IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION
- - -

IN RE: RISPERDAL® LITIGATION

W.C., ET AL., : MARCH TERM, 2013
Plaintiff :
:
vs. :
:
JANSSEN PHARMACEUTICALS, :
INC., JOHNSON & JOHNSON; :
AND JANSSEN RESEARCH & :
DEVELOPMENT, LLC., :
EXCERPTA MEDICA, INC., :
AND ELSEVIER, INC., :
Defendants : NO. 1803

Wednesday, March 4, 2015

- - -

Courtroom 253-City Hall
Philadelphia, Pennsylvania

- - -

BEFORE: HONORABLE VICTOR J. DINUBILE, JR., J.,
and a Jury

- - -

AFTERNOON SESSION

- - -

APPEARANCES:

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WITNESS	DR	CR	RDR	RCR
Carmen DeLoria (As of Cross)	--	4	--	--

1 - - -
2 (Whereupon, the jury entered the
3 courtroom at 2:09 p.m.)
4 - - -
5 THE COURT: Good afternoon, everyone.
6 You may proceed, Mr. Kline.
7 MR. KLINE: Your Honor, thank you.
8 THE COURT: Just one second.
9 (Pause.)
10 MR. KLINE: Your Honor, thank you,
11 again.
12 Good afternoon. Good afternoon, all.
13 THE JURY PANEL: Good afternoon.
14 - - -
15 AS OF CROSS-EXAMINATION
16 (continued)
17 - - -
18 BY MR. KLINE:
19 Q. And, Dr. DeLoria, good afternoon.
20 A. Good afternoon.
21 Q. Continuing our conversation, you mentioned on
22 a number of occasions during the morning session
23 about a mindset being, we're thinking about the
24 autism approval and getting approval down the road,
25 okay, remember that generally?

1 A. Yes, correct.
2 Q. And I think we could agree that you said it a
3 number of times in various forms; can we also agree?
4 A. What, that --
5 Q. We were looking ahead and looking for the
6 approval down the road.
7 A. Yes, yes, that is the reason we had a business
8 plan. There wouldn't have been a business plan if
9 we had no indication of seeking an indication.
10 Q. Well, you were interested in the -- you were
11 actually interested in then, sir, was the here and
12 now, not only the future, correct?
13 A. Well, the here and the now in terms of the
14 miss -- misconceptions, so we need to identify what
15 the issues were today so we could address those
16 issues -- and some of them were the reanalysis or
17 other data that we would generate, so...
18 Q. Sir, would you agree with me what you just
19 said is not correct?
20 A. In what way?
21 Q. In the way that you were concerned about
22 market share erosion then.
23 You were actually concerned about
24 market share erosion. And erosion means something
25 that's going to happen to what's already here. Can

1 we agree?
2 A. Correct, in the context of the fact that we
3 were developing this new indication around we need
4 to know what the perceptions were of physicians.
5 And if physicians, for example, wanted to see
6 additional information as it related to a particular
7 side effect or a symptom, then we want to see what
8 data we could generate to try to address those
9 questions that we knew physicians would have or
10 currently had.
11 Q. That's not what the document says, is it?
12 A. If in what way -- well, what does it say
13 that's inconsistent with what I just said?
14 Q. Well, let's look at it.
15 You talked about -- and we're now
16 on -- and I'm going to show you both plans, frankly.
17 A. Okay.
18 Q. In 2001, July 2001, you were looking to be
19 proactive with education and public relations.
20 Do you recall seeing that, sir, even
21 before we put it up? If not, I'll put it up.
22 A. Correct.
23 Q. Okay. And let's put up Plaintiff's Exhibit
24 63, 724 -- 725 Bates number. Again, let's look at
25 the words that are on the page. Okay, sir?

1 A. Sure.
2 Q. Because when this speech was being given -- or
3 this presentation was being given, both by Mr.
4 Bockes in 2001 and by you in 2002, the way these
5 slide presentations are generally given, at least to
6 what I'm accustomed to, is there's a presenter and
7 there's a group and the presenter has the PowerPoint
8 behind him or her and they're saying, Here's the
9 PowerPoint, and this is -- this is my speech. My
10 speech is actually both oral and written, correct?
11 A. Correct.
12 Q. And that's kind of a modern way that people do
13 speeches, correct?
14 A. Correct.
15 Q. There are very few old-fashioned
16 talk-to-people kind of speeches anymore, correct?
17 A. There's generally some media that's involved
18 in terms of PowerPoint --
19 Q. What, sir?
20 A. -- multimedia PowerPoints.
21 Q. Multimedia PowerPoints, right.
22 And so what's going on here, Lessons
23 Learned -- let me understand. Mr. Bockes, am I
24 pronouncing it right?
25 A. Bockes.

1 Q. Mr. Bockes is presenting to the group, and he
2 is -- is he standing or sitting at the table?
3 A. Standing.
4 Q. Standing at the table. PowerPoint behind him,
5 correct?
6 A. Correct.
7 Q. And he's saying to the group, he's saying,
8 among other things, "Without a proactive approach to
9 education and public relations, we run the risk of
10 negative press and" -- and underline -- highlight
11 that, if you would -- "market share erosion,"
12 correct?
13 A. Correct.
14 Q. Now, sir, agree with me -- let's see if we can
15 agree. Market share erosion -- I hope I don't have
16 to keep going to the dictionary, I find that
17 difficult for everyone -- but erosion is something
18 that erodes what's already there, correct?
19 A. Correct.
20 Q. And so what you have here is a concern of a
21 market share erosion from something that was already
22 there; namely, the significant sales of Risperdal to
23 the pediatric and adolescent market, correct, that's
24 what it says?
25 A. Correct.

1 Q. And, in fact, the same concept, sir, having
2 nothing to do with whether you're going to get
3 approval later, whether you're going to get FDA
4 approval or not FDA approval -- and, by the way,
5 question, that was never a sure thing, that you were
6 going to get FDA approval for anything for children
7 and adolescents, correct?
8 A. Correct. Nothing's ever assured. You can
9 only submit the information and wait until you hear
10 back from the FDA. Nothing is ever guaranteed.
11 Q. Right.
12 As of 2005, every pediatric indication
13 that had been requested in 1997, to put some
14 information on the label on dosing, in 2000 for
15 conduct disorder -- the words didn't come to me --
16 2005 for autism, the history of the drug was it had
17 been on three occasions for some pediatric
18 information in the label, it had been turned down,
19 correct?
20 A. Correct.
21 Q. And so being talked about here -- and let's go
22 to 2002.
23 In 2002, on 241, Exhibit 241, what
24 we've just seen in 241, in 2002 what we see, that
25 would be exhibit -- the observation made by you to

1 the group -- and, by the way, if we can take this
2 down for one moment, when you're giving this
3 presentation, sir, what you're doing is you're
4 talking behind you and you go over all the points,
5 correct?
6 A. Yeah, in general.
7 Q. General, right.
8 You're basically reading to everybody
9 and they're getting it down and seeing you say it
10 and reading it. Here's what you told them: You
11 told them, among other lessons learned -- we went
12 over some of them, but I didn't highlight this, I
13 don't believe -- "C&A market growth has flattened."
14 Do you see that?
15 A. Correct.
16 Q. Now that's not talking about anything to
17 happen in the future, correct?
18 A. Correct.
19 Q. C&A market growth, there had been a growth,
20 correct?
21 A. In the whole market, correct, for C&A.
22 Q. Well, that's right. Well, not only in the
23 whole market. There had been a growth -- there had
24 been a growth -- there had been a significant growth
25 in Risperdal sales, correct?

