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Pledger v. Janssen, et al.

<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 17</p> <p>1 reason it's a problem is because it's not 2 filtered. 3 See, here we have evidence that comes 4 in and then it gets filtered by the Rules of 5 Evidence and I -- we get to apply some laws 6 to it, and then you consider that as 7 filtered. Not so when it's on the Internet. 8 We don't know what you're reading there. 9 Some of it's true, but a lot of it is fraud. 10 A lot of it's fake. 11 So that's -- so I'm letting you know 12 really up front how important it is. Because 13 in the end, you will find out in this case -- 14 or many of these cases -- that we're going to 15 hear from expert witnesses who are some of 16 the world's most experts in their expertise, 17 in what they're going to talk to you about. 18 Why do we -- what do we need the Internet 19 for, okay? We have the experts that are 20 coming in here to tell you their views of 21 this case, all right? 22 Finally, you have those blue notes, 23 these notebooks, right? Here's my 24 instructions about that: 25 You know, until a few years ago -- I</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 19</p> <p>1 your jury. That's what it's really for. 2 But, you know, I'm not going to -- I can't 3 tell you what to do, but that's my suggestion 4 to you. 5 And the other thing about it is, is 6 that these notes are confidential, and no one 7 else is going to see them unless you share 8 them. And they are kept by us over the 9 breaks, you know, when we take breaks, and 10 also overnight and all of that. And you're 11 allowed to take notes for everything in this 12 case but the final jury charge that I give 13 you. So, you know, use them wisely, okay. 14 In the administration of this case, 15 what we're going to do is we're going to 16 start this case. We may just hear the 17 openings today. That's possible. There's 18 still lots of legal work out there for 19 everybody. But so we might just do the 20 openings. 21 And then on Monday we're going to 22 start at 1 o'clock. That's because of a 23 personal matter of mine on Monday morning 24 that you all know about. And then after that 25 I think we're just going to roll, okay?</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 18</p> <p>1 guess the country, we've been what, 250 2 years, or whatever we are, right? We never 3 had notes. It wasn't our custom to have 4 juries take notes in jury trials. Again, I 5 don't really know the reason for that. I 6 know that when I went to law school and I was 7 trying cases, no, there were no notes. You 8 know, everybody had to remember all the 9 facts. We changed that. 10 However, it is also important to 11 remember that it is your observation of the 12 witnesses that is as important as some of 13 these details that is actually said, okay? 14 It's like when you're talking to your 15 kids or neighbors, whatever, you know, how 16 did they look like when they're talking? You 17 know, what kind of emotion are they showing? 18 What do you see? If you're kind of 19 squirreling around in your notebook, you 20 know, like we're in second grade and that's 21 what you're doing, you miss a lot of that. 22 So I'm encouraging you to take notes 23 but to do so for an important point that's 24 going to jog your memory when you want to 25 talk about the case with the other folks in</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 20</p> <p>1 You are -- we're going to go for 2 about 45 minutes to an hour at a time and 3 then we'll stop. If any of you have to stop 4 before, you know, during the testimony, just 5 raise your hand, and Marianne will get me to 6 stop, okay, or I'll stop, but after a 7 stoppage or something. 8 But we are -- then we're going to 9 take a lunch break. Usually my custom is 10 from 12:30 to about quarter to 2:00, all 11 right. So that's the game plan, all right. 12 Again, thank you for being here. 13 It's going to be interesting. And under the 14 Rules of Civil Procedure, it is the plaintiff 15 that addresses the jury first in opening 16 arguments. So I will now have the pleasure 17 of introducing Mr. Thomas Kline to address 18 the jury. 19 - - - 20 OPENING STATEMENTS 21 - - - 22 MR. KLINE: Your Honor, thank you 23 very much. It's a pleasure to be in your 24 courtroom. 25 Good morning, everyone. Good</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 21</p> <p>1 afternoon, I guess it is. It seems like 2 morning. Let me angle myself. I think I'll 3 be fine. 4 It's my job in an opening 5 statement -- of which I've given many, many 6 over a long time -- to outline the evidence 7 for you and both to let you know the 8 challenge as well as the opportunity as well 9 as to kind of keep track of me. I have some 10 extensive notes in front of me, and my job is 11 to be disciplined and organized and very 12 thorough and to stay on track. So you'll see 13 that I have a very specific outline in the 14 works for you to help guide you through the 15 evidence that we're going to see. 16 The plaintiff has a very specific 17 burden of proof. We have a very specific 18 case, and we intend to prove it in a very 19 disciplined and a very organized fashion so 20 that you can understand it. 21 With that in mind, this case is about 22 a drug, a pharmaceutical drug called 23 Risperdal, R-I-S-P-E-R-D-A-L, also known as 24 risperidone, and a boy named Austin Pledger. 25 Austin was an autistic boy, now a</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 23</p> <p>1 from a -- both a rise in his body's prolactin 2 level -- and I'll tell you what that is -- as 3 well as something that happens on the drug 4 which is his weight gain. Austin took 5 Risperdal first when he was 8 years old, a 6 little boy. He's now 20. 7 The condition of these female breasts 8 is known as -- and you'll hear this word over 9 and over and over again -- gynecomastia, 10 G-Y-N-E-C-O-M-A-S-T-I-A, gynecomastia. 