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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  
Pharmaceutica 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.  
Friday, February 27, 2009  
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1 Q. And the purpose of the scientific process  
2 is what?  
3 A. You are in a study, you are testing, you  
4 are addressing a question, you are testing a  
5 hypothesis. You subject the data to statistical  
6 analysis to examine whether the findings are chance  
7 or not likely to be chance, and you draw conclusions  
8 based on your findings.  
9 Q. It is a search for the greatest truth that  
10 can be obtained. Correct?  
11 A. It is a method to investigate.  
12 Q. And the method to investigate that you use  
13 requires that you be very precise. Correct?  
14 A. As precise as the field allows.  
15 Q. And you are a very precise individual, are  
16 you not?  
17 A. I am.  
18 Q. You are a very deliberate individual, are  
19 you not?  
20 A. I am not sure what you mean by that.  
21 Q. Well, what you do is a result of your  
22 intentional conduct?  
23 A. Well, what I do is I ask questions that I  
24 have about how to improve the life of the people  
25 under my care. So all my research is based on  
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1 trying to understand the diseases that the children  
2 that are under my care are afflicted and how to  
3 better approach them therapeutically, with medicines  
4 and with psychosocial treatments.  
5 Q. Now, you've already told us that you  
6 consider yourself a world-renowned scientist.  
7 Correct?  
8 A. It is not what I consider myself. It is  
9 what others consider myself.  
10 Q. So you're familiar with your reputation  
11 across the world. Correct?  
12 A. I am familiar with my reputation.  
13 Q. And your reputation is that you are a  
14 specialist in the field of bipolar disease in  
15 children?  
16 A. I am a specialist in pediatric  
17 psychopharmacology.  
18 Q. Which includes bipolar mania?  
19 A. It is one of many conditions that afflict  
20 children.  
21 Q. Well, I thought you indicated to me  
22 yesterday -- and correct me if I'm wrong -- that  
23 your two subspecialties within the field of  
24 psychopathology are bipolar mania and ADHD.  
25 A. I indicated that that's the predominance  
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1 of my scientific work, not the only work that I do  
2 or the only type of research that I do.  
3 Q. When the Grassley committee hearing or the  
4 Grassley investigation was initiated, you were the  
5 subject of newspaper comments, were you not?  
6 A. I was.  
7 Q. And I have today a copy of a page from The  
8 New York Times, November 25, 2008. Was that  
9 approximately when this issue came to the public's  
10 eye? Approximately.  
11 A. November 2008, I think The New York Times  
12 published e-mails that you released to the press  
13 from some attempt to quash the subpoena. This is  
14 what I think happened in the paper in 2008. There  
15 was an article, there are articles before that, but  
16 the 2008 I believe is related to e-mails that you  
17 released to the press.  
18 Q. You think I released something to the  
19 press?  
20 A. Obviously somebody released.  
21 Q. Well, you said "you" and you looked at me.  
22 Do you think I released it?  
23 A. I am using the "you" generically.  
24 Q. Okay. So the "you" could be anybody in  
25 the world. Right?  
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1 A. No, could be somebody related to this  
2 case.  
3 Q. Well, who?  
4 A. I don't know. It's not -- I have no  
5 access to that information.  
6 Q. Well, the purpose for this is that in this  
7 document, and I only have one copy but I will  
8 represent to you that I'm going to read it  
9 accurately, it says "Dr. Joseph Biederman, a  
10 world-renowned child psychiatrist." And that's how  
11 people see you, do they not?  
12 A. Yes.  
13 Q. Would you consider yourself the leading  
14 psychiatrist in the world for the treatment of  
15 bipolar mania or bipolar disease in children?  
16 A. One of the leaders.  
17 Q. One of the leaders?  
18 A. (Witness nodded.)  
19 Q. Are you a football fan?  
20 A. Fair-weather.  
21 Q. Fair-weather. We had a football coach in  
22 Texas named Bum Phillips. You ever hear of Bum  
23 Phillips?  
24 A. No.  
25 Q. His son Wade Phillips is actually the  
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1 opposite." That research is not forthcoming.  
2 So the people, the mostly vocal critics  
3 are people that have not done any critical body of  
4 research disputing the findings. They're only  
5 saying I don't like it, which in science is not the  
6 same. You're not having the same interlocutors by  
7 saying I don't like that. You can say it about a  
8 hamburger or a hotdog but not in science. In  
9 science in order for you to say that this is not  
10 true, you need to show equal amount of work that  
