

- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 his teachers and therapists, they noticed the 2 difference. And you're going to see some of 3 the school records in this case that went to 4 his mother. 5 "I feel Austin has had a successful 6 year." These are his teachers writing. "I 7 feel Austin has had a successful year this 8 year." "He's made good social improvements 9 and unacceptable behaviors have decreased." 10 "His frustration behavior has 11 improved greatly." "He's made communication 12 improvements." "He's improved his attention. 13 It's felt that it -- his new medicine has 14 been very beneficial to Austin." 15 Risperdal worked for this kid and 16 made his life and his family's life and his 17 colleagues in school, his classmates, his 18 teachers' life better. 19 And you'll see those records and 20 you'll hear from his prescribing doctor who 21 will say, yes, it worked. It helped him. 22 And, you know, parents with kids who 23 have problems like this, they have horrible 24 choices. 25 <b>MR. KLINE:</b> Your Honor, objection.</p>	Page 81	- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 <b>THE COURT:</b> That's sustained. 2 Counsel, please stick to an outline 3 of your case as opposed to an argument at 4 this point. 5 <b>MS. SULLIVAN:</b> Your Honor -- 6 <b>THE COURT:</b> Are you intending to 7 present all of this evidence? 8 <b>MS. SULLIVAN:</b> Yes, Your Honor. 9 <b>THE COURT:</b> All right. Then why 10 don't you tell us which witnesses you are 11 going to use to make these points. 12 <b>MS. SULLIVAN:</b> Sure. Fair enough. 13 You're going to hear from one of the 14 world's leading child psychiatrists, 15 Dr. Adelaide Robb, who treats a lot of 16 children. Her specialty is treating children 17 with mental disorders, including children 18 with autism. And she's going to talk about 19 this class of medicines and that all of them 20 have serious side effects. 21 Some of them increase your risk of 22 diabetes and weight gain more than others. 23 Some of them cause these muscle or 24 neurological side effects. Some of them, as 25 I mentioned, are associated with fatal skin</p>	Page 83
- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 <b>The case is about the -- the warnings. We've</b> 2 <b>heard 15 minutes about how great the drug</b> 3 <b>was.</b> 4 <b>THE COURT:</b> Well, I'm just not -- 5 <b>that's denied. Overruled.</b> 6 <b>MS. SULLIVAN:</b> Parents with children 7 like this, they have difficult and horrible 8 choices. Because nobody wants to put their 9 kids on medicines, especially this -- 10 Risperdal is a class of medicines called 11 antipsychotics, and they're serious medicines 12 with serious risks. And all of them have 13 serious -- there's a whole bunch of them now, 14 first generation and second generation that 15 we'll talk about, but they all have serious 16 risks. 17 And Austin's been on an antipsychotic 18 his whole life, since he first started on 19 Risperdal. He's been on something else for 20 the last couple years. And there's no 21 dispute in this case he needs an 22 antipsychotic. The drug he's on now has been 23 reported to have -- by the FDA; the FDA put 24 out a warning it causes fatal skin diseases. 25 <b>MR. KLINE:</b> Objection.</p>	Page 82	- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 <b>diseases, fatal blood diseases.</b> 2 <b>There are no perfect choices. All</b> 3 <b>medicines have risks. And all medicines, if</b> 4 <b>they go through the FDA approval process,</b> 5 <b>have been found to have benefits. And so all</b> 6 <b>medicines have risks and benefits, including</b> 7 <b>Risperdal. And you're going to see that</b> 8 <b>Mr. Pledger's doctor made choices about which</b> 9 <b>one was best. And his doctors after</b> 10 <b>Risperdal had made choices in terms of after,</b> 11 <b>the medicines that were best.</b> 12 Now, I think Mr. Kline mentioned 13 something about weight gain and said 14 Risperdal caused Mr. Pledger's fixation on 15 food. 16 Well, kind of just to start from the 17 beginning, Mr. Pledger, even before he 18 started on Risperdal, was what they call -- 19 probably some of you have heard about body 20 mass index. He when he was five or six years 21 old was already in the obese category before 22 he ever started Risperdal. So he was obese 23 before he started. And that's, 24 unfortunately, not uncommon for children who 25 have autism because -- and you'll hear from</p>	Page 84

- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 our psychiatry expert, Dr. Robb, and I think 2 if they bring their psychiatry expert, him as 3 well -- that children with autism get fixated 4 on fattening foods because it comforts them. 5 It calms their frustration down. And so 6 Ms. Pledger, his mother, reported that he 7 liked Pop-Tarts, cheeseburgers, French fries, 8 peanut butter and banana sandwiches, pizza -- 9 things that are not necessarily the most 10 low-cal. And so you're going to see that his 11 diet was part of what was going on here in 12 terms of his weight and that he was obese 13 before he started Risperdal.</p> <p>14 He also gained some weight on 15 Risperdal. And you're going to see the 16 studies show that Risperdal is associated 17 with weight gain, but about 10 pounds or so. 18 And Mr. Pledger gained a lot more than that, 19 in large part because of his diet. And 20 you're also going to see that weight gain was 21 warned about in the label from the very 22 beginning. It talked about the fact that 23 there was a statistically significant greater 24 incidence of weight gain right from the 25 beginning. And you're going to see that</p>	Page 85	- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 some weight. And they talked about taking 2 him off the Risperdal, but his mother said, 3 no, it's working. And so, again, not great 4 choices, but informed decisions.