11 Essentially, you'll hear a couple of little 12 twists on the definition, but it's abnormal 13 breast growth in a male, or a boy, as it was 14 in this case. 15 Austin had this breast development 16 when he was a little boy. Austin's lived 17 with the condition for over a decade. He 18 has -- which is half of his life. It is 19 permanent unless they were to be removed by a 20 significant surgery, which is called a 21 mastectomy. Either way, he has 22 disfigurement. 23 Now, we're going to show you that 24 Janssen knew all the time that he took the 25 drug that the drug had increase in prolactin</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 22</p> <p>1 young man, age 20. There will be no dispute 2 he has just the most loving, wonderful 3 mother, Benita Pledger. He lives with his 4 parents in Alabama. And they are, without 5 dispute -- it will not be disputed in this 6 case -- a nice family, and a boy who has 7 significant -- a significant disability. Mom 8 is his legal guardian. 9 Janssen Pharmaceuticals, part of 10 Johnson & Johnson, is a company. They are 11 incorporated in Pennsylvania. They have 12 facilities outside of Philadelphia, and they 13 also are in New Jersey. They're a 14 Pennsylvania corporation, so we're here 15 bringing you here to this courthouse. 16 Austin has a deformity. He has a 17 deformity not for a woman but for a man. He 18 has large female breasts, obvious. You'll be 19 seeing photographs during the case. They 20 are, I think, what we could describe as large 21 pendulous breasts, not some small, little 22 thing, but a significant, for a male, 23 deformity. 24 Janssen made the drug Risperdal. It 25 caused him to develop those female breasts</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 24</p> <p>1 levels and that there was an association with 2 children and adolescents taking the drug 3 having this distressing result. Did I make 4 that term up, "distressing result"? No. 5 You're going to see it right in the medical 6 literature that they helped create. It is 7 indeed a distressing result. 8 Janssen knew all the time that he was 9 taking the drug, from July of 2002 through 10 April of 2007, that this drug, this drug, had 11 a greater incidence of the condition of 12 gynecomastia than any of the other 13 antipsychotic drugs that were on the market. 14 How do I know that? Because they say it in 15 their own internal documents. 16 Lawyers like myself, Mr. Itkin, 17 Mr. Gomez, when we represent a family -- or 18 in this case a little boy -- we get the right 19 to see the internal documents, to see what 20 they're saying, what they're thinking, inside 21 the company. 22 Austin's on the drug from July 10, 23 '02 to April 21, '07 -- 2,011 days, 302 24 weeks. 25 Austin's mom, this good mom here,</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 25</p> <p>1 knew nothing about this risk. And, in fact, 2 she even called the company and she asked the 3 question -- it's in their notes. Whenever 4 you call a company, a pharmaceutical company, 5 they take down what you say. She asked them, 6 "What are the dangers?" 7 I'm here to show you now that Austin 8 has this condition what the real dangers 9 were. 10 And Austin's physician, to whom a 11 warning in a case like this is directed -- it 12 is a pharmaceutical prescription medication, 13 and therefore, a warning goes to the doctor 14 in an official form, in an official label, or 15 other ways. 16 For example, you're going to hear 17 that in this case, this drug, which was not 18 approved at the time by the FDA, not approved 19 at this time by the FDA for use in 20 adolescents and children, Janssen 21 Pharmaceuticals visited this doctor 21 times 22 and never told them the real risks that I'm 23 going to tell you here that we've discovered. 24 He didn't know that there was a 25 higher incidence of gynecomastia with the</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 27</p> <p>1 the drug, and 2003 and '04 and '05, and a 2 label change in 2006. And I'm going to show 3 you what they say in 2006, which is that the 4 drug was worse than the competitors. Never 5 told his doctor that at the time. 6 Now, this drug company had a duty to 7 be transparent -- transparent, seeing through 8 the window, that window I can see out; it's 9 transparent -- or should you be translucent, 10 opaque glass? The sun might come in a little 11 bit, but I couldn't see what's out there. 12 You know, I'm going to show you a 13 document in this case where they were 14 actually trying to decide with the key 15 information whether they were going to be 16 transparent or translucent. That's going to 17 be part of what you'll need to measure, 18 whether they negligently failed to provide an 19 adequate warning. 20 Nearly the entire time that Austin 21 was taking the drug, it was not approved, as 22 I said, by the FDA. And when it was finally 23 approved by the FDA, when it was finally 24 approved in 2007, Janssen admitted that 25 breast deformity was frequent, as in more</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 26</p> <p>1 drug. Austin's doctor, Dr. Mathisen, didn't 2 know that the drug was worse than the other 3 choices in terms of creating female breasts. 4 And he didn't know that the drug was known to 5 raise -- and I'm going to give you a little 6 bit more than you might want at first, but I 7 have to tell you -- peak prolactin levels -- 8 that's a blood test, and you can tell -- that 9 directly correlated to gynecomastia. 10 They knew that the drug increased 11 prolactin levels at weeks 8 to 12 and that 12 that was associated with gynecomastia. They 13 never told Austin's mom. They never told 14 Austin's doctor. They had a key table that 15 they never even told the FDA, and I'll get to 16 that story in a minute. 17 Now, one important part of the case, 18 one important part of the case is when faced 19 with a choice, was this drug worse than other 20 drugs that he could have used that wouldn't 21 have had this problem -- and you're going to 22 see in this case two different prescribing 23 labels: One from 2006, which was in effect 24 when he took the drug, and one from -- I'm 25 sorry. Did I say 2006? 