1 A. Risperdal sales for --
2 Q. For children and adolescents.
3 A. I don't believe, but if that's -- that's what
4 it said.
5 Q. I'm going to find it. It was something that
6 we had earlier. I want you to -- I want to -- let's
7 do this, and then we'll go to that.
8 So when you're talking about -- when
9 you were presenting that day and you were telling
10 the assembled high level group that market growth
11 has flattened, that's something that had happened
12 already, correct?
13 A. Correct.
14 Q. And so you were reporting to them as to the
15 fact that sales had gone up for Risperdal for
16 children and adolescents and had now flattened off,
17 correct?
18 A. This is referring to the child -- child and
19 adolescent market flattening.
20 Q. But had the same been true for Risperdal, or
21 don't you know?
22 A. I would assume that's probably the case since
23 it was approximately half the market.
24 Q. It appears that between '01 and '02 -- and if
25 I have to get the documents out, I will, but I think

1 you probably have a general recollection of them --
2 the market share, which I think we saw, in 2001 was
3 53.9 and in 2002 it was 52.5, and that would be
4 flattened?
5 A. Correct.
6 Q. It wasn't going any higher, at least it didn't
7 look like it was?
8 A. No.
9 Q. And, of course, what you're measuring -- as
10 you stood in front of this group, what you're
11 measuring is a -- not only what's going to happen in
12 the future, but what's happening now, meaning in
13 2001 and for you in 2002, correct?
14 A. Correct. The reason why we were reporting
15 that in this particular document, why we brought it
16 up, is because we're developing an indication for
17 use in the child and adolescent segment, so it is
18 noteworthy to look at what is happening to the
19 market that you develop an indication for. So every
20 year we would track as for any indication we were
21 pursuing, what are the dynamics going on in that
22 marketplace.
23 Q. Sure.
24 A. Is it flat, is it growing? So that would be
25 normal to actually say, okay, what is happening to

1 the market. What we observed is a market that is
2 growing, this one year appeared to flatten, and that
3 was a lesson learned.
4 Q. It was -- yes, but let's look at a couple of
5 words you just said. It was growing -- it was
6 growing, even though it hadn't been approved for any
7 indication for children and adolescents, correct?
8 A. Correct. It was growing because of a number
9 of products that were now available that child
10 psychiatrists were comfortable using. And,
11 secondly, there was much more data that was being
12 published. In the past, there was old
13 antipsychotics that were being used that many
14 psychiatrists didn't want to use because of the side
15 effect profile.
16 Q. Yeah, people were being -- the doctors were
17 being influenced in what they were reading in these
18 articles that were being published, correct?
19 Correct?
20 A. Well, I don't know the word "influence." They
21 now actually had something they could use.
22 Remember, there was no product used for children and
23 adolescents.
24 Q. No, no.
25 A. It wasn't as though there wasn't mental

1 illness 30 years ago, there was always mental
2 illness. They now have something that they can use.
3 It wasn't just Risperdal. It was Zyprexa, it was
4 Seroquel. The growth in the market is that
5 psychiatrists said, Wow, there's something in the
6 market I can actually use that are helping these
7 children. That was the growth in the market to this
8 day.
9 Q. Do you recall the question?
10 A. No.
11 MR. KLINE: Yeah. Could I have the
12 question read back?
13 - - -
14 (Whereupon, the court reporter read
15 the record as requested.)
16 - - -
17 BY MR. KLINE:
18 Q. That's the question. It can be answered yes
19 or no or I don't know.
20 A. I don't know for sure, but I would assume they
21 were being educated, which could then maybe
22 influence their prescribing.
23 Q. Yes. And if you educate someone, you have to
24 educate them with full, complete, and accurate
25 information, correct? Can we agree?

1 A. Yes.
2 Q. Up until 2000 -- and if you go to -- we're not
3 going to display this, subject to the Court's
4 ruling -- but if you, sir, would go to 727 in the
5 Bates numbers on the 2001 business plan.
6 A. Yes, I have it.
7 Q. And if you would look from '97 to '98 there
8 was a 95 percent increase in the sales in dollar
9 amounts, correct?
10 A. Correct.
11 Q. In other words, from '97 to '98, when --
12 before any of the -- before RIS-41 and before the
13 pooled analysis was even thought of, the drug had
14 doubled its dollar value to the company, correct?
15 MR. WINTER: Objection, Your Honor.
16 MR. KLINE: I'll take the qualifiers
17 away. I will try to avoid that all the time so
18 we can move through this.
19 BY MR. KLINE:
20 Q. Doubled between '97 and '98, correct?
21 MR. WINTER: Objection, Your Honor.
22 BY MR. KLINE:
23 Q. Between --
24 MR. KLINE: I'll withdraw that
25 question because I've established it.

1 BY MR. KLINE:
2 Q. '98 to '99.
3 MR. WINTER: Judge, I thought this
4 case was about 2002.
5 MR. KLINE: Yes, it is. And this
6 shows that the market share was going up. It
7 flattened and there's a motive. That's what
8 the purpose is.
9 THE COURT: Well, if you can run
10 through them quickly.
11 MR. KLINE: I will.
12 BY MR. KLINE:
13 Q. '98 to '99, there was a 51 percent increase in
14 the drug, correct, in the dollar sales, correct?
15 A. I think you're looking at the entire class.
16 Q. Oh, yeah, yeah. Okay. Thank you. Thank you,
17 thank you, thank you. '97 to '98 -- thanks, I do
18 see the error there.
19 '97 to '98 for Risperdal only, there
20 is a 60 percent increase, correct?
21 A. Correct.
22 Q. And '98 to '99 there's another 70 percent
23 increase, correct?
24 A. Yes, 69 percent, correct.
25 Q. 69 percent over 1998. And then --

1 A. Correct.
2 Q. -- 2000, there's another 45 percent increase
3 from '99, correct?
4 A. Correct.
5 Q. So in that period of time, before there was
6 any safety study on children and adolescents
7 performed, any safety study, the drug had propelled
8 in its usage from -- let's see, hold on -- or in its
9 dollar sales, almost four times, this to this,
10 correct?
11 A. Correct.
12 Q. Before there was a safety study, correct?
13 A. Well, the drug was approved --
14 Q. Oh, I asked that.
15 A. The drug was approved in Europe. It wasn't as
16 though there was no safety issue.
17 MR. KLINE: Your Honor, move to strike
18 and move for an instruction.
19 May we see you at sidebar, please?
20 THE COURT: I don't think that's
21 necessary.
22 MR. KLINE: May we have an
23 instruction?
24 THE COURT: For what? I don't think
25 he answered it.

1 MR. KLINE: At issue in this case is
2 whether it was approved in the United States.
3 THE COURT: Well, I think you covered
4 that.
5 MR. KLINE: Since Your Honor won't see
6 us at sidebar, I will respectfully ask to see
7 the Court at some later point.
8 THE COURT: All right. Very well.
9 MR. KLINE: Thank you. Much
10 appreciated.
11 BY MR. KLINE:
12 Q. Yeah, these figures, sir, this is the child
13 and adolescent market in the United States, correct?
14 A. Correct.
15 Q. Where the drug is regulated by the Food and
16 Drug Administration, correct?
17 A. Correct.
18 Q. Not in Europe, Australia, New Zealand, or any
19 parts other, correct?
20 A. Correct.
21 Q. And what ya'll were tracking at the Janssen
22 company on all of these charts, all of these
23 charts -- in fact, in chart 727, respectfully, sir,
24 727 charts how much money and how much -- how much
25 money was being made on the drug at the time,

1 correct?
2 A. Correct.
3 MR. WINTER: Objection, Your Honor.
4 THE COURT: Overruled.
5 BY MR. KLINE:
6 Q. Correct, sir?
7 A. Correct.
8 Q. The chart we've been discussing, sales for
9 child and adolescent market, has nothing to do with
10 projections for the future, correct?
11 A. Correct.
12 Q. And on page 241, that's Bates 241 --
13 MR. KLINE: If you're with me, Corey.
14 BY MR. KLINE:
15 Q. -- on the fourth bullet point on Lessons
16 Learned "C&A market growth has flattened," this is
17 the 2002 business plan that you presented, sir?
18 A. It was presented in 2002, correct. It was for
19 2003, but it was a 2000 -- I'm just looking at the
20 bottom, it says 2003 business plan.
21 Q. And the second -- the second bullet point
22 under -- if you'd leave that up, please. The second
23 bullet point which we'll also highlight under
24 Implications "dissemination of re-analyses of safety
25 databases is critical," correct?