</p> <p>5 You're also going to see that 6 something happened in -- after his five years 7 on Risperdal in 2007, the spring of 2007, his 8 mother decides to go see a psychiatrist who's 9 close and more convenient who lives closer to 10 Austin's school. And his name is 11 Dr. Paoletti. And you're going to see some 12 testimony from him in this case, I think by 13 video as well, because these guys were all in 14 Alabama where the Pledgers live.</p> <p>15 And Dr. Paoletti -- and so she goes 16 to Dr. Paoletti and talks about, you know, 17 her concern about weight gain, and 18 Dr. Paoletti takes him off of Risperdal and 19 puts him on another antipsychotic called 20 Abilify and then another antipsychotic called 21 Geodon. And what happens to Mr. Pledger?</p> <p>22 Well, the first thing that you're 23 going to see from his medical records and his 24 school records is that his behavior and his 25 communication abilities dramatically spiraled</p>	Page 87
- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 Dr. Mathisen, Mr. Pledger's doctor, knew 2 about that and talked to his mother, 3 Mr. Pledger's mother about the issue of 4 weight gain.</p> <p>5 And you're also going to hear that 6 after five years on Risperdal, where it 7 worked pretty well for Mr. Pledger -- oh, I 8 should have mentioned. In fact, you're going 9 to see notes where Mrs. Pledger was talking 10 to her son's doctor about maybe taking him 11 off Risperdal because of weight, maybe that 12 would help in addition to giving him a better 13 diet, because he lost weight, too, when he 14 was on Risperdal, when he was dieting. But 15 the mother decided, no, doctor, I see he's 16 gaining weight -- and you'll see the 17 pictures -- I see he's gaining weight 18 everywhere, proportionally. He's obese and 19 he's continuing to get obese. I see he's 20 gaining weight, but please don't take him off 21 the Risperdal, it's working. And you'll see 22 those records. And there's a couple 23 discussions like that.</p> <p>24 They talk about the fact, you know, 25 try diet, try more exercise, and he did lose</p>	Page 86	- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 downwards. Things don't go well for 2 Mr. Pledger, unfortunately, once the second 3 doctor takes him off of Risperdal.</p> <p>4 And I'm going to read to you some 5 notes from his education facility. It's 6 called Clanton Middle School, just in the 7 year after he stops, you know, within the 8 year after he stops taking Risperdal.</p> <p>9 And they say -- his school says: 10 "Austin's medication was changed this year. 11 He has kicked and punched his 12 paraprofessionals. He's pinched his 13 classmates. He's hit two different children 14 with his fists. There's several times we put 15 him on the bus. He's been headbutting the 16 floor. He's throwing books, paper, pencils, 17 chairs. He hits himself in the head. At 18 times he bites himself on his hands," et 19 cetera, et cetera, et cetera. This is the 20 year after he stops Risperdal. His teachers 21 are reporting things are not going as well.</p> <p>22 <b>MR. KLINE:</b> Your Honor, respectfully, 23 I hate to interrupt, but there is nothing 24 here --</p> <p>25 <b>THE COURT:</b> Is there an objection?</p>	Page 88

<p>- PLEDGER, et al. -vs- JANSSEN, et al. -</p> <p>1       <b>MR. KLINE:</b> Yes. I object. 2       <b>THE COURT:</b> Overruled. You know, I'm 3 going to have to alert counsel that if 4 there's a legitimate reason for that 5 particular piece of evidence, it will be 6 admitted. 7       <b>MR. KLINE:</b> Okay. I'll be quiet. 8       <b>MS. SULLIVAN:</b> And you'll hear the 9 doctor's testimony. Both sides were asking 10 doctors about how Mr. Pledger was doing on 11 and off Risperdal, and you'll get the records 12 at the end of the case and you'll see the 13 evidence and you'll be able to evaluate it 14 for yourself. 15       But -- and so the notes continue. So 16 he stops taking Risperdal when he's 12; and 17 in the spring of 2007, and there's a note 18 that talks about when he stops Risperdal and 19 after because it happened late April is when 20 he switched in 2007. So his school writes in 21 April, when he's still on the Risperdal in 22 the beginning: "Austin was reported to be 23 initiating interaction and being more verbal. 24 However, after returning from spring 25 break" -- it changes to this other medicine</p>	Page 89	<p>- PLEDGER, et al. -vs- JANSSEN, et al. -</p> <p>1 school decided when he was 15 that they had 2 to expel him; that he couldn't go to school 3 anymore. And the school writes: We have to 4 put him homebound starting Monday from the 5 standpoint that he has hurt someone, and we 6 must look out for everyone's safety. And 7 you're going to see the records. He's been 8 hitting teachers. He had been hitting other 9 students and throwing desks, et cetera, and 10 the school said for everyone's safety, we 11 have to put him homebound. This was 12 Mr. Pledger's life after Risperdal on other 13 antipsychotic medicines, after the second 14 doctor took him off of Risperdal. 15       One of the other things you're going 16 to hear is off of Risperdal, he gained a lot 17 more weight off of Risperdal than he ever did 18 on it from these other -- from these other 19 causes, the diet, and also he's homebound 20 now. He's not in school anymore. So off of 21 Risperdal he became what's categorized by 22 doctors as morbidly obese. He went to 23 321 pounds. He's now lost some weight, but 24 he's still in the obese category. But off of 25 Risperdal, you're going to see, he gained</p>	Page 91
