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1 report.
2 **THE COURT:** All right. So what is it
3 you're requesting?
4 **MS. SULLIVAN:** I'd like to talk
5 about -- it's also one of Dr. Kessler's
6 opinions. I'd like to talk about the
7 industry standard in this negligence case
8 that we had to establish safety and efficacy
9 and the FDA approved this medicine as safe
10 and effective. I think the door's been
11 opened.
12 **THE COURT:** I don't know. We'll look
13 at that over the break as far as what the
14 actual language was used.
15 **MS. SULLIVAN:** All right. Thank you,
16 Your Honor.
17 **THE COURT:** All right. Okay. Thank
18 you. We will take a recess and let's just
19 get whatever that is. We'll clarify that,
20 okay.
21 **COURT CRIER:** Yes, Your Honor.
22 This court stands in recess.
23 - - -
24 (Whereupon a recess was taken.)
25 (Whereupon an off-the-record

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1 discussion was held.)
2 - - -
3 (The following transpired in open
4 court outside the presence of the jury:)
5 - - -
6 **COURT CRIER:** Come to order, please.
7 This court is reconvened.
8 **THE COURT:** All right. Before we
9 proceed -- you may be seated everybody.
10 Before we proceed to Ms. Sullivan's
11 opening, regarding the issue of safe and
12 effective, that is denied, and there are two
13 reasons. One is the phrase "safe and
14 effective" was not used together. It was
15 used in terms of the purpose of the tests
16 that were taken by the pharmaceutical company
17 itself, for what purposes they would be used,
18 for safe and efficacy as far as the tests
19 themselves.
20 And, more importantly, this whole
21 case involves the off-label use of a
22 particular medication which was never used --
23 it was never actually signed off on by the
24 FDA until 2006 as a safe and effective use
25 for a particular drug. And, therefore, as

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1 far as 2002 to 2006 is concerned, at this
2 time it is a confusing -- confusion in order
3 to interject a safe and effective response by
4 anybody when we haven't had any evidence yet.
5 **MS. SULLIVAN:** I understand your
6 ruling, Your Honor. The doctor continued to
7 prescribe after it was approved as safe and
8 effective for autism.
9 **THE COURT:** Well, let's hear -- let's
10 hear the actual evidence in the case. I do
11 not find that the opening -- the comments in
12 an opening argument require any kind of
13 correction or cautionary instruction.
14 **MS. SULLIVAN:** Thank you, Your Honor.
15 **THE COURT:** All right.
16 **COURT CRIER:** May I, Your Honor?
17 **THE COURT:** Yes, please.
18 **COURT CRIER:** All rise as the jury
19 enters the courtroom.
20 - - -
21 (Whereupon the jury entered the
22 courtroom at 3:29 p.m.)
23 - - -
24 (The following transpired in open
25 court in the presence of the jury:)

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1 - - -
2 **THE COURT:** All right. You may be
3 seated.
4 All right. Members of the jury, when
5 Ms. Sullivan is ready, she will address you
6 on behalf of the defendants in the case,
7 Janssen Pharmaceuticals, Johnson & Johnson.
8 **MS. SULLIVAN:** Thank you, Your Honor.
9 And thank you for the privilege of
10 hearing me in your court.
11 - - -
12 **OPENING STATEMENTS**
13 - - -
14 **MS. SULLIVAN:** Counsel.
15 Good afternoon, everyone.
16 **JURY PANEL:** Good afternoon.
17 **MS. SULLIVAN:** I'm the lucky person
18 that gets to talk to you late on a Friday
19 afternoon, and I apologize, but maybe you'll
20 bear with me for a little bit.
21 You heard Mr. Kline talk for about an
22 hour or so and he said a lot of bad things
23 about the folks at Johnson & Johnson and
24 Janssen, and that's too bad. And it's easy
25 for people to kind of throw mud and say a lot