2002, when he was on</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 28</p> <p>1 than one in a hundred, rather than what it 2 told the world and every doctor who 3 prescribed the drug the time when Austin got 4 it as an eight-year-old; that the risk was 5 less than one in a thousand, rare. 6 His doctor was told that the 7 condition was rare. It's right in their 8 label. You're going to hear a big fancy 9 presentation, and you're going to see all 10 things that are going to go on here for all 11 the weeks. Keep your eye on whether anything 12 changes in the statement that I told you. 13 They said it was rare, and it in fact was 14 frequent. They said it was less than one in 15 a thousand, and it in fact was something like 16 two to three in a hundred or maybe as many as 17 twelve in a hundred, which I'll get to in a 18 minute. 19 That's my introduction to tell you 20 that's why we're here on this very serious, 21 very important mission for this little boy -- 22 to prove to you that drugs should be safe and 23 that drugs should be warned about and that 24 this drug did not have the correct 25 prescribing information and this doctor did</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 29</p> <p>1 not have the information that he needed. And 2 he'll tell you that directly. His deposition 3 testimony says so. And any characterization 4 of it you will weigh it against what you 5 really see and read in his deposition. 6 Now, how am I going to prove the case 7 to you? Out of their documents, number one. 8 Keep your eye on them. 9 Number two, I'm bringing to the 10 courtroom early next week David Kessler, M.D. 11 Dr. Kessler was the former commissioner of 12 the Food and Drug Administration. Ran the 13 FDA under President Bush, Bush one, George 14 H.W. Bush, and then President Clinton kept 15 him on for four years. And he'll tell you 16 and show you -- and I'll walk him through the 17 documents as he reviews them -- how this 18 pharmaceutical company was not transparent. 19 And I'll ask him the ultimate question, as to 20 whether they provided an inadequate warning. 21 And I will expect, based on his review, that 22 he will tell us yes. 23 Now, what is sought here? Why is 24 Mr. Kline here for Ms. Pledger on behalf of 25 her autistic son? Permanent disfigurement,</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 31</p> <p>1 What is Risperdal? Risperdal is an 2 antipsychotic drug. It was approved in this 3 time period -- it was approved in this time 4 period for adults. But make no mistake about 5 it, this was no secret to Janssen, no secret 6 at all, that it was widely-prescribed, 7 widely-prescribed to pediatrics and 8 adolescents. And they knew it. 9 Dr. Kessler will tell you that when 10 you find out you have a problem -- and in 11 this case a big problem -- what you need to 12 do is you need to warn about it. And you'll 13 hear them say, "Oh, but our hands were tied." 14 You'll hear the former commissioner tell you 15 their hands weren't tied and that when you 16 have a real distressing side effect -- their 17 words -- you have to warn. 18 It's something called -- and here 19 comes the prolactin stuff -- ready for the 20 mini lesson? Risperdal is something called a 21 dopamine antagonist. It interferes with 22 dopamine. This is the simple version. Got 23 it? Dopamine antagonist, interferes with 24 dopamine. Dopamine regulates prolactin. 25 Prolactin's the hormone that eventually can</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 30</p> <p>1 one way or the other; mental anguish; 2 embarrassment and humiliation, for a man 3 who's autistic but has a sense -- you're 4 going to find out -- of where he is, who he 5 is, and that he has female breasts. 6 Autism. Yes, autism may have a role 7 in this. It was a drug that was prescribed 8 for controlling irritability of autism. It 9 didn't cure autism. It didn't cure the 10 world. These children, adults, have behavior 11 problems. No fault of their own. God only 12 knows, no fault of their own. And so 13 medications are given. There are lots of 14 different medications in the field. 15 It has -- there are developmental 16 delays; there are communication problems; 17 frustration; aggression. I know we agree on 18 this because I'm reading off of a document 19 provided by Janssen. They have intellectual 20 disabilities, social impairment, self-injury, 21 fixation on food, and repetitive behavior. 22 Fixation on food is a big problem 23 with autistic children, and they sometimes 24 have weight spikes and weight reductions, and 25 this drug caused that when he was on it.</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 32</p> <p>1 cause lactation in breasts. And less 2 dopamine means more prolactin. 3 And, by the way, other drugs cause 4 increase in prolactin of this type, but not 5 like Risperdal. Not like Risperdal. 6 Risperdal meant increased prolactin, 7 according to one of their studies -- you 8 okay? 9 According to one study, showed that 10 87 percent of children and adolescents who 11 went on the drug had increased prolactin 12 levels. 13 We know that while Janssen 14 Pharmaceuticals didn't tell doctors, "Hey, 15 watch out. Maybe do a prolactin level blood 16 test. Watch out. Be careful. We have more 17 of a problem here than somebody else might 18 have," Austin didn't have a prolactin test 19 during the time that he was taking the drug. 20 In fact, Austin's doctors didn't know it at 21 the time. 22 Oh, and, by the way, you're going to 23 hear, "Oh, he found out he got the 24 diagnosis," something like, "when he got a 25 lawyer," or something like that.</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 33</p> <p>1 Yeah, his mom found out and looked 2 and said, "Oh, wow." "Oh, my. Yes." 3 He was heavy. And you're going to 4 see pictures of Austin. He was heavy. They, 5 I'm sure, will focus on, "Oh, he's a heavy 6 boy." 7 I would like to tell you, though, 8 every time you see that picture, you look and 9 you see, what do his breasts look like? And 10 is this right? Is this something that was 11 right? 