1 A. Correct.
2 Q. And this particular page, sir, in 2002, then
3 we'll go back to 2001, this page in 2002 would have
4 taken you five minutes to discuss?
5 A. Yeah, probably about five, ten minutes.
6 Q. And the points that we've been discussing
7 would have been also clear to those who were in
8 attendance, correct?
9 A. The points made there?
10 Q. Yes.
11 A. They would have been communicated to those in
12 attendance, correct.
13 Q. Now, as it was seen in 2002, sir, there were
14 key child and adolescent markets. And let's put up
15 731 and continue our discussion.
16 Now, sir, do you remember you told us
17 you were looking to the future and autism and all
18 these other things, remember?
19 A. Yes.
20 Q. Now, the fact of the matter is that by 2000
21 the conduct disorder indication had been denied by
22 the FDA, correct so far?
23 A. Correct.
24 Q. And the only indication that you were looking
25 to in the future -- the only indication you were

1 looking to in the future was autism, that was the
2 only thing that was on the board, can we get
3 approval for autism, correct?
4 A. Correct. There was discussion if there was
5 anything else, but that was the only thing we were
6 actively pursuing at the time.
7 Q. Right.
8 You were actively pursuing and you
9 knew this, because I'm going to show the Court and
10 the jury the documents that you were copied in on,
11 you know that they were doing these studies to try
12 to show that the drug was efficacious -- when I say
13 "they," Janssen -- and they were doing studies to
14 try to show that the drug was safe, correct?
15 A. Correct.
16 Q. And that was as it pertained to autism. And,
17 in fact, there was a group of studies called the
18 autism studies, correct?
19 A. Correct.
20 Q. On autistic kids, correct?
21 A. Correct.
22 Q. Which is not one of the kids in this case.
23 You know this case is not about an autistic child,
24 correct?
25 A. Yes, I do know that.

1 Q. And so -- but yet the key markets, the key
2 markets in 2002 that you were looking at, the
3 largest key market was anxiety, correct, kids with
4 anxiety?
5 A. Correct.
6 Q. Correct?
7 A. Correct.
8 Q. And the next largest market that you were
9 looking at was kids with depression, correct?
10 A. Correct. Well, I wouldn't say we were looking
11 at it, we were just reporting what the key markets
12 were.
13 Q. Reporting what the key markets were?
14 A. Correct.
15 Q. Thank you. Reporting the key markets. And
16 the next key market was ADHD, correct?
17 A. Correct.
18 Q. None of those three, that's about -- I'm
19 eyeballing it, but that's 95 percent of what's on
20 this table?
21 A. In terms of total.
22 Q. In terms of the markets, in terms of the
23 market?
24 A. Right.
25 Q. I mean, I can do the math, I should have, but

1 looks to me like about 95 percent of it is -- in
2 fact, in fact, the next largest market is bipolar,
3 correct?
4 A. Correct.
5 Q. And the next largest market that you have for
6 the drug is schizophrenia, correct?
7 A. Correct.
8 Q. Well, what you had on the table, sir, and you
9 correct me if I'm wrong, what you had on the table
10 for an approval from the FDA was less than one
11 percent of what the markets were that you were
12 evaluating here, correct?
13 A. Correct.
14 Q. You knew when you were applying for an
15 autism -- an autism indication that that's a very
16 specific indication for a very small group of what
17 was a very large market at the time, correct?
18 A. It was definitely one of the smaller markets
19 for sure within the whole child adolescent market.
20 Q. It wasn't one of the smaller markets, sir.
21 Look at the numbers. It was by far -- it was the
22 smallest market, correct?
23 A. Well, schizophrenia is 194, autism is 185, I
24 would say that's the same.
25 Q. Again, at the time there was no movement at

1 that time in the company to get a schizophrenia --
2 an adolescent schizophrenia approval by the FDA,
3 correct, at that time in 2002?
4 A. Not for an indication that I recall. Not for
5 an indication that I recall for schizophrenia?
6 Q. Yes.
7 A. No.
8 Q. So your key markets, when it comes right down
9 to it, correct me if I'm wrong, your key market --
10 your key markets were ADHD, depression, and anxiety
11 which were being sold off-label to kids and
12 adolescents and which were going to continue in the
13 future to be sold off-label to kids and adolescents,
14 correct?
15 A. No, we were not selling it off-label.
16 Again --
17 Q. Put aside my selling it off-label. Were going
18 to be prescribed off-label, correct?
19 A. It was being prescribed off-label by
20 psychiatrists, yes.
21 Q. It was the biggest market that was there and
22 then and was going to be in the future was the
23 off-label market, correct?
24 A. For child and adolescent?
25 Q. Yes, for child and adolescents.

1 A. It was likely to remain that way.
2 Q. You're coming away from the microphone when
3 you answer the questions.
4 It was likely to remain that way,
5 correct?
6 A. Yes. I would say the autism bar would
7 probably be much higher today because there was a
8 significant underdiagnosis of autism back then. But
9 it's a smaller market than, for example, ADHD, which
10 is much more common just by its very prevalence.
11 Q. But my point goes to what you were looking at
12 and what you all were thinking about then and what
13 you were looking at. And what you were thinking
14 about was the market share for a drug that was being
15 used off-label and would continue to be used
16 off-label primarily in children and adolescents,
17 agree?
18 A. Again --
19 Q. It was a drug that was being then used
20 primarily off-label in children and adolescents and
21 would continue off-label, primarily in children and
22 adolescents, agree?
23 A. Agree.
24 Q. And, just briefly, sir, there's a presentation
25 about -- on page 733, one or two questions on it.

1 This is 2001, you were present, and it talks about
2 the dosing of Risperdal; do you see it?
3 A. Yes.
4 Q. The dosage is described in milligrams per day,
5 correct?
6 A. Correct.
7 Q. And it doesn't say anything there, does it,
8 about milligrams per kilogram per day, does it?
9 A. Correct.
10 Q. And it even goes as far as to break it down,
11 the primary care physicians, it looks like were
12 prescribing 3.8 milligrams a day on average compared
13 to the psychiatrists who were prescribing 2.1
14 milligrams per day, correct?
15 A. Correct.
16 Q. And for kids with conduct disorder and ADHD,
17 you knew that they were getting on average -- when I
18 say "you," the you always refers to you, refers to
19 Janssen, obviously, you're in the meeting with the
20 president, conduct disorders, Janssen in that
21 meeting would know that 1.5 milligrams a day was the
22 average being used by kids ranging from literally a
23 couple of years old through their teens, correct?
24 A. Correct.
25 Q. And this drug, sir, as we've seen, was used in

1 children as young as four, five, six years old,
2 correct?
3 A. Correct.
4 Q. Now, there is a summary, child and adolescent
5 market summary. And there is a document before we
6 display it, 5 -- 734 -- and bear with me one moment.
7 MR. KLINE: Your Honor, the document
8 has dollar numbers, but it has one for the 2000
9 estimate. I just need some guidance if I can
10 show that number.
11 THE COURT: Let me see it. I don't...
12 This may be easier if I can see it.
13 (Pause.)
14 THE COURT: Instead of showing it, why
15 don't you read it?
16 MR. KLINE: Okay.
17 THE COURT: Just delete that.
18 MR. KLINE: Okay. But I can use the
19 number?
20 THE COURT: Yes.
21 MR. KLINE: Okay.
22 BY MR. KLINE:
23 Q. Sir, looking at the document -- and, for the
24 record, this is JJRE00575734 and, for the record,
25 not being displayed to the jury -- the child and

