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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. Civil Action  
Docket Number  
L-6661-06

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

Video Deposition of Joseph Biederman, M.D.  
Friday, February 27, 2009  
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1 Q. Are these the side effects associated with  
2 Risperdal?  
3 A. Yes.  
4  
5  
6  
7  
8  
9  
10 Q. The next point -- And, by the way, the use  
11 of Risperdal in the pediatric population was off-  
12 label at this time, wasn't it?  
13 A. Yes  
14 Q. And what does that mean?  
15 A. Off-label means that the medicine is used  
16 by physicians that is not specifically approved by  
17 the FDA for that use.  
18 Q. So it means a drug is being used for  
19 something that the FDA hasn't approved it for.  
20 Right?  
21 A. Yes.  
22 Q. Okay. And so you were proposing to do  
23 research on off-label uses of Risperdal. Right?  
24 A. I was proposing to do research on the  
25 efficacy and safety of risperidone relative to other  
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1 A. It was approved, to my recollection, for  
2 individuals older than 18.  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12 Q. So what you're saying is there's evidence  
13 that is accumulating that kids or that pediatric  
14 bipolar disorder onsets in these preschool kids, who  
15 I assume are three and four years old?  
16 A. Usually four to six.  
17 Q. Okay. So pediatric bipolar disorder  
18 onsets in four- to six-year-old kids coupled with  
19 the fact that the drugs are widely used, despite  
20 that, there's not a lot of data on efficacy. Right?  
21 MR. PECK: Object to form. It's a  
22 compound question.  
23 A. On efficacy and safety, yes.  
24 Q. And so basically what you mean is, what  
25 you're trying to say is that we have kids suffering  
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1 medicines.  
2 Q. In an off-label population. Right?  
3 A. The use in children at that time was off-  
4 label and two years ago has been approved.  
5 MR. TRAMMELL: Objection, nonresponsive.  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17 Q. One of the things you wanted to study was  
18 the efficacy of Risperdal in preschoolers. Right?  
19 A. Yes.  
20 Q. And how old are preschool kids?  
21 A. Could you repeat the question?  
22 Q. How old are preschool kids?  
23 A. Four to six.  
24 Q. And what age range was Risperdal approved  
25 for at that time?  
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1 from this disease or it's possible that they're  
2 suffering from this disease in the preschool years,  
3 the drug is used a lot in these kids, we ought to  
4 have some data to instruct doctors about whether  
5 it's safe and effective to be doing this?  
6 A. Yes.  
7  
8  
9  
10  
11  
12  
13 Q. Who makes Wellbutrin?  
14 A. Bupropion was initially made by Glaxo or  
15 Wellcome, Burroughs Wellcome, and then when they  
16 merged I don't know who owns Wellbutrin. I think  
17 GlaxoSmithKline, I think.  
18  
19  
20  
21  
22  
23  
24 Q. Did Janssen fund any studies that you did  
25 to study other companies' drugs?  
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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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<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 383</p> <p>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 <b>Today pediatric bipolar illness is accepted by the</b> 13 <b>practicing community</b> 14 MR. FIBICH: Object to that as being 15 nonresponsive. 16 BY MR. FIBICH: 17 Q. Do you disagree with this statement: The 18 diagnosis of pediatric bipolar disease is 19 controversial? 20 A. I disagree. The controversy is about how 21 to best define, what are the best ingredients. 22 That's the controversy, not that a group of children 23 that are very sick with high levels of morbidity and 24 disability exist. That controversy is over. The 25 controversy today is about how to best define it. Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 384</p> <p>1 That's the controversy. 2 MR. FIBICH: Mark this as the next 3 exhibit. And we're skipping one but I'll come back 4 to it. 5 MR. BURNEY: So I'm sorry. The number on 6 this is 19 or 20? You said the next exhibit but 7 we're skipping one. 8 MR. FIBICH: Hold on. 9 THE WITNESS: This is 18. 10 MR. FIBICH: This is going to be 20. 11 MR. BURNEY: This is going to be 20? 12 Okay. 13 (Biederman Deposition Exhibit 20 marked 14 for identification.) 15 BY MR. FIBICH: 16 Q. Let me show you what I've marked as 17 Exhibit 20, Dr. Biederman. 18 A. Mm-hmm. 19 Q. And this is an article out of The 20 Washington Post, February 2005 Do you see that? 21 A. Mm-hmm. 22 Q. And if you would turn to page 3 and under 23 the heading Very Disturbed Children, read the 24 comments that are attributed to you, sir. 25 A. Mm-hmm. Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 385</p> <p>1 Q. Did you talk to The Washington Post? 2 A. I don't remember who I talked to, but 3 apparently I talked to this person. 4 Q. The comments that are contained in the 5 first two paragraphs are comments of yours and you 6 were quoted accurately. Correct? 7 A. This is not a quote, this is an 8 interpretation of what I said. 9 Q. Is it a correct interpretation of what you 10 said? 11 A. I said the same as I said to you. I did 12 not compare myself to Galileo. I said that Earth 13 was once flat. The reporter is not quoting me here. 14 It is her interpretation. She could have said that 15 I am comparing myself to God. This is her 16 interpretation of what I said. I said that Earth 17 was once flat. This is what I said. 18 Q. Well, why didn't you compare yourself to 19 God? 20 A. Because I am not God. I am saying that 21 the interpretation of my statement is her 22 interpretation. 23 Q. Is her interpretation of your statement an 24 accurate statement? 25 A. I said that Earth was once flat. I did Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 386</p> <p>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 <b>most forceful advocates of the aggressive treatment</b> 18 <b>of preschoolers?</b> 19 <b>A. It is her statement about me</b> 20 <b>Q. I didn't ask you if it was her statement</b> 21 <b>about you. I'm asking you if you agree that you are</b> 22 <b>one of the most forceful advocates of the aggressive</b> 23 <b>treatment of preschoolers.</b> 24 <b>A. I am.</b> 25 Q. Doctor, what is the purpose of publishing Stratos Legal Services 800-971-1127</p>