<p>- PLEDGER, et al. -vs- JANSSEN, et al. -</p> <p>1 -- "his behavior has regressed. It was 2 reported that his medications had changed and 3 this could explain the difference in his 4 behavior. Now when he gets frustrated he can 5 try to hit whoever is with him. He has been 6 known to throw desks and tables and try to 7 break things," and now he's a bigger kid. 8 This is when he's 13 or teenage years. And, 9 again, records continue into 2009, when he's 10 15: "Given Austin's history in school of 11 significant behavioral difficulties that may 12 cause harm to himself or others, it is 13 recommended that all staff" -- these are the 14 teachers and aides -- "with Austin receive 15 training in appropriate deescalation and 16 restraint procedures." 17       So after Risperdal, his teachers are 18 getting training in restraint procedures 19 because this disruptive, distressing behavior 20 that's associated with autism is returning. 21 It never goes away completely, even on 22 Risperdal. But it was a lot better on 23 Risperdal. When they took him off, things 24 went bad. 25       In fact, things went so bad that the</p>	Page 90	<p>- PLEDGER, et al. -vs- JANSSEN, et al. -</p> <p>1 substantially more weight than he did on. 2       And you're going to see pictures in 3 this case that show that he gained weight 4 proportionally, in his stomach, in his 5 breasts, you know, in every -- different 6 places. 7       And -- but the records are pretty 8 clear in terms of the medicine that worked -- 9 how the medicine was working for Mr. Pledger 10 while he was on Risperdal as compared to what 11 happened to him when he was off. 12       In fact, his doctor had to add 13 another psychiatric medicine. So he's on 14 this antipsychotic, Geodon, now that's not 15 approved for children at all. Risperdal is 16 now approved for children with autism. He's 17 on one now that's never been approved for 18 children called Geodon, and it wasn't working 19 so his doctor had to add another antianxiety 20 medicine, Prozac. So now he's on Geodon or 21 was for a while -- and I think still now -- 22 Geodon and Prozac. When on Risperdal he just 23 needed that and it was, as his mother said, 24 working well. 25       But now, as you heard, the Pledgers,</p>	Page 92

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<p>1 So I thank you late on a Friday 2 afternoon for sticking with me, and I look 3 forward to talking with you at the end of the 4 case.</p> <p>5 Thank you.</p> <p>6 <b>THE COURT:</b> All right. Thank you, 7 Ms. Sullivan.</p> <p>8 All right. Members of the jury, the 9 argument is joined, okay. So we're going to 10 take a break now until Monday. We have heard 11 the opening arguments at this hour, 4:20. 12 We'll call it a day. I know some of you have 13 been here since 9:30, so...</p> <p>14 What I want to tell you now is the 15 following: I'm going to ask that you wear 16 your yellow badges, okay? The yellow badges 17 are important, certainly around City Hall, 18 it's for us to help preserve the integrity of 19 the case so that we don't talk to you by 20 mistake, and certainly the appearance of -- 21 everyone's very concerned, as we are, about 22 the appearance, but also the reality is we 23 don't want to engage in any conversations 24 that could throw you off, all right? So 25 that's the one thing.</p>		<p>1 <b>THE COURT:</b> All right. You may be 2 seated.</p> <p>3 Are there any objections or 4 exceptions now to Ms. Sullivan's argument?</p> <p>5 <b>MR. KLINE:</b> Yes.</p> <p>6 <b>THE COURT:</b> Okay.</p> <p>7 <b>MR. KLINE:</b> Your Honor, plaintiff 8 objects to the issue of efficacy, which was 9 maybe 50 percent of her opening, maybe 60. 10 I thought -- and I was guided in my 11 opening by the Court's admonition -- that the 12 issue in this case is going to be whether the 13 warning was adequate or inadequate as to 14 gynecomastia. And what she has outlined in 15 the opening is essentially a collateral issue 16 which has to do with whether the drug was 17 efficacious or not.</p> <p>18 We heard very little in her opening 19 about a direct response to anything that had 20 to do with the studies. I don't think she 21 mentioned Study 41, which is the core of our 22 case, and Study 70, which is the core of our 23 case, the pooled analysis, which is the core 24 of our case.</p> <p>25 What we have to say in this</p>	