12 So we know Austin -- and I don't 13 think there's a dispute because our expert 14 and their expert said that had they done a 15 prolactin test at the time he was having the 16 medication, that he would have likely had an 17 increased prolactin level. And we know that 18 he grew these large female breasts, and Mom 19 will tell you that that's what happened and 20 that she did notice it. And, of course, you 21 put two and two together eventually. 22 Now, many people think -- kind of 23 common perception -- that the FDA studies and 24 tests drugs. We kind of think somewhere down 25 there near Washington, DC they have test</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 35</p> <p>1 soda -- although you're going to hear 2 Dr. Kessler was actually the FDA commissioner 3 responsible for all the nutrition information 4 that we have on every label in America. 5 And the pharmaceutical official 6 prescribing information gives the indications 7 for a drug, the side effects of the drug, the 8 precautions of a drug, the warnings of a 9 drug. It has the key safety information in 10 it. And it, at the end of the day, is owned 11 by the pharmaceutical company. You know how 12 I know that, in this case and in every case? 13 It has a copyright on it, "Janssen 14 Pharmaceuticals." 15 So everything they say in the label 16 in this case in 2002 -- which we're going to 17 be comparing in a moment -- and 2006, when 18 they changed the label to say something 19 totally different as to the risks, well, 20 those are statements of the pharmaceutical 21 company -- in this case Janssen. 22 Now, as I alluded to earlier, 23 pharmaceutical companies sell medicines. I'm 24 not criticizing them for selling medicines. 25 And you've all seen TV advertisements about</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 34</p> <p>1 tubes and people in white coats and they're 2 testing our drugs. That's not the case at 3 all. 4 The FDA actually relies on 5 pharmaceutical companies to provide proof 6 that a drug works; that it means that it's 7 safe; that it has what's called efficacy, and 8 that it's safe for the intended use. And the 9 drug companies submit the tests to the FDA. 10 And the drug company tests are supposed to be 11 scientific and ethical and transparent and 12 not obfuscate, hide, or manipulate data. 13 Now, let's see what we have here. 14 And, by the way, the pharmaceutical 15 company has to tell the FDA what it knows, 16 good and bad, everything, timely, especially 17 if there's a public health danger. 18 Now, the official prescribing 19 information for a drug goes to the doctor, 20 not directly to the patient. You probably 21 know that. You get a label in your drug when 22 you get a medication at the pharmacy, but the 23 official prescribing information is, in the 24 pharmaceutical industry, called a "label." 25 But it doesn't mean a label like on a can of</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 36</p> <p>1 medications, and you see all the side effects 2 that are listed. Well, this one had a side 3 effect, and the real side effect of this drug 4 wasn't warned about, as I'm going to show 5 you. 6 They also have sales representatives 7 that visit doctors. And in this case, they 8 had a sales rep visiting this doctor over and 9 over and over and over again. Is that doctor 10 being criticized in that way here? Is the 11 company being criticized in that way here in 12 this case? No. 13 Here's what that was: Every time 14 that salesman went into that doctor's office 15 who was treating her boy, he had an 16 opportunity to tell the doctor, "We got 17 testing going on back in Pennsylvania and New 18 Jersey and in Belgium, and we have some 19 concerns." And I'll get to that in a minute. 20 In this case, the important 21 information that came to this doctor was 22 coming from what was in the official 23 prescribing information, known as the label, 24 and it was coming from the salesman who was 25 in the office of a pediatric neurologist for</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 37</p> <p>1 a drug that wasn't indicated for children and 2 adolescents 20 -- I hope I counted it 3 right -- 20 or 21 times, leaving samples 4 behind. 5 Let's talk about the development of 6 the drug. Janssen very proudly -- and I'm 7 sure Ms. Sullivan, my learned colleague, will 8 stand up and she will tell you that Janssen 9 did the most tests ever on a drug, on this 10 drug. 11 Yeah, but let's look at what tests 12 counted; 13 That they had a lengthy process with 14 the FDA. 15 Yeah, but let's see what they told 16 the FDA; 17 That they were approved repeatedly. 18 Yeah, but I'm going to show you when 19 they were denied repeatedly in 1996 when they 20 wanted to prescribe the drug to children 21 without any safety data and the FDA told 22 them, "You have meager safety data." 23 In 2000, when they asked the FDA to 24 let the drug be used for conduct disorder, if 25 the kid acts out, if the kid has autism, if</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 39</p> <p>1 Austin's born in '94. And by '96, Janssen 2 knew that pediatric physicians were 3 prescribing the drug. Well, that doesn't 4 come as bad news, even though it's not 5 indicated for children. They could have seen 6 it as a responsibility. Instead, they saw it 7 as an opportunity. 8 In '96, they go to the FDA, they say, 9 "Hey, we want to add some information about 10 the drug." And the FDA says, "No. You 11 cannot put it in because you have meager 12 safety data." 13 By the way, at this point, we have 14 documents to show it, they knew that the drug 15 controlled people's behavior. They didn't 16 know exactly how -- what doctors call the 17 mechanism. 18 And according to Janssen themselves, 19 which never changed -- strike that. I'm 20 sorry. It did. It did. 21 They say to the FDA: "The efficacy 22 and the safety have not firmly been 23 established in children." 