<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 459</p> <p>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. <b>And are you aware that the label contains</b> 13 <b>a statement that the mechanism of action for</b> 14 <b>Risperdal is unknown?</b> 15 A. Correct. 16 Q. And what does that mean? 17 A. <b>It means that the exact way that the</b> 18 <b>risperidone and other medications work in the brain</b> 19 <b>is not fully elucidated.</b> 20 Q. Well, I'm not interested in other 21 medications. I'm just interested in Risperdal with 22 respect to that question. Okay? 23 A. Yes, yes. 24 Q. What it means is we don't know really how 25 it works. Right? Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 460</p> <p>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. <b>There are studies today of a few years,</b> 22 <b>not more than a few years' follow-up. When a drug</b> 23 <b>is, say, brought to market there is a requirement</b> 24 <b>that there is at least one or two years of</b> 25 <b>follow-up, so I believe that risperidone has some</b> Stratos Legal Services 800-971-1127</p>
<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 461</p> <p>1 <b>type of follow-up data.</b> 2 Q. You believe so? You don't know so? 3 A. <b>I do not know for sure.</b> As I told you, I 4 did not participate in the study so I do not know. 5 But that's a standard requirement of the FDA. 6 Q. And of course if the drug is being used 7 off-label, then the FDA would not have required that 8 type of study. Correct? 9 A. Physicians use all the time medicines 10 available to them to help their patients off-label. 11 It's a legal activity; it's done all the time; and 12 many of the discoveries in medicine, in psychiatry 13 and other fields occurred through using medications 14 off-label. So off-label is not a bad practice 15 necessarily. Only means that the pharmaceutical 16 company has not yet conducted the clinical study. 17 In the case of risperidone, as you know, the pivotal 18 studies were conducted. 19 MR. FIBICH: Object to that as being 20 nonresponsive. 21 BY MR. FIBICH: 22 Q. What I was asking you was, were there any 23 long-term studies of the effect of Risperdal on 24 children? And you said -- 25 A. To my knowledge we, in our research, we Stratos Legal Services 800-971-1127</p>	<p style="text-align: center;">Joseph Biederman February 27, 2009</p> <p style="text-align: right;">Page 462</p> <p>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 <b>Are you aware of any published data that established</b> 14 <b>the safety of Risperdal on children for a long</b> 15 <b>period of time?</b> 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. <b>There is not only absence of long-term</b> 21 <b>data in pediatrics, but there is neither long-term</b> 22 <b>data in adults.</b> 23 Q. <b>So this is a drug that we don't know how</b> 24 <b>it works and you propose giving it to certain</b> 25 <b>children under the age of six. Correct?</b> Stratos Legal Services 800-971-1127</p>