<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 69</p> <p>1 of bad things about folks in the interest of 2 winning a lawsuit and -- 3 MR. KLINE: Objection, Your Honor, 4 right from the beginning. This is not an 5 outline of evidence. It's an attack. 6 THE COURT: I will grant some leeway 7 as to in an opening argument. 8 You may proceed, Ms. Sullivan. 9 MS. SULLIVAN: It's easy to throw a 10 lot of allegations out there, but it's going 11 to be for you to decide what's the truth, 12 what's the evidence. And at the end of the 13 day, a lot of the things Mr. Kline says is 14 not going to be supported by the evidence. 15 It's not going to be the truth. 16 In fact, you heard the Judge tell 17 you, and even Mr. Kline tell you, that this 18 is a failure-to-warn case. Did the company 19 warn about the possible risk of gynecomastia? 20 And Mr. Kline spent about an hour 21 talking, and maybe some of you noticed, 22 there's one thing that he didn't talk about. 23 He read from a bunch of documents, but 24 there's one thing that he didn't read from or 25 talk about, and that's the label that was on</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 71</p> <p>1 in the precautions section of the label that 2 this doctor had, that's on every bottle of 3 medicine that leaves the factory, that's in 4 every doctor's office in these big books that 5 they used to have -- now they're all on 6 iPhones or iPads -- but of all the labels of 7 all the medicines, it said -- and Janssen and 8 J&J told people -- "that risperidone elevates 9 prolactin," and "gynecomastia had been 10 reported." It was there right from the 11 beginning in black and white. 12 And you're going to see that -- 13 you're going to hear testimony from 14 Mr. Pledger's doctor, a man named 15 Dr. Mathisen. And he's going to testify that 16 he knew about the potential risk of this 17 hormone, prolactin, elevating, and about the 18 potential risk of gynecomastia. It was in 19 the label in black and white from the 20 beginning. 21 And the Judge is going to instruct 22 you on the law in this case. And the law is 23 that you have to have an adequate warning. 24 The law wants people to be reasonable. You 25 don't have to be perfect. It's a good thing</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 70</p> <p>1 the medicine from the very beginning. 2 And the FDA-approved label -- and 3 just to be clear, I think Mr. Kline said the 4 medicine wasn't FDA approved. It was FDA 5 approved from the beginning. It wasn't 6 approved for autistic kids until later, and 7 we'll talk about this. But from the 8 beginning it was approved by the FDA for 9 adults. 10 And on that FDA label from the 11 beginning, in the precautions section -- when 12 the FDA approves your label, there's 13 different sections of a label, and the two 14 most important are precautions and warnings. 15 And at the end of this case you folks will 16 get the evidence and you'll get the labels 17 back in the jury room to look at. And I wish 18 I could put it on the screen now to show you, 19 but the rules here are we can't put up any 20 documents until they come into evidence. But 21 I'm going to read to you what was in the 22 FDA-approved label that you'll get to see as 23 part of this case. 24 And from the very beginning, and for 25 ten years before Mr. Pledger took the drug,</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 72</p> <p>1 because none of us are perfect. But the law 2 says you have to act reasonably. Was the 3 warning adequate? Not perfect, but adequate. 4 Did it give a doctor a heads up that this was 5 a possible risk? And from the beginning in 6 the precautions, one of the most important 7 sections of the label, in the precautions 8 section, Janssen warned that this medicine, 9 Risperdal, could elevate this hormone, 10 prolactin, that you've heard some about, and 11 that gynecomastia had been reported. 12 And you're going to hear that 13 Mr. Pledger's doctor testified he knew about 14 both of those risks. He didn't know 15 everything in the world. But he knew about 16 the two risks that we're talking about in 17 this case. Hormone elevation of prolactin 18 and gynecomastia. And so you'll get to see 19 that label as part of this case. 20 Now, there's no dispute in this case 21 that Mr. Pledger, unfortunately, was born 22 autistic. He suffers from autism. He was 23 diagnosed when he was three years old, years 24 before he first started taking Risperdal. 25 And some of you probably know something about</p>