24 Now, in 2000 they go back for conduct 25 disorder and they're denied. And Janssen</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 38</p> <p>1 the kid has anything, you know what the FDA 2 told them in 2000? "We're worried it's going 3 to be a chemical straitjacket," and they told 4 them "no." FDA words: "Chemical 5 straitjacket." 6 They went back in 2005. And you know 7 what the FDA told them in 2005? This is now 8 after Austin had been on the drug for three 9 years and had developed breasts. Too late 10 for Austin. In 2005, they told -- the FDA 11 told them for children and adolescents, not 12 for schizophrenic adults. There's a market 13 for schizophrenic adults for this drug. For 14 children and adolescents, they kept going 15 back. Kept going back and saying, "We want 16 to get it approved for children and 17 adolescents." And they were told again "no, 18 inadequate data." 19 In 2006, I'm going to show you, as my 20 story goes on, and I get back to my notes, 21 they went back and they pushed it through. 22 Now, a lot of work, and I just want 23 to make sure I don't get way behind. 24 In 1993, the drug goes on the market. 25 It has a birthdate kind of similar to Austin.</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 40</p> <p>1 said, Well, geez, we want to get this 2 approved for pediatrics and adolescents. How 3 do they do it? They're going to run safety 4 studies. And they ran safety -- I'm sorry. 5 They ran efficacy studies and safety studies. 6 See if it's effective in children. See if 7 it's safe in children. 8 And you're going to hear these 9 studies. Here are the five that they ran. 10 I'm going to give you numbers so when you 11 hear them later, you'll know: 19, 20, 93, 97 12 and 41. 41 is the key. RISP International, 13 43, an international study of children. And 14 they had this one study of all of them. 15 They're going to tell you we did 18 studies, 16 all these studies. They did one study. 17 Hang in with me and I promise I'll 18 pick up the speed. 19 They did one study which was a quote, 20 their words, "Special Attention Study." 21 Special attention to what? Special attention 22 to prolactin and gynecomastia. Oh, what we 23 actually care about. 24 And by late 2000, the study results 25 are in. Remember there was a label. The</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 41</p> <p>1 label said nothing about children. But if 2 you looked at it on its face, it said 3 gynecomastia, less than one in a thousand. 4 Somebody who was prescribing for a child 5 would have no reason to know anything else. 6 By late 2000, nearly two years before 7 Austin ever took the drug, they had interim 8 results. And you know what the interim 9 results showed in this special attention 10 study, "Special Attention Study"? That they 11 had something called prolactin-related 12 adverse events. They actually gave it an 13 acronym which they later changed to soften 14 the words. They later changed it to "SHAP," 15 "symptoms hypothetically associated with 16 prolactin." 17 But in their own documents, they knew 18 that these were prolactin-related adverse 19 events, "PRAE." And this wasn't only boys 20 with breasts. They had little girls, little 21 girls lactating. They had little girls 22 growing breasts. And they studied it; and 23 what they found was something that was -- oh, 24 the words aren't there, but we'll show it to 25 you -- alarming. Alarming.</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 43</p> <p>1 here were the final results of Study 41: 2 Twenty-three out of 419 boys had 3 gynecomastia. That's 5.5 percent. That's 4 five or six in a hundred getting it. 5 Sixteen of 419, in their own words, 6 were probably or very likely related to the 7 drug. And 15 of 419, that is to say, 3 and a 8 half percent, still had it at the end of the 9 one-year study. 10 Now, in the face of this highly 11 distressing symptom, what do they do? Well, 12 they published the four studies in the 13 medical literature. You're going to learn 14 how this works. Company does a study; the 15 company hires some outside writers; the 16 company recruits some doctors to have their 17 names on the study and be associated with the 18 study, and they go to publish the study. 19 This study, Study 41, wasn't published in 20 2001 and 2002. It was published in 2005. 21 The study -- the study that flags the high 22 incidence of the problem. 23 Now, Janssen knows they have a 24 problem. I'm going to pick up speed. 25 THE COURT: Sorry. It's just the</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 42</p> <p>1 319 children studied between the ages 2 of 5 and 14, 5 percent of them had 3 prolactin-related adverse events -- breasts; 4 teenage girls' lack of period -- things that 5 were affecting them -- their endocrine 6 system. 7 Now, the study design called it 8 prolactin-related adverse events. A couple 9 of months later they -- I'm sorry. They had 10 the interim results. Ten of 266 boys had 11 gynecomastia. 3.7 percent. 12 Now, gynecomastia was rare in adults, 13 and the label said it. They studied 2,607 14 individuals, adults, and it was less than a 15 thousand. But it wasn't less than a thousand 16 in the children. And that was alarming. And 17 by August of 2001, again, like a year before 18 Austin took the drug, they got what's called 19 a topline report. You get kind of a headline 20 if you're the -- you're the pharmaceutical 21 company doing a study. 22 4.8 percent had gynecomastia. 23 Twenty-four of 504. And the final results 24 came out in October of 2001, and the study 25 that they paid special attention to this,</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 44</p> <p>1 buzzing. 2 (Checking microphone.) 3 MR. KLINE: Okay. How's that? 4 Janssen knows they have a problem. 5 Remember I told you they had these 6 studies, the five studies. They pool them 7 all together. Pool all the data together, 8 that should be better, because four of the 9 studies they weren't even looking for the 10 problem. They weren't doing breast exams. 