11 shows the opposite result, and that's the dispute.  
12 **Today pediatric bipolar illness is accepted by the**  
13 **practicing community**  
14 MR. FIBICH: Object to that as being  
15 nonresponsive.  
16 BY MR. FIBICH:  
17 Q. Do you disagree with this statement: The  
18 diagnosis of pediatric bipolar disease is  
19 controversial?  
20 A. I disagree. The controversy is about how  
21 to best define, what are the best ingredients.  
22 That's the controversy, not that a group of children  
23 that are very sick with high levels of morbidity and  
24 disability exist. That controversy is over. The  
25 controversy today is about how to best define it.  
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1 Q. Did you talk to The Washington Post?  
2 A. I don't remember who I talked to, but  
3 apparently I talked to this person.  
4 Q. The comments that are contained in the  
5 first two paragraphs are comments of yours and you  
6 were quoted accurately. Correct?  
7 A. This is not a quote, this is an  
8 interpretation of what I said.  
9 Q. Is it a correct interpretation of what you  
10 said?  
11 A. I said the same as I said to you. I did  
12 not compare myself to Galileo. I said that Earth  
13 was once flat. The reporter is not quoting me here.  
14 It is her interpretation. She could have said that  
15 I am comparing myself to God. This is her  
16 interpretation of what I said. I said that Earth  
17 was once flat. This is what I said.  
18 Q. Well, why didn't you compare yourself to  
19 God?  
20 A. Because I am not God. I am saying that  
21 the interpretation of my statement is her  
22 interpretation.  
23 Q. Is her interpretation of your statement an  
24 accurate statement?  
25 A. I said that Earth was once flat. I did  
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1 That's the controversy.  
2 MR. FIBICH: Mark this as the next  
3 exhibit. And we're skipping one but I'll come back  
4 to it.  
5 MR. BURNEY: So I'm sorry. The number on  
6 this is 19 or 20? You said the next exhibit but  
7 we're skipping one.  
8 MR. FIBICH: Hold on.  
9 THE WITNESS: This is 18.  
10 MR. FIBICH: This is going to be 20.  
11 MR. BURNEY: This is going to be 20?  
12 Okay.  
13 (Biederman Deposition Exhibit 20 marked  
14 for identification.)  
15 BY MR. FIBICH:  
16 Q. Let me show you what I've marked as  
17 Exhibit 20, Dr. Biederman.  
18 A. Mm-hmm.  
19 Q. And this is an article out of The  
20 Washington Post, February 2005 Do you see that?  
21 A. Mm-hmm.  
22 Q. And if you would turn to page 3 and under  
23 the heading Very Disturbed Children, read the  
24 comments that are attributed to you, sir.  
25 A. Mm-hmm.  
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1 not compare myself to Galileo.  
2 Q. Sir, I'm asking you, what she says is  
3 "Joseph Biederman, a professor of psychiatry at  
4 Harvard and one of the most forceful advocates of  
5 the aggressive treatment of preschoolers, thinks  
6 bipolar disorder has been severely underdiagnosed in  
7 children." Is that a correct statement?  
8 A. That is correct. That's a quote.  
9 Q. Okay, that's a quote. And the next  
10 statement is "He likens the criticism he has  
11 encountered to the outrage that greeted Galileo's  
12 challenge to the notion that the Earth was flat."  
13 Is her interpretation of what you said accurate?  
14 Yes or no.  
15 A. Yes, it was accurate.  
16 Q. And do you agree that you are one of the  
17 **most forceful advocates of the aggressive treatment**  
18 **of preschoolers?**  
19 **A. It is her statement about me**  
20 **Q. I didn't ask you if it was her statement**  
21 **about you. I'm asking you if you agree that you are**  
22 **one of the most forceful advocates of the aggressive**  
23 **treatment of preschoolers.**  
24 **A. I am.**  
25 Q. Doctor, what is the purpose of publishing  
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1 that you do not consider the research you do to be  
2 what is termed clinical research?  
3 A. No, it is clinical research.  
4 Q. You what?  
5 A. It is clinical research.  
6 Q. Okay. There seemed to be some  
7 misunderstanding about that.  
8 Now, before we go any further, I'd asked  
9 you if you generally understood what was in the  
10 label for Risperdal.  
11 A. Yes.  
12 Q. **And are you aware that the label contains**  
13 **a statement that the mechanism of action for**  
14 **Risperdal is unknown?**  
15 A. Correct.  
16 Q. And what does that mean?  
17 A. **It means that the exact way that the**  
18 **risperidone and other medications work in the brain**  
19 **is not fully elucidated.**  
20 Q. Well, I'm not interested in other  
21 medications. I'm just interested in Risperdal with  
22 respect to that question. Okay?  
23 A. Yes, yes.  
24 Q. What it means is we don't know really how  
25 it works. Right?

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

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

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

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