<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 73</p> <p>1 autism. I know some of you said in jury 2 selection that you knew people or had people 3 in your family. But autism is a devastating 4 mental illness. And one of the hallmarks of 5 this illness are these disruptive behavioral 6 symptoms that these kids with autism can 7 have -- and you'll hear that Mr. Pledger 8 did -- can have shrieking, screaming, head 9 banging, tantrums, pinching and biting and 10 throwing things, that last anywhere, and his 11 mother testified, anywhere from 45 minutes to 12 two hours and could occur as many as eight 13 times a day. 14 And there's no cure, unfortunately, 15 for autism. And you're going to hear that 16 doctors talk about the fact that autism kind 17 of walls these children off in some way from 18 the rest of the world. It affects their 19 ability to communicate, to interact, to 20 understand, and it's also often associated 21 with developmental disability. And you're 22 going to hear that Austin had a very, very 23 low IQ. So he really -- he really got the 24 short straw in life, the fact that he got 25 autism and he also was developmentally</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 75</p> <p>1 Help." And he's only seven years old. 2 Imagine how bad things have to be if you go 3 and say is there a medicine for this 4 behavior? He's having so much trouble in 5 school and at home. 6 And Dr. Mathisen had treated other 7 kids like Austin who had autism, and he had 8 had some success with Risperdal. It was 9 approved for adults, but it was being 10 prescribed for kids by many doctors. Because 11 one of the problems, especially back then, is 12 that there were no medicines for children 13 with mental health disorders. There weren't 14 many medicines at all, FDA approved, for 15 children because it's really, really hard to 16 get a medicine approved for a child. It's 17 hard to have parents agree to put their kids 18 in studies that you need to do to get a 19 medicine approved, and it's hard to keep 20 children with mental illness in studies. And 21 so at the time there were no drugs available 22 to help kids with autism like Mr. Pledger. 23 And so doctors like Mr. Mathisen, 24 Mr. Pledger's doctor, would prescribe 25 medicines what they call off-label, for</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 74</p> <p>1 disabled. Even though he's 20 years old now, 2 his mom, in notes and in records, say that he 3 has a mindset of a five-year-old. And that 4 fact makes it even harder to deal with these 5 disruptive behavioral problems. 6 And so you're going to see from his 7 medical records that when Austin was just 8 five years old in school, his teachers were 9 writing -- he's just five years old -- that 10 he's hitting classmates; that he's biting, 11 pinching, screaming, throwing things; that 12 he's showing aggression; that he's wandering 13 around without any sense of danger. And his 14 mother reported these tantrums, these 15 difficulties in behavior that go along, 16 unfortunately, with children with autism. 17 And so his mother, in an effort to 18 help her son and help her family, went to a 19 pediatric neurologist in Alabama, 20 Dr. Mathisen, who you'll hear about. I think 21 you're going to see his testimony on video. 22 If they don't play it in their case, we'll 23 play it in ours so you can hear from his 24 doctor. And she went to this doctor and 25 said, "Help. Is there a medicine for my son?"</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 76</p> <p>1 things that they weren't yet approved for. 2 So -- and that -- and sort of an 3 example of off-label is -- and you folks 4 probably already know this, but an example 5 is -- so aspirin was originally approved by 6 the FDA as an over-the-counter medicine for 7 headache or for backache. But then doctors 8 figured out -- and there were studies -- that 9 it could reduce heart attacks and strokes. 10 So doctors would tell some patients: Take an 11 aspirin a day or take an aspirin every other 12 day to help yourself reduce your risk for 13 heart attack. And so that was off-label, 14 because it wasn't approved for that yet. It 15 was off-label prescribing. And now some 16 aspirin companies have gotten an approval for 17 that, too. But it had been prescribed 18 off-label for a long time. And that's what 19 was happening with Risperdal. 20 Mr. Pledger's doctor and a lot of 21 doctors were prescribing Risperdal for kids 22 off-label. Why? There was nothing else. 23 They were stuck. We want to help these kids 24 with these horrible behavioral symptoms and 25 we need a medicine. And there have been a</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 77</p> <p>1 lot of studies, including by the government, 2 a government-funded study, a big study back 3 in 2002 when Mr. Pledger started taking 4 Risperdal that show that Risperdal worked 5 really, really well with children in autism 6 and it was well tolerated. And so many 7 doctors were prescribing a lot of medicines 8 off-label for mental illness, but especially 9 Risperdal for children with autism because it 10 worked, and they were trying to help their 11 patients. 12 And so the label for Risperdal when 13 doctor -- when Ms. Pledger's doctor -- 14 Mr. Pledger's doctor first started 15 prescribing it made clear -- and you'll see 16 the label. I wish I could put it up. It 17 will be easier. But you'll see that from the 18 very beginning the label said not approved -- 19 not proven safe and effective in kids yet. 20 It told doctors: Heads up. This hasn't been 21 proven safe and effective in kids yet. 22 So his doctor, Mr. Pledger's doctor, 23 knew two things. He knew -- and he admitted 24 this in his deposition -- he knew it hadn't 25 been approved in kids yet, and he knew there</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 79</p> <p>1 studies, more studies, whatever's out there. 2 So the company sent him a pretty long letter 3 that summarized every study that was 4 published on kids with autism, including 5 summarizing all the side effects. And you're 6 going to see in the summaries, there's 7 reports of gynecomastia. And that letter 8 went from the company to Mr. Pledger's 9 doctor. And he acknowledged, he knew about 10 these possible -- possible risks. 11 And what happened when Mr. Pledger 12 started taking Risperdal? Unbelievable. And 13 you're going to see from the medical records 14 that -- and Mr. Pledger went to the doctor 15 pretty regularly because of his autism. But 16 the benefits and the change in this child 17 from Risperdal were dramatic and incredible. 18 His mother writes, just after he starts 19 taking it, he's doing much better on the 20 medicine. She's telling the doctor. These 21 are the doctor's notes. He is much more 22 tolerant of his environment, less pinching, 23 no tantrums. From eight a day that last for 24 45 minutes to two hours, kicking, screaming, 25 hitting, to no tantrums as of July of 2002.</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 78</p> <p>1 was a possible risk for gynecomastia in 2 adults. So of course you're going to think 3 there's going to be a risk in kids if it's in 4 the label that there's a risk in adults. 5 So the doctor, knowing these two 6 things, still made the decision to prescribe 7 the medicine. 8 And what else is he going to do? He 9 wants to help the child. This was the best 10 medicine he thought was available, the 11 studies showed. And so the doctor made a 12 decision to prescribe it, even though he knew 13 it wasn't approved for kids and even though 14 that there was a risk reported in the label 15 of elevated prolactin and a possible side 16 effect reported of gynecomastia. 17 And you're going to hear that 18 Dr. Mathisen -- I think Mr. Kline talked 19 about sales reps going to his office. Well, 20 one of the things the sales rep did was 21 actually give Dr. Mathisen sort of an extra 22 warning. So in addition to having the label, 23 Dr. Mathisen had asked for information from 24 the company about studies in autistic kids 25 and he said let me see, you know, the</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 80</p> <p>1 Austin is doing very well at this 2 time. Again, six months later. Mom is very 3 pleased with his school year. The 4 medications appear to be effective without 5 any notable side effects. 6 And then Austin Pledger stayed on 7 this medicine for five years. And during 8 those five years, there's lots of medical 9 records, and you'll see the entries where his 10 mother reports to Mr. Pledger's doctor he's 11 doing very well. The recent increases in the 12 dose have been very helpful. As he's 13 growing, they're increasing the dose and it's 14 very helpful. Austin's doing very well. 15 Mother extremely pleased, extremely pleased 16 with the effectiveness of Risperdal. His 17 behavior is excellent. Mom is extremely 18 pleased with how he's doing in school. And 19 these are just some examples. 20 But you'll see the medical -- the 21 change was dramatic from going from a kid who 22 couldn't -- who was having so many problems 23 in school, hitting, punching, learning, he's 24 in school. He's doing better. His behavior, 25 according to his mother, is excellent. And</p>

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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 MR. KLINE: Your Honor, objection.

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1 The case is about the -- the warnings. We've
2 heard 15 minutes about how great the drug
3 was.
4 THE COURT: Well, I'm just not --
5 that's denied. Overruled.
6 MS. SULLIVAN: 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 MR. KLINE: Objection.