11 What do you have, when all is said and done? 12 A bigger problem, bigger problem. They do 13 what's called a pooled analysis. It's a 14 fancy way of saying they pooled all the 15 studies together. And the incident rate is 16 about the same. They now know that it 17 happens in boys. Something like four or five 18 out of a hundred boys get this condition 19 called gynecomastia. But they also have a 20 very disturbing finding when they pool all 21 the data together. 22 And there's one document in this 23 case, and we're going to have to spend some 24 time with it. And it's a little bit 25 complicated, but not too complicated to</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 45</p> <p>1 understand. 2 And what they found was that of the 3 boys that were in these studies who were on 4 the drug, some of them got increased 5 prolactin levels and some didn't. I've 6 already told you that. But the ones that 7 increased the prolactin level, they were 8 going to go on at a much more likely rate to 9 get gynecomastia. It was called a 10 statistically significant finding. They 11 hired statisticians. They did the study, and 12 they found that there was an association 13 between the drug causing the increased 14 prolactin and the increased prolactin causing 15 the gynecomastia. And that was a big 16 problem. Because they now needed to figure 17 out how they weren't going to have this 18 problem. 19 And I'm going to give you the very 20 short version of what is a very much longer 21 story that you're going to hear. 22 They decided that there was -- they 23 knew that there was scientific confirmation, 24 scientific confirmation of a significant 25 safety risk of a highly distressing symptom.</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 47</p> <p>1 weren't physicians at all. One was a lady by 2 the name of Carin Binder, an MBA. That's 3 somebody who's trained in business 4 administration. And a psychologist, a guy by 5 the name of Pandina, who never prescribed a 6 pill in his life. And the first thing they 7 do is they change the word prolactin-related 8 side effect, as they're drafting this up, it 9 gets changed to SHAP, something that's 10 hypothetically associated with, you know, 11 perhaps. 12 They had as their objective to 13 explore any possible relationship of 14 prolactin level and prolactin-related side 15 effects. And they knew. They knew that 16 other competitor drugs and other competitors 17 were already out there saying that this drug 18 was a problem. 19 Now, they needed to get reassuring 20 data. Am I making that up? Am I just 21 criticizing them? In their own documents, 22 quote, "if we can demonstrate" -- and part of 23 the thing in a negligent failure-to-warn 24 case, you're going to have to decide if this 25 is the way you go about science.</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 46</p> <p>1 They decide they're going to write it 2 up and they hire an outside company to do it. 3 No one's faulting them for doing it. They 4 hire an outside company. They decided to 5 draft the document. Now, here's where it 6 gets interesting -- how they write up the 7 study. 8 It passes -- they pass the draft 9 through a lot of people, and you're going to 10 see e-mails here. You would think that the 11 study -- you know, in high school chemistry 12 is a benchmark. You design a study; you 13 carry out the experiment; you write up the 14 experiment. You're going to see here they 15 designed the study; wrote up the experiment; 16 didn't like the results; changed the design 17 of the study; got a result that looked 18 better. 19 Here's what happened. I'm going to 20 have to be brief on what I hoped I could be 21 longer, but I see where Mr. Kline is running 22 later than he thought. 23 They pass the drafts of the study 24 through Janssen people. You're going to see 25 that the key, pivotal people on this study</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 48</p> <p>1 "If we can demonstrate," said the 2 psychologist, "that the transient rise in 3 prolactin does not result in abnormal 4 maturation of SHAP" -- that's the 5 gynecomastia -- "this would be reassuring." 6 Looking for a result. But what they 7 were stuck with was that the drug -- was this 8 finding; that 8 percent of the kids who had 9 the elevated prolactin levels went on to get 10 gynecomastia, and 3 percent of the ones that 11 didn't have the elevated levels went on to 12 get gynecomastia. 13 And the label at the time, the label, 14 the prescribing information said as to 15 children -- and you're going to hear this 16 from Ms. Sullivan -- we said to the doctors, 17 safety and efficacy is unknown. But it 18 wasn't unknown, we will show you why 19 safety -- lack of safety, lack of safety was 20 established in a drug that wasn't approved 21 for kids. 22 Now, they have the studies. They 23 have Study 41 showing all the gynecomastia, 24 showing -- you pick the number -- 4 or 25 5 percent of boys get gynecomastia. They</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 49</p> <p>1 have the study when they pooled them 2 together. The ones that have the increased 3 prolactin are the ones going on to get the 4 gynecomastia. 5 And then they decide -- hang with me 6 a few more minutes -- they have that Study 41 7 that showed the 4 or 5 percent of 8 gynecomastia depending on which result, you 9 with me on this? And they decide let's run 10 that study another year. Let's extend it. 11 It's called an extension study. It has a 12 number in this case, Study No. 70. In their 13 own study when they kept the kids on two 14 years and combined the results, 12.4 percent 15 of the boys who were taking the drug and the 16 girls who were taking the drug had a 17 prolactin-related adverse event. And they 18 took no action at that time to tell 19 Mrs. Pledger who had called the FDA, 20 Dr. Mathisen, or any other doctor. 21 Now, back to the reassuring paper 22 that they're trying to write up on the 23 thing -- on this. They say to themselves, 24 huh, if we can -- oh, when they get 25 endocrinologies to tell them this.