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<p>1 The other thing is, again, I'm going 2 to remind you, as both counsel said, to keep 3 an open mind. Remember, we haven't heard a 4 stitch of evidence yet, not a stitch.</p> <p>5 So, therefore, please do not discuss 6 this case with anybody. I'm talking about 7 any of your family. Just, you know, yeah, 8 it's interesting, okay. It's going to be 9 interesting to tell them, but that's about 10 it. Do not discuss this case with anyone. 11 And please don't do your own investigation 12 about anything that's been touched on here. 13 I really would appreciate that.</p> <p>14 All right. So then have a great 15 weekend. We'll see you here at 1 o'clock on 16 Monday.</p> <p>17 <b>COURT CRIER:</b> All rise as the jury 18 exits the courtroom.</p> <p>19 - - -</p> <p>20 (Whereupon the jury exited the 21 courtroom at 4:22 p.m.)</p> <p>22 - - -</p> <p>23 (The following transpired in open 24 court outside the presence of the jury:)</p> <p>25 - - -</p>		<p>1 courtroom, Your Honor, pure and simply -- 2 guided by Judge New's decision, reinforced by 3 Your Honor -- is that we are limited to 4 proving whether the warning was adequate or 5 inadequate. That has nothing to do with 6 trying whether Austin had tantrums or not 7 tantrums. The doctor had made a decision 8 about the drug, and he then made a decision 9 whether to keep him on the drug or not keep 10 him on the drug. Those are all fact issues 11 that are in dispute.</p> <p>12 But I object and would truly seek 13 some guidance, because if this is all in the 14 case, if we're going to go off on this -- on 15 this whirlwind of how great the 16 pharmaceutical company was, how they 17 developed Haldol, how they developed 18 Risperdal, how they did all of these 19 studies -- frankly, none of which were 20 criticized, none of which we deal with, and 21 none of which have anything to do with 22 children and adolescents -- then we have a 23 different case in front of us. We have a 24 much longer, much more complex case, with 25 much more evidence and the like.</p>	

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1 So that's -- that's my first 2 objection, and -- 3 <b>THE COURT:</b> Well, wait a minute. 4 <b>MR. KLINE:</b> -- seeking guidance. 5 <b>THE COURT:</b> The objection is to what, 6 though? What are you asking for? 7 <b>MR. KLINE:</b> What I'm asking is to 8 limit this case -- 9 <b>THE COURT:</b> Well, I can't limit this 10 case unless you're asking for a cautionary 11 instruction or some kind of limiting 12 instruction to give to the jury on Monday. 13 <b>MR. KLINE:</b> Well -- 14 <b>THE COURT:</b> If that's what you're 15 asking for, then that's something that we can 16 discuss. But I can't, you know, just change 17 the nature of the strategy or theory of the 18 defense in this case. 19 <b>MR. KLINE:</b> Well, the theory of the 20 case, Your Honor, what I'm suggesting is that 21 the defense should be here to present 22 evidence contrary to our claims. And I would 23 suggest to the Court, they're going to have 24 some that they did these studies correctly; 25 that they warned correctly. But the issue of		1 exclude testimony in relation to whether 2 Risperdal was effective in treating 3 plaintiff's health and the drug's 4 effectiveness compared to other antipsychotic 5 medicines. Your Honor said, quote, in order 6 to prove an adequate warning, it has to be 7 adequate to make the doctor change his 8 decision; and in order to understand what 9 that decision was, there is a risk/benefit 10 analysis that is inherent in this whole case. 11 And Your Honor went on to talk about the 12 doctor's deposition and that whether the 13 medicine could work with this child was 14 clearly relevant. 15 Also denied was their motion to 16 exclude the benefits of this medicine to 17 others. That's part of the FDA approval 18 process, whether this medicine's effective in 19 autism. Your Honor, this was litigated 20 extensively in the in limine stage. Your 21 Honor has ruled. I submit my opening was 22 consistent with Your Honor's ruling. 23 <b>MR. KLINE:</b> Your Honor, 24 Dr. Mathisen's testimony, which you can 25 evaluate because it's transcribed, says that	
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1 whether it was safe and effective in Austin 2 or not safe and effective and how it compared 3 to his other drugs -- I mean, my word, they 4 talked about what he's -- she talked in her 5 opening about what he's on today and whether 6 it manages his -- his condition. 7 <b>THE COURT:</b> I heard the same opening 8 you did. 9 <b>MR. KLINE:</b> How could that -- that 10 cannot be -- 11 <b>THE COURT:</b> Mr. Kline, I heard the 12 same opening you did, and I understand the 13 objection. Let me hear from Ms. Sullivan and 14 I'll see what my views were. 15 <b>MR. KLINE:</b> That's -- that's my 16 first. 17 <b>MS. SULLIVAN:</b> Your Honor -- 18 <b>THE COURT:</b> We'll address it one by 19 one. 20 <b>MS. SULLIVAN:</b> Your Honor, once 21 again -- 22 <b>THE COURT:</b> Yes. 23 <b>MS. SULLIVAN:</b> -- this was one of 24 their in limine motions that was denied by 25 the Court. They wanted to -- they moved to		1 even though it was working, had he known the 2 risks, he would have not prescribed it. 3 Now, that means, at least in my 4 simple equation, that you can assume -- let's 5 assume all of these things happened, that it 6 did everything -- all these good things. It 7 was -- it was still -- it goes to the issue 8 of whether or not they warned about 9 gynecomastia, because he's going to say had 10 he known, he would have taken him off the 11 drug. 12 The Court now has a much better sense 13 of what they're going to do in the case, 14 which is -- which is not talk about anything 15 to do with the core issue, but rather try to 16 bollix us up in trying to prove or disprove 17 the efficacy of the drug when the issue in 18 the case is the safety of the drug, and -- 19 and it's the safety of the drug against the 20 risk of gynecomastia. 21 <b>THE COURT:</b> Yeah. All right. 22 Mr. Kline, let me respond. 23 So actually, before we do that, let 24 me hear your other objections. Go ahead. 25 <b>MR. KLINE:</b> Sure.	