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1 THE COURT: That's sustained.
2 Counsel, please stick to an outline
3 of your case as opposed to an argument at
4 this point.
5 MS. SULLIVAN: Your Honor --
6 THE COURT: Are you intending to
7 present all of this evidence?
8 MS. SULLIVAN: Yes, Your Honor.
9 THE COURT: All right. Then why
10 don't you tell us which witnesses you are
11 going to use to make these points.
12 MS. SULLIVAN: 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

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1 diseases, fatal blood diseases.
2 There are no perfect choices. All
3 medicines have risks. And all medicines, if
4 they go through the FDA approval process,
5 have been found to have benefits. And so all
6 medicines have risks and benefits, including
7 Risperdal. And you're going to see that
8 Mr. Pledger's doctor made choices about which
9 one was best. And his doctors after
10 Risperdal had made choices in terms of after,
11 the medicines that were best.
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

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 85</p> <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. 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>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 87</p> <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. 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. 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? 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>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 86</p> <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. 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. 24 They talk about the fact, you know, 25 try diet, try more exercise, and he did lose</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 88</p> <p>1 downwards. Things don't go well for 2 Mr. Pledger, unfortunately, once the second 3 doctor takes him off of Risperdal. 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. 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. 22 MR. KLINE: Your Honor, respectfully, 23 I hate to interrupt, but there is nothing 24 here -- 25 THE COURT: Is there an objection?</p>

<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 89</p> <p>1 MR. KLINE: Yes. I object. 2 THE COURT: 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 MR. KLINE: Okay. I'll be quiet. 8 MS. SULLIVAN: 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>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 91</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>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 90</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>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 92</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>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 93</p> <p>1 Mrs. Pledger and her family or her husband, 2 have come to believe that Janssen and Johnson 3 & Johnson have caused their son's 4 gynecomastia, as you heard, gynecomastia, 5 which is enlarged breasts or excess of breast 6 tissue. 7 And you're going to hear the evidence 8 that none of his doctors in Alabama, while he 9 was on Risperdal -- and this is a kid who 10 went to the doctor a lot. He was examined by 11 pediatricians. He was seen by psychiatrists. 12 None of them ever wrote in their medical 13 records that he had enlarged breasts while on 14 Risperdal or that Risperdal was causing that 15 kind of problem. You're not going to see any 16 medical records while he was on Risperdal 17 where his mother complained to doctors that 18 he was growing what Mr. Kline called "female" 19 breasts. None of that was in any of the 20 medical records while he was on Risperdal. 21 And in fact, the first time he was 22 diagnosed with gynecomastia, Mr. Pledger, 23 with this condition that we'll talk more 24 about, was seven years after he stopped 25 taking Risperdal, seven years after. After</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 95</p> <p>1 Risperdal was an expert hired for this 2 litigation by the plaintiffs' lawyer. He's 3 the only doctor who's examined Mr. Pledger 4 and diagnosed him with gynecomastia -- the 5 doctor hired by plaintiffs' lawyers here for 6 this lawsuit. And you're going to hear 7 something about Dr. Goldstein. And he saw 8 him just a couple months before this lawsuit, 9 seven years after Mr. Pledger stopped taking 10 Risperdal. And he said, yeah, seven years 11 later, oh, yeah, it must have been from the 12 Risperdal. And you'll hear from 13 Dr. Goldstein. You'll hear that he actually 14 practices in Missouri. He's an 15 endocrinologist in Missouri, and saw 16 Mr. Pledger not in a doctor's office but in a 17 Holiday Inn in Alabama with plaintiffs' 18 lawyers there and said, yeah, it's 19 gynecomastia from Risperdal, and so you folks 20 can evaluate that. 21 There's a condition called 22 pseudogynecomastia. And it's the same as -- 23 it looks the same as gynecomastia, in that 24 it's just men with excessive breast tissue. 25 And all of us know that everybody has</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 94</p> <p>1 he became morbidly obese, after seven years 2 on other medicines, he was diagnosed with 3 gynecomastia. 4 And the first time that the Pledgers 5 heard that Risperdal caused gynecomastia, it 6 wasn't from a doctor at all. It was from one 7 of those plaintiff lawyers' ads that run on 8 TV, 1-800 call if you've taken Risperdal. 9 Well, they called. The plaintiffs' lawyers 10 sued. But the truth is and the evidence is 11 going to show that Mr. Pledger looks just 12 like boys who get enlarged breast tissue from 13 obesity, including morbid obesity, and from 14 puberty. And we'll talk a little bit about 15 pubertal gynecomastia. 16 And pubertal gynecomastia -- and just 17 going back to that point. So none of their 18 doctors in Alabama ever told them that 19 Risperdal caused gynecomastia. In fact, 20 while he was on Risperdal, no one ever 21 mentioned it in the medical records. The 22 person that first told them that was a 23 lawyer. 24 And the only person to actually 25 diagnose Mr. Pledger with gynecomastia from</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 96</p> <p>1 breasts. Women have breasts. Men have 2 breasts. Women generally have larger 3 breasts, but all people have breasts. We all 4 come in different shapes and sizes. We've 5 all seen some men in the pool -- 6 THE COURT: Counsel, are you going to 7 present witnesses on this? 8 MS. SULLIVAN: Yes. 9 THE COURT: Who? 10 MS. SULLIVAN: This is going to come 11 from -- 12 THE COURT: Well, tell the jury, 13 because right now it sounds like you are 14 teaching us. 15 MS. SULLIVAN: And you're going to 16 see an endocrinologist come in, Dr. Vaughan, 17 from Alabama and talk about -- and their 18 expert as well, Dr. Goldstein, the guy from 19 Missouri -- will talk about the fact that 20 there's this phenomenon pseudogynecomastia. 21 And we've all seen men, you know, in public 22 pools or at the Jersey Shore or without their 23 shirt who have enlarged breasts. And it's 24 associated with obesity or with being 25 significantly overweight.</p>