</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 51</p> <p>1 physician's notes that they're consulting 2 with -- actually, it's a Janssen physician: 3 "When compared to competitors, only Risperdal 4 causes increased prolactin levels at 5 recommended doses." 6 What did they do? They persisted. 7 They got their message. And they ended up 8 telling the FDA eventually that there was not 9 a statistically significant association. 10 They said the opposite. They said as 11 with all other drugs that antagonize 12 dopamine, risperidone -- and I'll get to that 13 in a minute. 14 Now, they were going back and forth. 15 One doctor saying I don't think it's fair to 16 say the clinical significance of 17 hyperprolactinemia is unknown. 18 They end up writing a paper, and I 19 don't have it in front of you, but I'm going 20 to show it to you, where they distinguished 21 between children who were under 10 and over 22 10. And then in the write-up they only talk 23 about the ones who were over 10, and they 24 don't tell you that there is a big problem 25 because there is an association here with</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 50</p> <p>1 Endocrinologies tell them this -- if we take 2 out all of the boys in the study who are over 3 10 and we run the data as to whether increase 4 in prolactin results in gynecomastia and that 5 it's a statistically significant result which 6 scientists say is a problem, we'll get a 7 different result. They did it. They got a 8 much better result. It kind of sort of 9 showed that it was better, although you still 10 had nine kids who had elevated prolactin 11 levels that got gynecomastia versus three 12 that did not have elevated prolactin levels 13 that got it. I know it's complicated. But 14 hang with me. I want you to get a flavor for 15 it. 16 And they go to their -- they go to an 17 advisory board. They assemble the advisory 18 board. And the advisory board tells them 19 that if you do this, if you do this, you're 20 going to be hiding data. 21 They were told that they had to 22 include all the boys, not only the boys up to 23 10, but the boys over 10. And so they went 24 and they redrafted the document and they 25 circulated it back and forth. And one of the</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 52</p> <p>1 this drug causing elevated prolactin levels 2 leading immediately to -- leading to, I 3 should say, gynecomastia. 4 Now, in 2004 they gather up all this 5 data. The drug had already been taken by 6 Austin for two years. They go to the FDA. 7 The FDA says a review of safety information 8 did not satisfy them. And this is a key 9 sentence I was looking for. They tell the 10 FDA: "A review of safety information did not 11 show a correlation and adverse events that 12 are potentially attributable to prolactin." 13 We're going to show you that 14 statement was not a correct line. 15 Now, I want to show you and talk to 16 you about a couple of things. 17 You're going to hear all of that 18 evidence. And I actually in my own mind 19 don't know that I gave it justice, but I 20 tried. They had a drug and they had these 21 tests and they had a problem, and these are 22 the tests that you have to look at. They had 23 a label on the drug. And the label on the 24 drug in 2002, the prescribing information 25 said, as with other drugs -- bear with me for</p>

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<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 53</p> <p>1 another few minutes -- as with other drugs 2 that antagonize dopamine, risperidone 3 elevates prolactin levels and the elevation 4 persists during chronic administration. And 5 they're going to tell you that's good enough. 6 And where the issues joined in this case is 7 I'm going to tell you that in 2006, they came 8 clean, pushed to get the approval, and they 9 said, "risperidone is associated with higher 10 levels of prolactin than other antipsychotic 11 agents." 12 Her doctor didn't know that. They 13 said Risperdal has endocrine disorders, 14 gynecomastia, less than one in a thousand. 15 They eventually agree, after some wrangling 16 with the FDA, about whether it was 4 percent, 17 5 percent, 3 percent -- they even calculated 18 3.7 percent -- they agreed to put 2.3 in a 19 hundred in their label. 20 They admit the risk was 2.3 in a 21 hundred, not less than one in a thousand, of 22 a condition that her boy got and her doctor 23 wasn't told. 24 Now, let's talk about her son, 25 Austin. The story begins in '94. He's born</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 55</p> <p>1 A representative, Gilbreath, you're 2 going to hear his testimony, told 3 Dr. Mathisen about it. What he didn't tell 4 him was that while they were writing up a 5 paper, which I was inartfully talking to you 6 about, because there's so much in there to 7 talk about, that the MBA lady whose name is 8 Binder said at one point that there's a 9 nauseating amount of gynecomastia. They were 10 trying to figure out how they would report it 11 in a less transparent way. We're going to 12 walk through every one of these documents. 13 It's going to take us some while with 14 Dr. Kessler next week. 15 So what you ended up with was a label 16 that was inaccurate. You ended up with a boy 17 who had an injury. You ended up with a mom 18 who cares an awful lot. You ended up with a 19 lot of alternative drugs that this boy could 20 have been on; that this doctor could have put 21 him on. And you'll learn that they will tell 22 you, oh, the drug was wonderful for him and 23 mom thought the boy was doing well. And, oh, 24 the drug helps people. 25 Respectfully, the issue for you to</p>