1 adolescent market summary, it is stated here, sir,
2 that the child and adolescent market -- and do you
3 have it in front of you?
4 A. I do.
5 Q. Okay.
6 It doesn't say, will be, does it? It
7 says, is large and growing; did I read it correctly?
8 A. Yes.
9 Q. And those were important things to Janssen at
10 the time, that the market for children and
11 adolescents was large and growing, correct?
12 A. Correct.
13 Q. And it says here, 2000 child and adolescent
14 estimates, and it says here that the whole class of
15 drugs, the antipsychotic class of drugs, was $344
16 million; do you see that?
17 A. Yes.
18 Q. And Risperdal, we know it's a percentage
19 because we've seen it, Risperdal, the child and
20 adolescent market was worth $178 million; is that
21 correct?
22 A. Correct.
23 Q. And it says here in the next bullet point --
24 MR. KLINE: And, Your Honor, if I may
25 display the rest of the document? We will not

1 display the top. If I can start here.
2 BY MR. KLINE:
3 Q. Okay. We're now looking at Bates number
4 ending in 734, and it says Risperdal and --
5 "Risperdal Child and Adolescent TRXs" -- what are
6 TRXs? I failed to ask you that.
7 A. Total prescriptions.
8 Q. "Total prescriptions are growing in excess of
9 50 percent annually."
10 And that, by the way, is about the
11 here and now, not about the future, correct?
12 A. Correct.
13 Q. "High prevalence across a number of disease
14 states," that's the depression, ADHD that we were
15 looking at earlier, correct?
16 A. Correct.
17 Q. "APS are used to treat a variety of
18 conditions," and it talks about -- it talks about
19 that. And then there's a thing that says "APS have
20 low penetration in the largest markets." Do you see
21 that?
22 A. Correct.
23 Q. That's about the here and now, as well, isn't
24 it, about what was going on then?
25 A. Yes.

1 Q. And then it looks at who is prescribing it,
2 correct?
3 A. Correct.
4 Q. Now, sales and marketing for a moment. The
5 prescription medication, sir -- if I may digress, I
6 will put this down, and then we'll go back up in a
7 moment.
8 You've been in this world since 1991?
9 A. Correct.
10 Q. Twenty-five years or so?
11 A. Right.
12 Q. And celebrated an anniversary, I think?
13 A. Yep, just with...
14 Q. Pardon me?
15 A. Twenty-four years.
16 Q. Twenty-four years.
17 And prescription medications, none of
18 us can go out and buy a prescription medication
19 unless we have a prescription, that's why it's a
20 prescription medication?
21 A. Correct.
22 Q. And so the person who -- and I do not mean
23 this pejoratively -- but the person who, if you're
24 trying to influence someone that your product is
25 better, rightly so, you have to convince the doctor,

1 not the patient, at the end of the day, correct?
2 A. In general.
3 Q. Yeah, in general. I mean, there's a
4 direct-to-consumer advertising, but we don't want to
5 go into all that.
6 So the drug company, like Janssen,
7 would look to who's prescribing the drug if they're
8 interested in increasing the market share of a drug,
9 correct?
10 A. Correct.
11 Q. And so you would want to know questions like,
12 are the primary care physicians prescribing it, are
13 the psychiatrists prescribing it, or the pediatric
14 neurologist prescribing it, or the family doctor is
15 prescribing it, those are all fair questions to ask,
16 correct?
17 A. Correct.
18 Q. And those are, indeed, questions that you've
19 asked, here, correct? I'm sorry, that you were
20 asking about Risperdal back in 2002, correct?
21 A. Correct.
22 Q. And the fact is that you were looking, at
23 least on that day, Mister -- I'm never going to get
24 it right.
25 A. Bockes.

1 Q. Mr. Bockes was describing who is prescribing
2 the drug. And if we put this back up, he says,
3 PCPs. PCPs are primary care physicians?
4 A. Correct.
5 Q. And Peds are an increasing prescriber base,
6 correct?
7 A. Correct.
8 Q. That's also talking about what was going on
9 then, not what was going to go on in the future,
10 correct?
11 A. Correct.
12 Q. And then it says "education is critical in
13 this audience, given the low self-reported knowledge
14 of antipsychotics," correct?
15 A. Correct.
16 Q. So there was back then a plan to "educate"
17 some of these physicians, correct?
18 A. We supported medical education or continuing
19 medical education, so this would have been a group
20 that may have been included in the educational
21 grants that we gave.
22 Q. Well, sir -- bear with me. I just need to
23 find something.
24 MR. KLINE: Excuse me one second, Your
25 Honor.

1 (Pause.)
2 BY MR. KLINE:
3 Q. Let's move ahead to -- and then we'll come
4 back to 757. There was actually a plan in place not
5 for later on but rather for then to spend money
6 to -- let me just get this here. I'll start a new
7 question.
8 MR. KLINE: I lost my page, everyone.
9 I'm sorry. I apologize.
10 (Pause.)
11 BY MR. KLINE:
12 Q. All right. Let's look at this.
13 There's a Risperdal C&A PME by line
14 Item, correct?
15 A. Correct.
16 Q. And this only pertains to children and
17 adolescents, correct?
18 A. Correct.
19 Q. And I think I saw there was a budget of
20 something like 6.4 or 6.5 million dollars for these
21 kinds of purposes. Does that sound about right to
22 you?
23 A. Yeah, on the bottom you can see it's 5.24
24 million of what you're showing up on the slide.
25 Q. Oh, yeah. Thanks. 5.24, that's in '02?

1 A. Correct.
2 Q. So there were -- and this doesn't pertain at
3 all to educating or promoting or anything relating
4 to adults, correct?
5 A. Correct.
6 Q. And so there was in 2001 -- and I think we can
7 agree with this -- that these numbers are in
8 millions, so 1,200 is 1,200,000, correct?
9 A. Correct.
10 Q. One million two hundred thousand dollars was
11 spent on medical education in 2001 for doctors -- to
12 tell doctors about Risperdal as it's used in
13 children and adolescents, correct?
14 A. These were unrestricted medical grants that
15 were given. These are about the class of
16 antipsychotics, which did include Risperdal.
17 Q. I'm not on the grant. I'm on the medical
18 education.
19 A. Medical education, it's continuing medical
20 education which are educational grants. This is not
21 a sales rep disseminated. This is not Janssen
22 disseminated. These are grants given to medical
23 societies and other advocacy groups, and they're the
24 ones who go out and publish manuscripts or other
25 things educating physicians on a class. That's what

1 this is.
2 Q. Hopefully helpful to the drug, correct?
3 A. It may be helpful to the drug. But one of the
4 things that's important is if individuals were going
5 to use it, that they would use it correctly in those
6 patients.
7 Q. But this is all geared to children and
8 adolescents, Risperdal children and adolescents PME.
9 What's PME?
10 A. Product management expense.
11 Q. Product?
12 A. Management expense.
13 Q. So product management expense, this comes out
14 of the marketing department, correct?
15 A. Correct.
16 Q. Was there an education department?
17 A. No.
18 Q. It doesn't come under the medical affairs
19 department, does it?
20 A. Not at this time, no.
21 Q. Yes, I'm only interested in this time,
22 2001-2002.
23 In 2002, $2 1/2 million was spent on
24 "medical education," correct?
25 A. Correct.