<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 97</p> <p>1 And you're going to see the expert in 2 this case, Dr. Vaughan, who examined Mr. 3 Pledger for us. After Johnson & Johnson got 4 sued, we hired an endocrinologist in Alabama 5 who lived by Mr. Pledger, who's not been 6 involved in any of these lawsuits, and said 7 can you take a look at him for us? And he 8 said -- he examined him and he called us up 9 and he's got a report, and you'll hear from 10 him. 11 Are you okay? 12 A JUROR: I'm trying to move this 13 chair up. 14 MS. SULLIVAN: Okay. And he -- he 15 examined Mr. Pledger in his hotel -- in his 16 medical office in Alabama. And he found that 17 half of Mr. Pledger's enlarged breasts, which 18 is consistent with obesity, and the other 19 half when you feel it, it was glandular, and 20 it looked just like pubertal obesity, 21 pubertal gynecomastia, which he sees in boys 22 as an endocrinologist all the time. 23 And you may know of this, but 24 gynecomastia, this condition in men, has been 25 around a long time. Men have been getting</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 99</p> <p>1 condition. There's no -- thankfully, there's 2 no threat to physical health in any way. 3 It's not -- it doesn't have an adverse effect 4 on your physical health in any way. It's 5 benign. And many people correct it, as 6 you'll hear, through same-day surgery. They 7 can suck out the fat or cut out tissue and 8 your chest can look fine. And you'll hear it 9 cost a couple of thousand dollars. It's an 10 outpatient -- typically an outpatient 11 procedure. But you'll hear that apparently 12 Ms. Pledger doesn't want to do that. And 13 obviously everybody respects her decision to 14 do it. But a lot of people do have and can 15 have it corrected. 16 Now, the plaintiffs talk a lot in 17 this case about how -- how Risperdal elevated 18 this hormone, prolactin. And that was in the 19 label, as you'll see from the beginning. And 20 they think that Mr. -- or they're going to 21 claim that Mr. Pledger got gynecomastia 22 because Risperdal elevated his prolactin 23 level. 24 They have one problem with that. The 25 only test Mr. Pledger ever had for prolactin</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 98</p> <p>1 gynecomastia way before Risperdal was ever 2 discovered. It's actually fairly common in 3 puberty. Boys who go through puberty, their 4 hormones are going, you know, crazy and so 5 they can develop enlarged breasts. Some only 6 a little bit, some bigger, and some -- and 7 some men, about 20 percent in some studies, 8 it never goes away. 9 And so Mr. Pledger, even their expert 10 will acknowledge, has gynecomastia that looks 11 just like men and boys who have gynecomastia 12 from puberty and obesity who never took 13 Risperdal. It looks just like that. 14 And you'll see the pictures. It 15 looks the same. I mean, they keep calling 16 it, you know, female breasts. But it's a man 17 now, who's 20, who has excessive breast 18 tissue in part from obesity and in part 19 because he developed pubertal gynecomastia as 20 he went through puberty. And you'll see 21 those photographs and you'll hear that 22 evidence. 23 And one thing that the experts you'll 24 hear from will make clear is that 25 gynecomastia is what they call a benign</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 100</p> <p>1 elevation showed it was completely normal. 2 It wasn't elevated one iota. And so you're 3 going to hear that evidence. That test was 4 taken -- he was on the medicine for five 5 years; and when he switched doctors to this 6 Dr. Paoletti I talked about, so after five 7 years of taking Risperdal, every day for five 8 years, they test his prolactin. It's normal. 9 They have no evidence in this case that 10 Mr. Pledger ever had elevated prolactin. 11 And so when you hear that evidence, 12 you'll -- you can consider whether in light 13 of that, it's more likely that this is a kid 14 who has elevated -- who has excessive breast 15 tissue as a result of his being significantly 16 overweight and, like many boys, who get 17 pubertal gynecomastia. 18 I'm going to talk a little bit about 19 Johnson & Johnson and Janssen. Many of you 20 probably heard of J&J and Janssen. I should 21 reintroduce myself. We met in jury 22 selection, but I'm Diane, Diane Sullivan, and 23 I represent the folks at Johnson & Johnson 24 and Janssen. And Janssen is their 25 pharmaceutical arm. They make prescription</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 101</p> <p>1 medicines. And Johnson & Johnson, as you 2 heard, has research facilities here in 3 Pennsylvania, and they have facilities in New 4 Jersey, and also some of their global things 5 are in Belgium. And you're going to hear 6 from some of the folks at J&J in this case. 7 And we have with us one of the doctors at 8 J&J, Dr. Danielle Coppola. 9 Dr. Coppola, will you stand up and 10 say "good afternoon." 11 DR. COPPOLA: Good afternoon. 12 MS. SULLIVAN: And Dr. Coppola is one 13 of the many doctors at J&J who worked on 14 Risperdal, including on some of the drug 15 safety issues. So she'll be here throughout 16 the trial on behalf of the folks at J&J. 17 And J&J and Janssen, Johnson & 18 Johnson, has been in business for almost 150 19 years, since the 1800s. They're not some 20 fly-by-night company. And Janssen and J&J 21 have discovered and developed many, many 22 prescription medicines and have got FDA 23 approval. And you're going to hear from 24 those doctors. They know how to do these 25 studies. They know how to do the rigorous</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 103</p> <p>1 in that class, the first generation, that 2 were approved. But one of the problems with 3 the first generation antipsychotics -- and 4 some of us are old enough to remember the 5 '60s, people walking around with some of 6 these movement disorders, like -- they call 7 it tardive dyskinesia or muscle rigidity, and 8 so these poor people who had schizophrenia or 9 bipolar or other mental illnesses would take 10 these medicines. They were able to be out in 11 the world, but they sometimes would get these 12 horrible side effects. It might make them 13 feel like kind of like freaks. So 14 scientists, including scientists at Janssen 15 and J&J, said, you know, maybe we can do 16 better for these people, and they discovered 17 and developed what's called the second 18 generation antipsychotics. And Risperdal was 19 one of the first. 