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<p>1 The other objections have to do with 2 the -- which she's introduced all of these 3 risks of all of these other drugs, suggesting 4 to the jury -- improperly I might add -- that 5 Risperdal doesn't have these side effects. 6 My word, Risperdal is about the large -- 7 about the biggest offender, probably the 8 biggest offender in the class. And if she -- 9 now that she's opened the door, we should be 10 allowed to show the jury that because she 11 said, oh, the choices, she told this jury the 12 choices are -- all of these things -- tardive 13 dyskinesia in -- in children that were on 14 these other drugs.</p> <p>15 <b>THE COURT:</b> Well, what is it 16 specifically now, what is this that --</p> <p>17 <b>MR. KLINE:</b> I want to be able to show 18 the jury -- first of all, I want to eliminate 19 it. It's not in the case.</p> <p>20 <b>THE COURT:</b> Well, right now the 21 objection is to what?</p> <p>22 <b>MR. KLINE:</b> To the introduction and 23 the suggestion that other drugs in the class, 24 like Zyprexa, had all of these horrible, 25 horrible side effects and that Risperdal</p>		<p>1 do, Your Honor.</p> <p>2 <b>THE COURT:</b> Well, I have --</p> <p>3 <b>MR. KLINE:</b> The answer --</p> <p>4 <b>THE COURT:</b> I have all summer to try 5 that case. That's what it's going to come 6 down to in the end. We'll have to give you a 7 week's recess to get ready for that.</p> <p>8 <b>MR. KLINE:</b> Okay. The answer is that 9 we would need time, but that -- that it 10 would -- we have a psychiatrist who could 11 testify. We probably weren't going to call 12 him. We thought the issue in the case --</p> <p>13 <b>THE COURT:</b> I'll permit you -- I'll 14 permit a lot of leeway. If this trial 15 descends into a -- because fundamentally, to 16 answer Question No. 1, yes, I was waiting for 17 the defense statement of its case. And what 18 I get out of it is that they're challenging 19 the causation aspect of this particular -- 20 and they're entitled to.</p> <p>21 <b>MR. KLINE:</b> Right.</p> <p>22 <b>THE COURT:</b> They're entitled to 23 challenge the causation. The causation in 24 this case is would the doctor involved here 25 have changed his prescription had he known of</p>	
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<p>1 didn't somehow. I want that corrected and 2 eliminated from the case. That's -- that's 3 objection two.</p> <p>4 And if it's allowed, it's going to be 5 continuing prejudice.</p> <p>6 <b>THE COURT:</b> Well, do you have 7 evidence to the contrary in this case, ready 8 to go?</p> <p>9 <b>MR. KLINE:</b> Ready to go?</p> <p>10 <b>THE COURT:</b> Yeah.</p> <p>11 <b>MR. KLINE:</b> On the issue of their 12 other side effects of the drug.</p> <p>13 <b>MS. SULLIVAN:</b> He could show the 14 label, Judge. It has all the side effects.</p> <p>15 <b>THE COURT:</b> No, no, no. We're not 16 going to play that way, Ms. Sullivan.</p> <p>17 <b>MR. KLINE:</b> Well, first of all, the 18 label is --</p> <p>19 <b>THE COURT:</b> If you want a whole trial 20 and this bar community wants a whole trial 21 that really gets into the balances and risks 22 that a doctor will have to evaluate in terms 23 of comparing this particular medication to 24 others, you will have that trial.</p> <p>25 <b>MS. SULLIVAN:</b> That's what he has to</p>		<p>1 something. And that by itself does or could 2 involve an evaluation of the options open to 3 him, including using Prozac or whatever the 4 other drugs were that had been mentioned.</p> <p>5 If you want to go that route, I'm 6 here all summer.</p> <p>7 <b>MR. KLINE:</b> Okay.</p> <p>8 <b>MS. SULLIVAN:</b> Thank you, Your Honor.</p> <p>9 <b>MR. KLINE:</b> It appears they're going 10 to go that route, so --</p> <p>11 <b>THE COURT:</b> Yeah, apparently so.</p> <p>12 <b>MR. KLINE:</b> So we'll have to do it, 13 too.</p> <p>14 <b>THE COURT:</b> Again, still, no one's 15 going to criticize this Court, from my 16 understanding, if we go that route.</p> <p>17 But all I can tell you is you better 18 prepare, all of you, for that; because in the 19 end, the jury will make a very intelligent 20 decision that may not go the defense way.</p> <p>21 <b>MR. KLINE:</b> How we would plan to 22 handle that, Your Honor, was we did not -- we 23 do not believe that's what the case is about.</p> <p>24 And I'm not going to get -- pardon my use of 25 the language -- suckered in to having my</p>	

- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 plaintiffs' case be about that. But if they 2 go there, we will ask the Court for leave and 3 we will bring in the appropriate experts to 4 show -- 5       <b>THE COURT:</b> Well, I suggest that you 6 start working on who that might be over the 7 weekend. 8       <b>MR. KLINE:</b> Yes, we will. 9       <b>THE COURT:</b> And so that we're not 10 stuck for a week in the middle of February 11 waiting for you to do that. 12       <b>MR. KLINE:</b> We won't let that happen. 13       <b>THE COURT:</b> But if this case is going 14 to be joined in that fashion, I will permit 15 it. 16       <b>MS. SULLIVAN:</b> And, Your Honor, just 17 so we're clear, it always is -- it's always 18 what were the alternatives when you have to 19 evaluate. 20       <b>THE COURT:</b> Well, if you're going to 21 make a medical case about the treatment of 22 autism and psychotherapy, then you've got it. 23       <b>MS. SULLIVAN:</b> I'm not sure I 24 understand Your Honor's direction. 25       <b>THE COURT:</b> You are essentially</p>	Page 129	- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 have medical experts compare those, if those 2 are brought in here. It will be a different 3 kind of case, perhaps, but I'm not afraid of 4 it. 5       <b>MS. SULLIVAN:</b> Understood, Your 6 Honor. 7       <b>MR. KLINE:</b> Your Honor, on the narrow 8 question of their now having said that all of 9 these other -- that all of these other drugs 10 had all of these other problems, I must be 11 allowed to show that this drug had a whole 12 raft of other problems. 13       <b>THE COURT:</b> Absolutely. If we're 14 starting to get into what Ms. Sullivan 15 described as the various other side effects 16 of the other drugs, absolutely. This case is 17 wide open. And it will be wide open as to 18 the use of Risperdal and its side effects in 19 general, because all of these factors will go 20 into a doctor's decision whether or not to 21 prescribe. 22       <b>MS. SULLIVAN:</b> And then, Your Honor, 23 that's fair game to talk about all the other 24 drugs and all their side effects. 25       <b>THE COURT:</b> I don't know about any</p>	Page 131
- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 saying that the -- that other drugs would 2 have been more appropriate, and therefore, 3 this and that. I listened to your opening. 4 If you want to go that route, you can do it. 5 I consider that to be opening the door. I 6 think it would be devastating for the 7 defense, but you go that way. 8       <b>MS. SULLIVAN:</b> Your Honor, just so 9 I'm clear, opening the door to what? 10       <b>THE COURT:</b> To a trial basically on 11 the efficacy of this particular medication 12 versus others, compared to what they've 13 warned about others, in terms of their 14 medications and what they have warned 15 compared to what Johnson &amp; Johnson warned. 16       <b>MS. SULLIVAN:</b> Well, Doctor -- 17 Dr. Mathisen had to evaluate all of the risks 18 for all the medicines. 19       <b>THE COURT:</b> I don't know that. What 20 I do know at this point is that he did not 21 have the information that he didn't have in 22 2006; he didn't have it in 2001. And if 23 you're going to make an issue about what kind 24 of warnings were available for other 25 medication, we will compare those. We'll</p>	Page 130	- PLEDGER, et al. -vs- JANSSEN, et al. - <p>1 other drugs having been mentioned to me. You 2 only mentioned one or two so far. We'll have 3 to look at it all. 4       <b>But the fact of the matter is, if</b> 5 <b>this case is going down that route, you'll be</b> 6 <b>permitted to do it if it takes all summer.</b> 7       <b>But the fact of the matter is that I</b> 8 <b>don't think that's going to be beneficial for</b> 9 <b>the defense; because in the end, in the end,</b> 10 <b>if it can be shown by this plaintiff that the</b> 11 <b>other drugs had sufficient warnings on these</b> 12 <b>type of issues and you didn't, that is</b> 13 <b>devastating.</b> 14       <b>MS. SULLIVAN:</b> Well, Your Honor, none 15 of the other ones -- 16       <b>THE COURT:</b> That is a multi, multi, 17 big-time settlement, a potential verdict very 18 different from the little case we're having 19 here in this trial. 20       <b>MS. SULLIVAN:</b> Your Honor, none of 21 the other medicines were approved for autism. 22 This is the only one. 23       <b>THE COURT:</b> I don't know. I really 24 don't know. 25       <b>MR. KLINE:</b> They were all prescribed</p>	Page 132

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<p>1 off-label. That's the truth of the matter. 2       <b>THE COURT:</b> If they're all prescribed 3 off-label, then in the end, I think that one 4 day's testimony could solve the whole problem 5 from a physician as to what were the various 6 factors for these different drugs. 7       <b>MR. KLINE:</b> Your Honor -- 8       <b>MS. SULLIVAN:</b> Your Honor -- 9       <b>MR. KLINE:</b> So the Court's advised, 10 we do not intend to do that in the first 11 instance. I'm going to try to keep this case 12 narrow. 13       I just wanted -- I just needed 14 guidance, and I have it, as to what 15 they're going -- if they're going to go 16 there, I want to be able to have a rebuttal 17 case ready to go. 18       <b>THE COURT:</b> Absolutely. You are 19 granted that. 20       <b>MS. SULLIVAN:</b> And, Your Honor, maybe 21 we can save some time, because there's going 22 to be evidence in this case -- and I didn't 23 think there was a dispute -- that 24 Dr. Mathisen continued to prescribe in the 25 face of the label that they now hold up as</p>	Page 134	<p>1 Honor. 