1 Q. $150,000 was given out in grants to doctors,
2 correct?
3 A. Correct.
4 Q. 1,750,000 was given to doctors to sit on
5 advisory boards, correct?
6 A. That's not correct.
7 Q. Well, it says advisory boards.
8 A. Right. Well, you said that 1.75 million was
9 given to doctors. No, that would include the costs
10 of any logistics. That's not what was paid to
11 physicians.
12 Q. Oh, that would include the cost of the meals
13 and the sodas, correct?
14 A. That would include that, correct.
15 Q. But Janssen was going to spend -- and, look,
16 it went up from $400,000 in 2001 to $1,750,000 in
17 2002. Look at the increase, a 338 percent increase
18 in money spent on advisory boards, correct?
19 A. Correct.
20 Q. That's having doctors come in, in this case
21 largely pediatric psychiatrists, and providing them
22 with an opportunity to participate; is that correct?
23 MR. WINTER: Objection, Your Honor.
24 BY MR. KLINE:
25 Q. Is that correct?

1 THE COURT: Overruled.
2 THE WITNESS: It was for them to
3 participate in the advisory board, correct.
4 BY MR. KLINE:
5 Q. These are child doctors, by and large, because
6 this is a children and adolescent product management
7 expense, correct?
8 A. Yes, that's correct.
9 Q. And there was a half a million dollars
10 allocated -- I hope Pam didn't walk away with the
11 money, I see it says here $500,000 to Pam. Who's
12 Pam?
13 A. Pam was -- she was a vice president of public
14 relations at the time.
15 Q. Was that just a --
16 A. I don't know why that's --
17 Q. I don't think I get an objection, but is that
18 like a slush fund or something?
19 A. I don't know. I think that's probably because
20 that went to a separate budget. That's probably why
21 it's listed.
22 Q. Sir, there is $5,240,000 that's being spent
23 to -- spent on items on the product management
24 expense list, correct?
25 MR. WINTER: Objection, Your Honor.

1 THE COURT: Overruled.
2 You can answer this.
3 BY MR. KLINE:
4 Q. Is that correct?
5 A. Correct.
6 Q. And it's 178 percent, nearly double, from the
7 year before, correct?
8 A. Correct.
9 Q. And that, sir, is a window, you correct me if
10 I'm wrong, a window into the thinking of Janssen in
11 2001, in 2002, as to the child and adolescent
12 market, all off-label, correct? Correct?
13 A. That the uses were off-label?
14 Q. Yes.
15 A. Yes.
16 Q. This is a window into it, correct?
17 A. I don't know what you mean by "window into
18 it."
19 Q. I'll withdraw the question so we can move on.
20 Now, just to do the PME breakdown of
21 the two and a half -- this is what was -- this, by
22 the way, is what was going to be spent in 2002,
23 correct?
24 A. This is what was projected to be spent.
25 Q. By the way, in this particular meeting, did

1 you kick this around a little bit and discuss
2 whether some of these items were too big, too small,
3 or anything about it?
4 A. I don't recall any changes being made to what
5 was being proposed, no.
6 Q. Do you recall, sir, in July 2001 whether --
7 it's a whether question -- whether there was any
8 discussion about whether these were proper expenses?
9 Was there any discussion?
10 A. Well, the 2001 would have been presented in
11 2000, and I wasn't on the team.
12 Q. I meant 2002. How about for 2002?
13 A. Was there any discussion of whether this was
14 improper was the question?
15 Q. Yeah, yeah.
16 A. No.
17 Q. Okay.
18 Now, in the -- if you look here
19 quickly, medical expenses, the subcategories are
20 there, as well, correct, teletopics, DLN. What's
21 DLN?
22 A. It was an acronym for a medical education
23 company. I think it stood for distance learning
24 network.
25 Q. Distance learning.

1 And then audio conferences and
2 consensus guidelines?
3 A. Right.
4 Q. These regional advisory boards, sir, so a
5 regional advisory board, that would be like in
6 Philadelphia or in Wilkes-Barre or we're picking
7 Pennsylvania or Pittsburgh, you would have a group
8 of doctors come together and meet and the doctor --
9 the local doctors would be there, the child
10 psychiatrists, along with some Janssen people,
11 correct?
12 A. Correct.
13 Q. And what's an MSL?
14 A. MSL stands for medical science liaison.
15 Q. What's that that has a half a million dollar
16 budget?
17 A. I'm not -- I don't recall what that would have
18 been for.
19 Q. Who's KOL?
20 A. That stands for key opinion leader.
21 Q. Oh, and, by the way, key opinion leaders, you
22 had doctors who prescribed the drug who were known
23 as key opinion leaders, correct?
24 A. Correct.
25 Q. Those were doctors who could influence other

1 doctors in the prescription of the drug, correct?
2 That's as you saw it?
3 A. As we saw it, these were physicians that we
4 did work with or I should say have as consultants.
5 Q. Yeah, worked with.
6 A. The purpose with those physicians was to gain
7 input into our drug development and decisions that
8 we'd make as it relates to drug development.
9 Q. But, sir, the language is KOL, key opinion
10 leaders.
11 And a key opinion leader is one who
12 leads by example, correct?
13 A. Well, they're experts. That was the term that
14 was used for key experts.
15 Q. No, the key opinion leaders, they are people
16 who -- we can go to some documents -- they were
17 people who prescribed the drug and who were setting
18 an example for others who prescribed the drug, fair
19 enough?
20 A. Well, other people would look to see what they
21 were doing.
22 Q. Yes. And you knew that? There's no secret to
23 this, Doctor, is there, a key opinion leader is
24 someone who might influence other people in the
25 prescription of the drug, correct?

1 A. Correct.
2 Q. And so you were paying in 2002 -- the
3 projection here was to pay a half a million dollars
4 to key opinion leaders, child and adolescent
5 psychiatrists mainly, correct?
6 A. No. As I said before, these are not funds
7 that are being paid directly to a physician. Within
8 this sum of money, some of it would have gone
9 towards paying their honoraria or their fee for
10 attending a meeting to provide -- to give us
11 feedback.
12 This 500,000 would have been under the
13 budgets of medical science liaison which are
14 internal. Unless there's something else in this
15 document, I don't know what it refers to. I don't
16 recall.
17 Q. Correct me, I've seen doctors paid two, three,
18 five -- $10,000 to be a key opinion leader, would
19 you agree?
20 MR. WINTER: Objection, Your Honor.
21 THE COURT: Sustained.
22 BY MR. KLINE:
23 Q. So you would agree that doctors have been paid
24 as much as $10,000 as key opinion leaders?
25 MR. WINTER: Objection, Your Honor.

1 THE COURT: Sustained.
2 BY MR. KLINE:
3 Q. What's an HOV, sir?
4 A. Stands for home office visit.
5 Q. Home office visits, $250,000, what's involved
6 there?
7 A. They're similar to regional advisory board.
8 The only difference is rather than having it within
9 a region, the advisory board takes place within the
10 company, at the company, so that's what home office
11 is, another word for our company.
12 Q. Under public relations -- and, by the way,
13 public relations, this is public relations in 2002
14 as it pertained to child and adolescent usage of the
15 drug Risperdal, correct?
16 A. Correct.
17 Q. A hundred thousand dollars was allocated for a
18 response kit. What's a response kit?
19 A. Sure. So a response kit was there, had been
20 in the media, media coverage that they felt as
21 though kids were receiving antipsychotics in general
22 inappropriately. So there was a lot of what I would
23 say bad publicity about using antipsychotics, and
24 companies were getting contacted about the use of
25 their drugs in children.