20 And you're going to hear the second 21 generation antipsychotics like Risperdal were 22 heralded as big breakthroughs in the field of 23 mental health because it -- it could quiet 24 the voices of schizophrenia, it helped 25 bipolar patients. You're going to see it</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 102</p> <p>1 and exacting testing that you need to do to 2 get a medicine approved by the FDA. 3 And I'm going to talk briefly about 4 this class of antipsychotics. 5 So in the -- and you're going to hear 6 from our psychiatry expert, Dr. Robb, who 7 will talk a little bit about it, too. But 8 before the 1960s there wasn't -- there really 9 wasn't mental health medicines for people 10 with serious mental health issues like 11 schizophrenia, bipolar, autism, disruptive 12 disorders. There wasn't anything. And so 13 many times those folks would have to be 14 institutionalized. You read about horror 15 things like lobotomies and straitjackets. 16 And then the first generation antipsychotics 17 were discovered. And Haldol was the first. 18 And that was discovered by Janssen. And it 19 changed people's lives. It enabled people 20 who otherwise might have been 21 institutionalized or homebound to walk around 22 in the world, to have jobs. It controlled 23 the voices, the schizophrenia, and it worked 24 pretty well. 25 And then there were other medicines</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 104</p> <p>1 helped kids with autism, and it had less -- 2 these horrible muscle, neurological side 3 effects were much less frequent, according to 4 the Department of Health, with the second 5 generation antipsychotics as compared to the 6 first. And so they're now the first line of 7 treatment for mental health patients. 8 And you're going to hear that 9 Risperdal in particular is the most widely 10 prescribed antipsychotic in history because 11 it works. And it's got a relatively good 12 safety profile compared to other 13 antipsychotics. It's been on the market for 14 20 years. It's still on the market today. 15 We have 1,400, one thousand four hundred, 16 studies on Risperdal. It's been used in 17 millions of patients. 18 And doctors generally aren't stupid. 19 They prescribe what works for their patients 20 and what their patient -- and what's safe. 21 And the medicine's been on the market for 20 22 years; has a pretty good safety history. And 23 you're going to hear about that in terms of 24 the evidence during this trial. 25 If there was a big safety problem in</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 105</p> <p>1 terms of gynecomastia with this medicine, 2 after 20 years of use, we'd know it. 3 MR. KLINE: You do. 4 MS. SULLIVAN: And so you're also 5 going to hear in this case, Janssen has to 6 live in the world of FDA -- all 7 pharmaceutical companies have to live in the 8 world of FDA regulations. And even their 9 expert will admit that the FDA is sort of the 10 gold standard in the world; that we have the 11 most rigorous, exhaustive, exacting standards 12 for approval of medicines here in the United 13 States, in terms of what companies have to do 14 to get a medicine approved. 15 So after -- and so it usually takes 16 between seven and eleven years. So it's not 17 like you can discover a medicine and sell it 18 the next week. It takes about seven to 19 eleven years to get a medicine approved by 20 the FDA. It costs a fortune, and you have to 21 do a lot of study, including animal testing 22 for a couple years; studies in patients where 23 you compare people on the medicine as 24 compared to people who don't take the 25 medicine, and then you collect all of the</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 107</p> <p>1 warnings, this in adverse events, and the FDA 2 says thank you very much and then they mark 3 it up and say this is what we want you to say 4 in your label. 5 And the FDA label has pretty strict 6 formats in terms of where things go. And you 7 may look at it and say, oh, well, this looks 8 like little print. But that's the FDA form 9 that everybody has to follow because doctors 10 know exactly where to look. 11 And so the FDA reviewed and approved 12 the label for Risperdal not once but several 13 times as the company continued to study the 14 medicine and continued to get it approved for 15 other things, like autism, like bipolar 16 disease. 17 And you're going to also see the 18 evidence that one of the things the FDA 19 looked at in the course of studying this 20 medicine was prolactin and gynecomastia, 21 because all of the antipsychotic medicines 22 have that risk. And if you look at the 23 label, as you'll see in this case through our 24 expert, Dr. Robb, all of the antipsychotics 25 are labeled for elevated prolactin and</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 106</p> <p>1 side effect information and you have to send 2 all that stuff to the FDA. And that takes 3 years. 4 Risperdal was studied in patients for 5 eight years before it was first approved by 6 the FDA in 1993 for adults with psychosis 7 associated with schizophrenia and other 8 things. 