<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 54</p> <p>1 July 15, '94. He is diagnosed, as you know, 2 with autism. He was taking the drug two 3 years after Janssen knew that gynecomastia 4 was frequent. Frequent, by the way, is 5 described as greater than one in a hundred -- 6 not rare, less than one in a thousand. 7 He went to his doctor. His doctor 8 prescribed the drug. He gained a lot of 9 weight. He had gained weight beforehand. He 10 gained an enormous amount of weight actually 11 after he got on the drug. He lost a lot of 12 weight as well. Oh, and, by the way, when he 13 lost all the weight, of course breast tissue 14 remains. They're going to tell you, oh, he's 15 a fat boy. Pardon me for saying it. They're 16 going to be, I hope, polite about it, but 17 they're going to say he's a heavy boy. And 18 I'm going to tell you that, yes, he is that, 19 but he has these breasts that are real breast 20 tissue. And even they will admit that 21 they're -- I don't know. We're not going to 22 agree on much here, you're going to find out 23 very shortly. But they will agree at least 24 it was half breast tissue. So there you go 25 on that.</p>	<p>- PLEDGER, et al. -vs- JANSSEN, et al. - Page 56</p> <p>1 determine in the case when you hear all of 2 that out there -- and you're going to hear a 3 lot of it from the beginning to the end by 4 the pharmaceutical company -- the issue is a 5 narrow one: Was the warning adequate? 6 The evidence will show that they had 7 data and information in their files that they 8 did not communicate and had 21 opportunities 9 of a sales representative and another 10 opportunity with the label that the sales 11 representative was familiar with and which 12 the doctor was familiar with. 13 Other things you're going to hear in 14 the case are about the FDA approval. And I 15 will submit to you that at the time it was 16 prescribed to him, I will show you that it 17 was not approved. And I will also show to 18 you that the doctor who thought he was making 19 an intelligent decision was not because he 20 didn't have the evidence that should have 21 been provided to him. 22 And I will show you something else. 23 They will try to say in this case that little 24 boys who go through puberty develop 25 gynecomastia. And they're actually going to</p>

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1 bring in a doctor who wrote an article on
2 this. He also blogs on nearly every subject
3 known to man. They're going to tell you this
4 happened as a result of puberty. And then
5 we'll go back to their documents. You know
6 what their documents say, as we know from the
7 science anyway? Yes, there's a condition
8 known as pubertal gynecomastia. Gynecomastia
9 that happens, it's transient. The boys are
10 developing. They get a little bit of a kind
11 of chest, and their word, every time you hear
12 them say it -- I'm telling you in advance.
13 I'm going to have their document to show you,
14 in their words -- "it disappears."
15 All the language that I tried to use
16 today is out of their documents. "Highly
17 distressing symptom." "Pubertal
18 gynecomastia," "disappears." "Enough
19 gynecomastia to be nauseating," and on and
20 on.
21 So the things you're going to hear
22 about whether they could warn or not warn,
23 you're going to hear that they could for sure
24 warn when they had a problem. You're going
25 to hear these words at some time in this

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1 courtroom, and I would expect you to hear
2 them from Dr. Kessler: "A manufacturer of a
3 prescription medication is not prohibited
4 from warning doctors whenever harmful adverse
5 effects associated with the use of the drug
6 are discovered."
7 We will start the evidence on Monday.
8 You will hear in this courtroom -- you will
9 hear in this courtroom Dr. Kessler from the
10 FDA. You will hear testimony -- some of it
11 will be on videotaped deposition -- of
12 Dr. Mathisen, the doctor; Mr. Gilbreath, the
13 sales rep. You'll hear and see the documents
14 of the company. You will see in detail the
15 studies. I will march you through the key
16 studies. I will keep my focus at all times
17 with you on whether the drug causes
18 gynecomastia, whether they knew it, and
19 whether it matched up with what they told the
20 doctor at the time.
21 At the end I'll come back, we'll talk
22 about damages. You will learn that Austin is
23 a terrific young man. And you will learn
24 that he has this distressing problem. You
25 will learn that his mom would do anything for

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1 him. And you'll learn that she just doesn't
2 know if it's right to, you know, put him
3 through surgery right now or not. He's a
4 fragile human being.
5 And the issue in the case, as it's
6 framed, is when you're dealing with the most
7 fragile among us, most fragile among us, in a
8 drug that isn't even approved for the
9 indication, and you find a problem, a big
10 problem, do you open the window for everyone
11 to see in or do you try to pull the shades?
12 So we'll start on Monday. I thank
13 you for being patient with me. And there are
14 some complexities here. I will do my best,
15 my best, to slough through it with you in an
16 efficient manner.
17 Thank you.
18 **THE COURT:** All right, Mr. Kline.
19 Thank you.
20 We're going to take a recess here for
21 about ten minutes, and then we'll hear from
22 Ms. Sullivan for the defense, okay?
23 **COURT CRIER:** All rise as the jury
24 exits the courtroom.
25 - - -

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1 (Whereupon the jury exited the
2 courtroom at 3:04 p.m.)
3 - - -
4 (The following transpired in open
5 court outside the presence of the jury:)
6 - - -
7 **THE COURT:** All right.
8 **MS. SULLIVAN:** Your Honor, I just
9 wanted to raise a couple --
10 **THE COURT:** You want to raise some
11 objections?
12 **MS. SULLIVAN:** Just a couple issues.
13 **THE COURT:** Hold on one second.
14 Please close the door.
15 **MS. SULLIVAN:** And quickly, Your
16 Honor, I know we're pressed for time.
17 I believe that Mr. Kline opened the
18 door to good character evidence. He talked
19 about the wonderful mother, beautiful,
20 wonderful, loving family. I think that opens
21 the door to good character for J&J.
22 He also never said that Janssen never
23 told --
24 **THE COURT:** Character evidence as to
25 what?