1 So this response kit was to develop
2 essentially a response for when we had questions
3 that were coming in from the media. So this was not
4 proactive. This would be reactive, if we received
5 questions.
6 Q. The response kit was to say there's lots of
7 benefits to antipsychotic drugs, essentially,
8 correct?
9 A. I don't recall what was in the response kit.
10 Q. Well, it was positive towards the use of
11 antipsychotics, can we agree on that, sir?
12 A. Well, the response kit would have been
13 whatever fair balance information would have gone
14 through regulatory group, our legal group.
15 Q. Yeah.
16 A. It wasn't a promotional kit.
17 Q. It would be the company response, correct?
18 A. It is the company response, correct.
19 Q. And you spent $50,000 for advocacy success
20 stories, correct?
21 A. Correct.
22 Q. Now, this is one, clinical "seeding." Is that
23 seeding studies?
24 A. I don't know, because this is under public
25 relations.

1 Q. What's a seeding study, sir?
2 A. Seeding studies used to be studies -- I have
3 to think now exactly how it would be used.
4 Q. Let me try to help you.
5 A seeding study, sir, is a study which
6 would be published in the literature, which would
7 plant the seed in another doctor's mind that a drug
8 was good. You've heard that term, correct?
9 A. Yes, but a seeding study doesn't have to
10 necessarily refer to what you just said.
11 Q. Doesn't necessarily. But you've heard it used
12 just like I said?
13 A. I've heard it used, yes.
14 MR. WINTER: Objection, Your Honor.
15 BY MR. KLINE:
16 Q. Tell me what international consensus is.
17 A. I don't recall. My guess would be
18 international consensus would be some kind of a
19 consensus paper where we get a number of experts,
20 advocacy groups, together to come up with a
21 consensus on the role, for example, of
22 antipsychotics in the treatment of child and
23 adolescent, what was the consensus out there about
24 whether or not this should be done, that would be an
25 example of a consensus.

1 Q. None of this money, sir, none of it, correct
2 me if I'm wrong, was spent on the adult-approved use
3 of the drug for schizophrenia, correct?
4 A. None of this money here?
5 Q. Yes. Out of this money here, none of it was
6 spent on the approved adult schizophrenia use of the
7 drug in 2002; is that correct?
8 A. Correct.
9 Q. Let's continue on.
10 Now, this particular document, like
11 the 2002 document, has a SWOT analysis which is on
12 page 737, and we'll display it ever so briefly.
13 A SWOT analysis is a standard feature
14 in these presentations, correct?
15 A. Correct.
16 Q. Since it stands for -- on this particular one,
17 the safety perception is the No. 1 listed item with
18 prolactin in the parenthesis, correct?
19 A. Correct.
20 Q. And the threats, the first threat is
21 "PR-Damage to: RISPERDAL, Janssen, J&J," correct?
22 A. That is correct.
23 Q. Do you recall that discussion, sir?
24 A. Yes.
25 Q. And that -- PR means public relations,

1 correct?
2 A. Correct.
3 Q. Okay. Now let me move forward and then
4 we'll -- we may move back.
5 The next slide which I'd like to deal
6 with is Slide 739. We'll display it.
7 739, sir, talks about the child and
8 adolescent market as an "underdeveloped market,"
9 correct?
10 A. Correct.
11 Q. Now, if I can put -- if we can highlight that
12 for a moment.
13 MR. KLINE: I just want to do a split
14 screen.
15 BY MR. KLINE:
16 Q. Your prior slide or the prior slide of your
17 colleague, it talked about the markets, and this is
18 the market -- what we're looking at with the bars,
19 ADHD, depression and anxiety, bipolar,
20 schizophrenia, and autism, this was the entirety of
21 the child and adolescent market, correct?
22 A. You're referring to on the right-hand side?
23 Q. Yeah, on the right-hand side is the entirety
24 of the market, correct?
25 A. Well, there might have been other uses that

1 were smaller that just were not captured there.
2 Q. Oh, but doctor -- not doctor. Mr. DeLoria, de
3 minimis, correct, this is the market right here,
4 this is 99.9 percent of this market, this child and
5 adolescent market, correct?
6 A. It's the vast majority of the market, correct.
7 Q. The vast majority, the vast majority of the
8 market, we've already established what that is, and
9 now we know when we get to this slide that
10 Janssen -- as of that day, July 2001, Janssen viewed
11 it as an underdeveloped market, correct?
12 A. Correct.
13 Q. It doesn't say underdeveloped autism market
14 for the future, does it?
15 A. Correct.
16 Q. It says underdeveloped market, correct?
17 A. Correct.
18 Q. And what's the strategy? The strategy for
19 this non-approved FDA use, the strategy is to expand
20 the market, correct?
21 A. Correct.
22 Q. And the way that the market's going to get
23 expanded is by increasing awareness and appropriate
24 use of Risperdal, correct?
25 A. Correct.

1 Q. So what you have here, correct me if I'm
2 wrong, is a very specific strategy of what Janssen
3 had in mind in 2002, specifically -- I'm sorry -- in
4 2001, July of 2001, correct?
5 A. Correct.
6 Q. And, by the way, this is before the pooled
7 analysis, correct?
8 A. Correct.
9 Q. But after -- after the results of RIS-41 were
10 known, correct?
11 A. Correct.
12 Q. Is there anything on any one of these slides
13 in July 2001, anything in any of these slides in the
14 July 2001 presentation -- and you've looked through
15 it, correct?
16 A. Correct.
17 Q. Anything that has the word "gynecomastia"?
18 A. Not that I recall.
19 Q. Is there anything that says that we have a
20 rate of gynecomastia in -- strike that. You
21 answered the question.
22 How about in the 2002; does the
23 word "gynecomastia" even appear in that document?
24 A. Well, this is a business plan. This isn't a
25 clinical review of evidence of the product. This is

1 a business plan.
2 Q. Thank you. You talked about -- you talked
3 about risks and strategies.
4 The word "prolactin" is used, isn't
5 it?
6 A. Yes.
7 Q. That's a medical word, isn't it?
8 A. Yes.
9 Q. My question is now, is gynecomastia mentioned
10 at all?
11 A. No, not that I recall.
12 Q. The RIS-41 study that showed there was about
13 five out of a hundred boys getting gynecomastia, is
14 that mentioned?
15 MR. WINTER: Objection, Your Honor.
16 THE COURT: Sustained.
17 BY MR. KLINE:
18 Q. Okay. Now, what the next slide says in July
19 2001, Bates No. 740 --
20 MR. KLINE: Oh, by the way, can we
21 snapshot that so we have it, and we'll mark it
22 at the end of the presentation or give it a
23 number now, Mr. Gomez.
24 MR. GOMEZ: P-64.
25 MR. KLINE: P-64.

1 - - -

2 (Whereupon, Exhibit P-64 was marked

3 for identification.)

4 - - -

5 BY MR. KLINE:

6 Q. The next slide, which is Exhibit No. 740 -- by

7 the way, I assume that each one of these

8 presentations was -- was it an afternoon long, a day

9 long? It appears to be a lengthy slide

10 presentation.

11 A. This particular presentation?

12 Q. Yeah.

13 A. Would have been probably an hour.

14 Q. Okay. Psychopharmacology is a sensitive issue

15 in children. Do you see that?

16 A. Yes.

17 Q. And that was known and recognized to Janssen,

18 correct?

19 A. Correct.

20 Q. And so there were two strategies involved,

21 one, develop child and adolescent media management

22 plan. Do you see that?