9 And there's going to be no dispute in 10 this case -- and their experts will 11 acknowledge -- that in the course of those 12 studies, Janssen, the doctors and scientists 13 at Janssen, reported every single side effect 14 to the FDA. Every time gynecomastia was seen 15 in one of their studies, their experts will 16 admit we sent it to the FDA. And so the FDA 17 analyzed all of that data. And when your 18 medicine gets approved, one other thing that 19 happens, the FDA has final say on your label. 20 Companies can't just say, oh, anything they 21 want on the label for a prescription 22 medicine. What they do is send a draft -- 23 after the FDA approves you, you can send a 24 draft to the FDA, saying we think, you know, 25 we should say this in precautions, this in</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 108</p> <p>1 reports of gynecomastia, because it's -- it's 2 an associated risk with these class of 3 medicines. So it's no surprise that 4 Risperdal in this class would have that found 5 in their label as well because it goes with 6 this class of medicines. 7 And so J&J and Janssen continued to 8 study Risperdal after it was approved for 9 adults. 10 And I think Mr. Kline said the FDA 11 denied the approval for kids a couple of 12 times. Well, that's not going to be the 13 evidence, and that's not going to be the 14 truth. What Janssen wanted to do, as you'll 15 hear, is they -- they knew that doctors were 16 prescribing Risperdal based on the adult 17 approval before it was getting approved for 18 kids, and they were worried about dosing 19 information. So they said, Can't we tell the 20 doctors what we think is the right dose for 21 kids? And the FDA says, No, you can't do 22 that. And you know why? The FDA has very 23 strict rules about not putting in your label 24 something about an indication that's not 25 approved.</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 109</p> <p>1 So because the label -- because 2 Risperdal wasn't approved for autism yet, 3 Janssen was told they couldn't put anything 4 about dosing for kids in the label, but they 5 tried. 6 And you're also going to see that the 7 FDA in 2006 approved Risperdal for use in 8 autism. And you're going to hear about the 9 medical reviews that -- the FDA's statements 10 about Risperdal through some of the experts 11 and witnesses, company witnesses in this 12 case. And what the FDA said, that this 13 medicine would meet an important health need; 14 that there's currently no medicine approved 15 for this indication; that there is a public 16 health need for this drug; and that it was 17 effective; and that, quote, this approval 18 should benefit many autistic children as well 19 as their parents and other caregivers. 20 So looking at all of the safety 21 studies in children -- and there's 18 studies 22 that Janssen submitted to the FDA -- you'll 23 see that the FDA found that this was 24 effective and well tolerated in children and 25 approved it and touted it as a public health</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 111</p> <p>1 specifically, told doctors specifically that 2 Risperdal was associated with higher levels 3 of prolactin than other antipsychotics, in 4 black and white on the label. And it gave 5 the rates of gynecomastia in kids, 6 2.3 percent, which is higher than adults. 7 And you're going to hear, in large measure, 8 because of the kids going through puberty in 9 the studies, which drive up the number, but 10 they told doctors. 11 And what happened when Dr. Mathisen, 12 Mr. Pledger's doctor, got this label for 13 children that said that Risperdal was worse 14 on prolactin than others? Did he stop 15 prescribing? No. You're going to hear he 16 continued to prescribe the medicine for 17 Mr. Pledger even after he got the 2006 label 18 that had the specific warning for children. 19 And you'll listen to that evidence. It 20 didn't change his decision at all to 21 prescribe the drug. Why? Because it was 22 helping Mr. Pledger. 23 And you're going to hear -- I think 24 you heard a lot about the study Mr. Kline was 25 talking about, this Findling study, what was</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 110</p> <p>1 benefit for these kids that really needed 2 help. 3 And so they -- so Janssen did the 4 hard stuff. I mean, it's hard to get a 5 medicine approved for kids. They didn't give 6 up. They did the hard work. FDA at one 7 point said not approvable now, do some -- we 8 want more analysis, we want more safety data. 9 The doctors at Janssen and Johnson & Johnson, 10 they kept studying it and they kept giving 11 the FDA the information they wanted and the 12 FDA said, Yeah, you've done it. We've seen 13 the data. This is a good medicine for kids, 14 and we're going to approve it for kids who 15 have problems with autism. 16 And they also dictated -- you're 17 going to see the markup -- what Janssen 18 should say in that label for the pediatric, 19 for the kids' indication. 20 And I think Mr. Kline said something 21 like, Oh, when they got approved for the 22 autism in kids, Janssen, quote, came clean on 23 the label. 24 Well, the label in pediatrics did say 25 that -- and you're going to see -- it said</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 112</p> <p>1 in the study, what was not in the study, the 2 drafts. You're going to hear the actual 3 evidence on that. And there were different 4 time periods. And one of the things that the 5 plaintiffs' lawyers here and their experts 6 are trying to do, and you'll decide whether 7 it's right or fair, is kind of cherry-pick 8 out one time period and say, Ha, this means 9 Risperdal causes gynecomastia. 10 But if you look at all the data, if 11 you look at the whole 16 different time 12 periods that are looked at, no other time 13 period had any elevation of risk for 14 gynecomastia. And there was a famous aspirin 15 study where the doctor -- where aspirin was 16 shown to reduce heart attacks, and the 17 doctors wanted to look at what you do when 18 you chop up data, slice it up. And they said 19 let's slice it up by Zodiac sign. Let's see 20 if it reduces heart attacks in Leos and 21 Geminis and Virgos and they found -- 22 MR. KLINE: Your Honor, Your Honor. 