject to the protection of the protective order.

If anybody disagrees, please state it on the record

MR. SMITH: No, we agree subject to the challenges we have made to your method of --

MR PECK: But that's not been resolved yet, Ken That's not been resolved Right now that order is in effect.

MR. SMITH: I'm just saying yes, subject to that.

MR TRAMMELL: We certainly agree to abide by the orders.

MR PECK: Okay. Mr. Fibich?

MR FIBICH: What?

MR. SMITH: He's asking if you're going to abide by the court order.

MR. FIBICH: Yeah, I'm going to probably do so, because typically it's generally my practice to abide by court orders and by the confidentiality agreements I sign

MR PECK: That's good to hear.

MR. FIBICH: If you ever hear that I've

not done that, tell me

MR. PECK: Ms LaMacchia, do you degree?

MS. LaMACCHIA: I have always agreed.

MR. PECK: Ms. Ho?

MR. FIBICH: Do you agree to not disseminate these documents as your co-counsel agreed? Are you going to obey court orders? I can be just as insulting as you can.

MR. PECK: I don't think so

MR. FIBICH: Oh, I do, trust me, and we can get into that anytime Keep talking.

MR. SPIVACK: Before we leave, can we let Dr. Biederman go or do you want him here?

MR. FIBICH: No, I don't.

MR. SPIVACK: Okay Thank you.

THE VIDEOGRAPHER: The time is 5:12. We're off the record.

(Short recess taken)

THE VIDEOGRAPHER: We're back on the record. Time is 5:17. This is the end of tape number 5 and the deposition for day number 1. Going off the record now, it's 5:17.

(Short recess taken.)

(Deposition recessed at 5:24 p m. to the following day at 9:00 a m.)

COURT REPORTER'S CERTIFICATE

I, J Edward Varallo, RMR, CRR, Registered Professional Reporter and Notary Public in the Commonwealth of Massachusetts (my commission expires 12/24/2015), hereby certify that the deposition of Joseph Biederman, M D taken on February 26, 2009, in the matter of In re: Risperdal/Seroquel/Zyprexa Litigation, Case Code 274; Alma Avila, as next friend of Amber N Avila, an individual case v Johnson & Johnson Company, Janssen Pharmaceutical Products, L P , et al was recorded by me stenographically and transcribed; that before being sworn by me, the deponent provided satisfactory evidence of identification as required by Executive Order 455 (03-13) of the Governor

I certify that the deposition transcript produced by me is true and accurate to the best of my ability.

I certify further that I am not counsel, attorney, or relative of any party litigant, and have no interest, financial or otherwise, in the outcome of this suit

DATED: 3/6/2009 J Edward Varallo

WITNESS: Joseph Biederman, M D [Volume 1]
DATE: February 26, 2009
IN RE: Risperdal/Seroquel/Zyprexa Litigation, Case Code 274; Alma Avila, as next friend of Amber N Avila, an individual case v Johnson & Johnson Company, Janssen Pharmaceutical Products, L P a/k/a Janssen, L P , et al

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