23 A. Yes.

24 Q. Was that a media and management plan that you

25 were going to put in effect when you got an approval

1 down the road for autism?
2 A. No. This was, as I referred to before, if we
3 would receive questions from the media and being
4 able to respond to them, so that was along the same
5 lines.
6 Q. Well, sir, it specifically says it's a
7 management plan, correct?
8 A. Yes.
9 Q. The plan was to manage the media as to a
10 sensitive issue. Can we agree?
11 A. Yes.
12 Q. And since pharmacology was a sensitive issue
13 with children, the Janssen company was going to
14 develop a public relations plan, correct?
15 A. Correct.
16 Q. And in addition to a strategy, a word that I
17 asked you about earlier, which is tactics, let's see
18 what the tactics were.
19 First, you were going to have internal
20 and external spokespersons trained and available,
21 treatment guidelines disseminated, correct?
22 A. Correct.
23 Q. Family speaker's forum, was that to reach out
24 to families of disabled children?
25 A. I don't recall. It sounds like it would be a

1 forum where families could speak about their
2 experiences.
3 Q. And, by the way, all of these tactics were
4 going to cost money, correct?
5 A. Correct.
6 Q. And you were going to identify advocacy
7 spokespeople, correct?
8 A. Correct.
9 Q. The next slide that was presented that day on
10 5741 was the fact that the marketplace for this
11 off-label antipsychotic children and adolescent
12 market was being increasingly competitive, correct?
13 A. That's what we stated.
14 Q. And the strategy wasn't to do something in the
15 future, the strategy was to compete now, correct?
16 It says so.
17 A. Where does it say that?
18 Q. The strategy was to compete now. It says
19 right here "differentiate Risperdal from other
20 antipsychotics and other therapeutic classes." That
21 was something that was going to be done then and
22 there, correct?
23 A. If you look at these tactics, for example, the
24 second bullet point, "develop clinical programs to
25 meet U.S. regulatory market needs," that takes

1 several years to do that.
2 Q. Let's look at the first part.
3 The strategy is to differentiate
4 Risperdal from other antipsychotics, correct?
5 A. Correct.
6 Q. That was going to be done then and there,
7 correct, sir?
8 A. Well, you would start these programs, but
9 targeted EMRP studies that would take years before
10 they come out.
11 Q. Sure.
12 A. Post hoc analysis. You're saying here now
13 this is something we would do the next week, so...
14 Q. I'm not implying that.
15 In fact, all of these things that you
16 would have to do, the drug, sir, as you understood
17 it, as you understood it, the drug, and you correct
18 me if I'm wrong, the drug as of 2001 had hardly been
19 proven to be safe in children and adolescents,
20 correct?
21 A. That is not correct.
22 Q. Well, the label itself, sir, said safety and
23 efficacy is not established -- let me finish.
24 A. Okay.
25 Q. Do you know the label?

1 A. Yes.
2 Q. Did Janssen copyright the label? Is there
3 Janssen copywritten on the label?
4 A. There is a copyright on the label.
5 Q. Yeah. I can tell there is.
6 A. Yeah.
7 Q. The labeling is a Janssen statement, correct?
8 It's a Janssen-owned statement with a copyright by
9 Janssen and the Janssen logo on it, correct?
10 A. The Janssen logo is on it, correct. Yeah, the
11 logo is on it.
12 Q. Yeah. And, sir, you're doing all of these
13 things -- and the label of the drug, the label of
14 the drug says safety and efficacy in children has
15 not been proven; you were aware of that fact,
16 weren't you?
17 A. Yes.
18 Q. Is there anywhere in the slideshow -- is there
19 anywhere in the slideshow that mentions the label?
20 A. No, because we don't have an approved label
21 for use in child and adolescent.
22 Q. Yeah.
23 A. This is an internal document.
24 Q. Is there anything in the slideshow that says
25 what is in the label in 2002, which is safety and

1 efficacy in children has not been established? Is
2 that anywhere in the slideshow?
3 A. No.
4 Q. Is it anywhere in the 2002 slideshow?
5 A. No. But, again, it's an internal document, so
6 an internal document wouldn't need to state that.
7 Q. Do you think that everyone who was sitting in
8 the room up to the president of Janssen -- it's the
9 president of Janssen, U.S.A., correct?
10 A. Correct.
11 Q. Is there anyone up to Mr. Gorsky who you
12 believe didn't know that all of these things were
13 being done for a drug which the label said was
14 safety and efficacy hadn't been proven?
15 MR. WINTER: Objection, Your Honor.
16 THE COURT: I think you've covered
17 this.
18 Sustained.
19 BY MR. KLINE:
20 Q. Now -- in fact, sir, if you look at two slides
21 down, following all the slides that we've seen, all
22 the slides that we've seen, here are the critical
23 success factors.
24 And, by the way, can we agree, these
25 just aren't success factors, these are critical,

1 that's the word that was used, correct?
2 A. Correct.
3 Q. The critical success factor, No. 1, data is
4 needed -- needed, do you see that word?
5 A. Yes.
6 Q. It doesn't say desirable, it says that it's
7 needed.
8 And what's it need -- what do you need
9 to demonstrate? What does Janssen need to
10 demonstrate?
11 A. Long-term safety.
12 Q. As of this point in time, with all of the
13 things that we've seen for the last few hours, for
14 which I'm grateful of everyone's indulgence, the
15 presenter here told the group that we need data that
16 will show the long-term safety of the drug, correct?
17 A. Correct.
18 Q. And one of the things that we've seen here
19 that was being challenged by the competitors and
20 which was not yet established was whether the drug
21 had bad prolactin effects, side effects, correct?
22 MR. WINTER: Objection.
23 THE WITNESS: That was one of the
24 questions.
25 BY MR. KLINE:

1 Q. That was one of the?
2 A. The questions we were getting asked about, the
3 long-term safety of elevated prolactin. That was a
4 question that some of our advisors had asked us.
5 Q. Yeah. It wasn't established yet, correct?
6 A. There wasn't data on it, that's correct.
7 Q. Let me understand this, sir: There were 1.6
8 million total prescriptions to children and
9 adolescents, and Janssen didn't have safety data on
10 this point yet; is that correct?
11 MR. WINTER: Objection, Your Honor.
12 THE COURT: Sustained.
13 I think you've covered this, and it's
14 getting argumentative at this point, Mr. Kline.
15 BY MR. KLINE:
16 Q. I want to briefly go over a few more things to
17 go on to other documents.
18 I want to look at, if we can, the
19 Bates No. 753. 753 you have the average percentage
20 of antipsychotic prescriptions for C&A patients
21 allotted in each age group. And it appears, sir,
22 that five percent were in the -- this is total --
23 five percent were in the zero- to six-year range,
24 correct, bottom line?
25 A. Correct.

1 Q. A third, 33 percent, were in the 7- to 12-year
2 range and 63 percent were in the 13- to 19-year
3 range; is that correct?
4 A. Correct.
5 Q. And, sir, do you remember when we said that
6 safety as to prolactin had not yet been established?
7 Do you remember our discussion a moment ago?
8 A. Yes.
9 Q. I want you to look, sir, at 756, clinical
10 data, key messages. Highlight clinical data, key
11 messages, safety.
12 A. Correct. Yes, I see it.
13 Q. Sir, the message -- the clinical data key
14 message was to be the exact opposite; namely, low
15 prolactin, correct?
16 MR. WINTER: Objection, Your Honor.
17 BY MR. KLINE:
18 Q. Correct, sir?
19 THE COURT: I'll allow it. I'm not
20 sure that's --
21 MR. KLINE: I'll just ask it a
22 different way.
23 THE COURT: Pose the question and Mr.
24 DeLoria can answer it. I'll overrule the
25 objection if that's what it means.