2       <b>THE COURT:</b> Okay. 3       <b>MR. KLINE:</b> Yes. I'm trying -- 4       <b>THE COURT:</b> What else do you have? 5       <b>MR. KLINE:</b> Well, let me just think. 6 I just need to look at my notes for one 7 minute. 8       There was one other thing, I believe. 9       Yes. I do -- I do request that there 10 be an instruction as to Haldol. That's their 11 other drug. 12       <b>THE COURT:</b> Well, that's the one 13 where we got into this position with the 14 Court. 15       By the time we start tossing in first 16 generation -- we're going back to Tofranil. 17 You're going to go back to Tofranil now and 18 all of this? We're going to go into a 19 whole -- we'll get Dr. Beck in here. 20       I mean, where are we going with this 21 case, Counsel? 22       <b>MS. SULLIVAN:</b> Your Honor, Your 23 Honor, here's the issue, Judge: This is a 24 kid that no one, even they, does not dispute 25 needed antipsychotics. And so these are the</p>	Page 136
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<p>1       <b>MR. KLINE:</b> And the -- bear with me 2 one second, Your Honor. 3       (Pause.) 4       <b>THE COURT:</b> We're going to get into 5 drymouth; we're going to get into the whole 6 nine yards of this. I mean, I'm here all 7 summer, all summer. 8       <b>MR. KLINE:</b> It's slightly different, 9 but I just want to object to make sure that I 10 have it. I would object to anything that has 11 to do with the -- the approval of the drug 12 and the adult approval process. 13       The issue here, again, Your Honor, is 14 a narrow one that deals with the use of the 15 drug for pediatrics, the development of the 16 drug for pediatrics and adolescents, and the 17 approvals and submissions to the FDA and the 18 label as it pertains to pediatrics and 19 children. 20       The case boils down to simply, 21 frankly, a few things that are in the label. 22 And that's what I thought the case was about. 23       I did not think that the case was 24 going to be about the, for example, approvals 25 of the drug or that it was going to be</p>		<p>1 for that for a child, it's going to come in. 2       <b>MR. KLINE:</b> Okay. Thank you. 3       <b>MS. SULLIVAN:</b> All right. And, Your 4 Honor, going back to your risk/benefit 5 comments, Judge, they do have a psychiatry 6 expert in this case. And we do, too. They 7 both can come in and talk about the risks and 8 benefits of all the drugs. 9       <b>THE COURT:</b> And as I said, you know, 10 both parties are on notice that if this is 11 going to become a free-for-all, we'll manage 12 it. 13       <b>MR. KLINE:</b> We're going to try and 14 narrow a case on failure to warn. To the 15 extent they -- just as I've outlined and as I 16 promised the Court -- 17       <b>MS. SULLIVAN:</b> Your Honor, we don't 18 want a free-for-all. 19       <b>MR. KLINE:</b> -- what they -- what we 20 will need, and which we've been granted by 21 the Court, is if they go this way, then we 22 will have rebuttal experts and we will be 23 prepared, I am confident, given the length of 24 this trial, to be able to rebut it. But I'm 25 not going to change what we're going to do.</p>	
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<p>1 allowed that she would be able to prove the 2 approvals of the drug for adults, which has 3 nothing to do with the case. The approval 4 process to the FDA; the massive submissions 5 to the FDA; the testing to the FDA, none of 6 that's an issue. 7       <b>MS. SULLIVAN:</b> Your Honor -- 8       <b>MR. KLINE:</b> The only thing that we 9 have an issue in the case -- again, trying to 10 narrow it -- 11       <b>THE COURT:</b> Well, you may not be able 12 to. I mean, I would obviously have an 13 interest in narrowing it, Mr. Kline. But 14 where we are in this case, now that the cat 15 is out of the box, I am beginning to 16 understand that this is going to be a case 17 that I can only manage, and therefore, I 18 don't intend to change the -- the choices 19 made by either party. 20       And if this case becomes a matter of, 21 well, now, we had some approvals for autism, 22 and therefore, you know, Risperdal is 23 considered for that and the doctors are going 24 to look at the adult approval for autism in 25 terms of its relevance to my own prescription</p>		<p>1       <b>THE COURT:</b> You do it, then. Again, 2 I can't change how Ms. Sullivan wants to -- 3 I've given some warnings to both parties that 4 if you go this route, this is going to be the 5 response. This is what's going to happen. 6 Take it or leave it. 7       <b>MS. SULLIVAN:</b> And, Your Honor, this 8 is fair. This evidence comes in in all of 9 these cases, what are the alternatives and 10 what are the risks. They don't need a 11 rebuttal case. They have a psychiatry 12 expert. It's been in our report -- 13       <b>THE COURT:</b> No, no. I'm not reacting 14 so much to the approval process or whatever. 15 I mean, I have Dr. Kessler's report right 16 here. I'll be looking at it over the 17 weekend. That's not the issue. 18       The issue is whether or not we're 19 going to have to go down the route of 20 comparing different medications for a 21 particular -- what was really going on in the 22 mind of a doctor. I haven't read his 23 deposition. But certainly from a rebuttal 24 point of view, if it comes to that, he will 25 be permitted to rebut these issues.</p>	