23 THE COURT: That's sustained. 24 Sustained. 25 MR. KLINE: Really.</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 113</p> <p>1 MS. SULLIVAN: And the point is when 2 you slice and dice data, as the plaintiffs' 3 lawyers you'll see are trying to do here and 4 their experts, you get false results. You 5 got to look at all the data for all the time 6 periods. You can't just slice it up and 7 cherry-pick out one piece. And you'll hear 8 that from the experts. 9 Now, they talked a little bit about 10 Dr. Kessler, and he used to work at the FDA. 11 They said he was the former commissioner of 12 the FDA; and he was. But that was 20 years 13 ago. Dr. Kessler hasn't been at the FDA for 14 20 years. He's going to be their first 15 witness. He's going to have to acknowledge 16 he's not here speaking for the FDA now. He's 17 not authorized to speak for the FDA now. 18 What Dr. Kessler's been doing for the 19 last eight years or so is making millions of 20 dollars testifying for plaintiffs' lawyers. 21 He charges \$1,000 an hour. He's going to be 22 their first witness, and he's going to dump 23 all over Janssen. And so you're going to 24 decide whether what he's saying is credible 25 after you hear the whole case or whether this</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 115</p> <p>1 you're going to hear a lot of science and 2 regulatory issues and statistics. And some 3 of it may sound confusing to you, at least it 4 was confusing to me because it's the first 5 time you're hearing it. But you've got 6 something that's going to let you cut through 7 a lot of that stuff and get to the truth and 8 get to the evidence. 9 And as you're listening to the 10 evidence, I just ask you to hold the 11 plaintiffs' allegations up into the light of 12 your common sense. As you're listening to 13 the evidence, ask yourself: If Risperdal 14 caused Mr. Pledger's gynecomastia, why is it 15 that the first person who said that was the 16 plaintiff's lawyer, not one of his doctors? 17 If Risperdal really caused 18 Mr. Pledger's gynecomastia, why wasn't he 19 diagnosed with that while he was on 20 Risperdal? Why did it take a plaintiff's 21 lawyer's expert to say it seven years ago? 22 And if Risperdal really caused 23 Mr. Pledger's gynecomastia, why does he look 24 just like boys, now a young man, who have 25 enlarged breasts from obesity and pubertal</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 114</p> <p>1 is just a hired \$1,000-an-hour expert who 2 testifies, literally, every couple weeks 3 against some pharma company. 4 He's never -- every single case he 5 comes in: Bayer failed to warn; Merck failed 6 to warn; GSK failed to warn; Pfizer failed to 7 warn; Allergan failed to warn. But you'll 8 hear from Dr. Kessler and you can decide for 9 yourselves how credible he is because he's 10 going to be fired up, because he testifies a 11 lot against pharmaceutical companies. He's 12 going to be fired up to dump all over the 13 folks at Janssen. And he's going to say we 14 failed to warn. 15 But the people who actually work at 16 the FDA now, the good public servants who are 17 working hard, who don't make a thousand 18 dollars an hour, they've never concluded that 19 Janssen failed to warn. They've never said 20 that. And they've seen a lot more data than 21 Dr. Kessler. 22 So the Judge gave you an instruction 23 in this case to use -- I think in the 24 beginning -- to use your common sense, and 25 he'll tell you that again at the end. And</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 116</p> <p>1 gynecomastia? 2 And as you're listening to the 3 plaintiffs' evidence, ask yourself: How is 4 it that Janssen failed to warn if the 5 possible risk of gynecomastia and elevated 6 prolactin was in the label from the 7 beginning? And his doctor knew. 8 If you -- if you listen to the 9 evidence with your light of common sense, I 10 think it will guide you here. It will get 11 you to the truth. It will get you to the 12 facts. 13 One last thing. The plaintiffs are 14 lucky here. They get to go first. They get 15 to put on their case for about two weeks 16 before we can put on any witnesses or any 17 evidence. So if you'd be good enough to just 18 keep an open mind until you hear the whole 19 case, to hear our part of the case, too, I'd 20 really, really appreciate it. 21 As you listen to them, say I heard 22 that, you know, and I'm thinking what that 23 sounds like, but I'm going to wait to hear 24 the other side, and I would really, really 25 appreciate it.</p>

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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.
5 Thank you.
6 **THE COURT:** All right. Thank you,
7 Ms. Sullivan.
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...
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.

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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.
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.
14 All right. So then have a great
15 weekend. We'll see you here at 1 o'clock on
16 Monday.
17 **COURT CRIER:** All rise as the jury
18 exits the courtroom.
19 - - -
20 (Whereupon the jury exited the
21 courtroom at 4:22 p.m.)
22 - - -
23 (The following transpired in open
24 court outside the presence of the jury:)
25 - - -

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1 **THE COURT:** All right. You may be
2 seated.
3 Are there any objections or
4 exceptions now to Ms. Sullivan's argument?
5 **MR. KLINE:** Yes.
6 **THE COURT:** Okay.
7 **MR. KLINE:** 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.
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.
25 What we have to say in this

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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.
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.