<p>- PLEDGER, et al. -vs- JANSSEN, et al. -</p> <p>1       <b>MS. SULLIVAN:</b> Well, they have -- 2 Your Honor, just so we're clear, this issue 3 has been in the case from the beginning. No 4 secret it's been in our expert reports. He's 5 got a psychiatry expert. 6       <b>THE COURT:</b> It may be. But the way 7 it's been framed by you with Haldol and now 8 go to the first generation. I don't know 9 what their preparation is and -- 10      <b>MS. SULLIVAN:</b> They're in the 11 reports. 12      <b>THE COURT:</b> And the fact of the 13 matter is, the fact of the matter is, as far 14 as I can tell, the effort to establish 15 causation is a very important aspect of the 16 defense, and I believe that if it's going to 17 hang on what other choices were available, 18 the defense is on notice that they are 19 permitted to rebut to that. 20      <b>MS. SULLIVAN:</b> Understood, Your 21 Honor. But I don't think it should be a 22 rebuttal case, Judge. They have an expert 23 that's been in the case from the beginning. 24      <b>THE COURT:</b> I don't know. Again, the 25 way this case was presented to me up to now</p>	Page 141	<p>- PLEDGER, et al. -vs- JANSSEN, et al. -</p> <p>1       <b>MS. SULLIVAN:</b> Understood, Your 2 Honor. 3       <b>MR. KLINE:</b> As I've said, "bet the 4 company." 5       We have a -- 6       <b>MS. SULLIVAN:</b> And he's a small-town 7 country lawyer, Judge. 8       <b>THE COURT:</b> He's a small-town country 9 lawyer and everyone knows him in this town. 10      But, frankly, he has to prove his case, too. 11      <b>MR. KLINE:</b> I'm gonna prove my case. 12      That's what I'm here to try to do. And I'm 13 just trying to do it in an efficient way. 14      Your Honor, I heard you say you have 15 a report. There are two reports of Kessler. 16      <b>THE COURT:</b> I only have one. 17      <b>MR. KLINE:</b> I'm going to give you 18 these. 19      <b>THE COURT:</b> The exhibits would be 20 nice. 21      <b>MR. KLINE:</b> It's a supplemental. 22      <b>THE COURT:</b> I'd like the exhibits. 23      <b>MR. KLINE:</b> We can give you the book 24 with exhibits. 25      <b>THE COURT:</b> Yeah.</p>	Page 143
<p>- PLEDGER, et al. -vs- JANSSEN, et al. -</p> <p>1 was that this was a fairly limited approach 2 from both parties. It's going to be tried 3 like a small case. If it's not going to be 4 tried that way, it will become a big case and 5 the risks are not on me. 6       <b>MS. SULLIVAN:</b> And, Your Honor, it's 7 a small -- it's one expert from each side. A 8 psychiatrist, here are the benefits of this 9 medicine versus the others. They have one, 10 and we have one. 11      <b>THE COURT:</b> I don't know. I know 12 that by the time you are tipping off the jury 13 to, you know, Johnson &amp; Johnson developed 14 Haldol and this and that and this and that, 15 we're in for a long haul. 16      <b>MS. SULLIVAN:</b> And, Your Honor, that 17 was just to credential us as someone who has 18 experience in psychiatric medicines. 19      <b>THE COURT:</b> I know you are an 20 extremely fine attorney and you're very 21 experienced. Everybody knows who you are, so 22 therefore, I'm just letting you know that 23 these are decisions that your team has to 24 make, as to how to approach the trial in this 25 courtroom, with this trial.</p>	Page 142	<p>- PLEDGER, et al. -vs- JANSSEN, et al. -</p> <p>1       <b>MR. KLINE:</b> We can have them sent 2 over. They're in two binders. But this is 3 his supplemental. 4       <b>THE COURT:</b> Okay. 5       <b>MR. KLINE:</b> Which will help. 6       <b>THE COURT:</b> Again, on the issue of 7 the exhibits, I mean, after all, you've heard 8 what I have to say about that. Yet I heard 9 from both parties we're going to go ahead and 10 show all these documents, so I'm kind of 11 curious where that goes, so we'll see. 12      <b>MS. SULLIVAN:</b> Thanks, Judge. 13      <b>THE COURT:</b> All right. We'll see you 14 at 1 o'clock on Sunday. Have a great 15 weekend, everybody. 16      <b>MR. KLINE:</b> Monday. 17      <b>THE COURT:</b> Monday. 18      <b>COURT CRIER:</b> Monday. 19      <b>MR. KLINE:</b> Looking forward to it. 20      Thank you, Your Honor. 21      <b>MS. SULLIVAN:</b> Thank you, Judge. 22      - - - 23      (Court adjourned at 4:45 p.m.) 24      - - - 25</p>	Page 144