1 BY MR. KLINE:
2 Q. Does the question say safety -- the clinical
3 data key message, sir, a key message is the most
4 important message, can we agree?
5 A. Yes.
6 Q. And we've talked about what a message is, and
7 No. 1 is safety, correct?
8 A. Correct.
9 Q. And A1 is something we're not talking about.
10 A2 says low prolactin, correct?
11 A. Correct.
12 Q. Sir, at that time, that key message -- that
13 was the key message, correct?
14 A. Correct.
15 Q. I'm going to have some documents to show you.
16 I think this will move quicker. We have, first of
17 all -- so, sir, just as benchmarks, the business
18 plans we were looking at were July '01, and that
19 doesn't have a specific date.
20 Do you have it pinned to a specific
21 date, sir?
22 A. I don't.
23 Q. Okay.
24 And then the second one is -- these
25 appear to come out in July. It's kind of a July

1 thing; is that correct?
2 A. Yes.
3 Q. Planning for the following year?
4 A. Yes, generally summer, July or August, yeah.
5 Q. Because we're now going to talk about a number
6 of documents that kind of flow in between, and I
7 just wanted to put our benchmarks up in front of us.
8 First of all, sir, we have here --
9 sir, there's an e-mail which you are on, I'm quite
10 confident there's an e-mail dated September 6th,
11 2001. It ends in Bates No. 142. And it's an e-mail
12 transmitting the topline RIS-41 results to many
13 people, including you.
14 Do you recall seeing the topline
15 RIS-41 document?
16 A. Yes.
17 Q. Did you read it?
18 MR. WINTER: Your Honor, can we wait a
19 second? I haven't seen the exhibit.
20 THE COURT: Very well.
21 MR. KLINE: Your Honor, I was talking
22 with Mr. Winter. Do you plan to go to about
23 4:00? We're trying to see if we can get him
24 out of here.
25 THE COURT: 4:00, yes, if you can do

1 that.
2 MR. KLINE: Let's see what I can do.
3 He may get held over, but I'm hoping not, given
4 the weather.
5 BY MR. KLINE:
6 Q. Maybe we can accomplish some of this stuff
7 without documents. Let's try it. We'll see where
8 we go. We'll see what you know, don't know. If you
9 don't know, I'll refresh your recollection. Fair
10 enough?
11 A. Fair.
12 Q. RIS-41 topline results, did you get them?
13 A. Yes.
14 Q. Would that be standard for you to get them?
15 You're in marketing. Did you get them -- I mean,
16 were you on the RIS-41 topline results, the interim
17 results, the final results?
18 A. Yeah, I would have received them.
19 Q. We don't have to run for those documents,
20 anyone. I'll try to do as little with documents as
21 possible and try to save all the stuff.
22 Sir, was it your practice when you get
23 the topline results, you get the results to read
24 them?
25 A. Yeah, I would have probably gone through the

1 summary and skimmed through it.
2 Q. Right. You'd read the key thing, correct?
3 A. Right.
4 Q. Just like when you see a medical article, you
5 read the abstract?
6 A. Yeah, exactly.
7 Q. Grab a hold of the basic concept. Okay?
8 A. Yes.
9 Q. So would it be fair to say that you generally
10 knew about the gynecomastia percentages that were
11 being reported in the topline, interim, and final
12 results?
13 A. In general, sure.
14 Q. You had an understanding that they were
15 finding about five percent of the boys were having
16 gynecomastia, would that be fair?
17 MR. WINTER: Objection, Your Honor.
18 MR. KLINE: Well --
19 THE COURT: Overruled.
20 THE WITNESS: In this particular
21 study, yeah, I was aware of that.
22 BY MR. KLINE:
23 Q. Yeah, in this particular study, that's good.
24 I think we saved 20 minutes doing it that way.
25 Thank you for helping.

1 Now, sir, there was an October '01
2 tactical plan -- are you familiar with October 9,
3 2001, tactical plan?
4 A. Yes, I know what it is.
5 Q. Tactical plan --
6 A. These are the projects that would be run -- or
7 conducted.
8 Q. So what it does is it -- this is a plan as to
9 what is going to be done to push the project of
10 Risperdal forward as it pertains to children and
11 adolescents, correct?
12 A. It's the execution of the business plan.
13 Q. Okay. So October 9, '01 is when that
14 happened, okay. And there's a page there.
15 MR. KLINE: Do you need a copy, Mr.
16 Winter, or do you have it in front of you? If
17 you do, I'll get you one quickly. The tactical
18 plan, October '01 tactical plan.
19 MR. WINTER: Thank you.
20 MR. GOMEZ: We'll mark it.
21 MR. KLINE: Mark it as P --
22 MR. GOMEZ: -- 65.
23 - - -
24 (Whereupon, Exhibit P-65 was marked
25 for identification.)

1 - - -

2 BY MR. KLINE:

3 Q. And I'll hand you a copy. I'm going to

4 display a page or two.

5 A. Okay.

6 Q. Did you review this in advance of your

7 testimony?

8 A. I did not, not that I recall, no.

9 Q. We're going to look at one page, which is

10 ending in Bates No. 232.

11 And, sir -- and this comes out of the

12 marketing department?

13 A. The publication budget comes out of the

14 marketing department. The actual people that are

15 writing the papers, for example, the lead authors,

16 obviously, are not, but the funding for the

17 publication plan comes out of the marketing

18 department.

19 Q. Oh, I see. So these various studies when they

20 were -- help me with this -- you have -- for

21 example, let's take RIS-41, okay, who funded it, the

22 marketing -- did the budget come out of the

23 marketing department?

24 A. Just the -- not the study.

25 Q. Right.

1 A. Just the -- there's a vendor that we would
2 hire that would help the author in getting the paper
3 together and submitting it to the journal and
4 formatting them. The marketing department has the
5 budget to pay that vendor.
6 Q. Okay.
7 A. So that that's -- that's why it was in this
8 budget, because that money goes towards paying the
9 vendor that assists the lead author, wherever he or
10 she needs assistance in formatting it, etc.
11 Q. All this says is key data available for
12 dissemination. The only point I wanted to try to
13 get to is as of October 9, 2001, RIS INT-41 --
14 that's the study we've discussed in this courtroom a
15 lot -- that is -- that was available for
16 dissemination, correct?
17 A. The data was available?
18 Q. Yes.
19 A. Yes.
20 Q. What does this mean, does this mean something
21 different?
22 A. No, no.
23 Q. And it says here JF -- JRF generated. What
24 does JRF generated mean?
25 A. Janssen Research Foundation.

1 Q. Okay. I'm looking at an e-mail. I want to go
2 through a few of them. Looking at an e-mail dated
3 January 10, 2002. Yeah, if I might, let me step
4 back one second.
5 All of these studies that are on this
6 form are Janssen research fund generated would
7 include all of the studies that are on that list,
8 correct, if we can put back up this exhibit; is that
9 correct?
10 A. Yeah, these were funded or generated by
11 Janssen.
12 Q. Very well.
13 And let me look at an e-mail that is
14 dated January 10, 2002. It's from you. It's to
15 Mister --
16 A. Pandina -- Bockes.
17 Q. Bockes.
18 A. Okay.
19 MR. KLINE: We'll hand a copy to
20 counsel. Mark it as an exhibit. P-66.
21 - - -
22 (Whereupon, Exhibit P-66 was marked
23 for identification.)
24 - - -
25 BY MR. KLINE:

1 Q. Now, sir, are you familiar with this e-mail?
2 A. I don't recall it, but I just read it.
3 Q. Okay.
4 A. So...
5 Q. And it's you to Mr. Bockes, January 10, 2002?
6 A. Yes.
7 Q. And all I want to establish is what it says in
8 the second sentence, "we currently have one
9 prolactin reanalysis project underway," correct?
10 A. Correct.
11 Q. That would be you in marketing to Mr. Bockes
12 in marketing, correct?
13 MR. WINTER: Mr. Kline --
14 MR. KLINE: I'm sorry. It's from
15 Bockes to you. Thank you, thank you, thank
16 you. I'm rushing. I was hoping to get done
17 today, so I apologize. I'm trying. I don't
18 know if I can do it.
19 BY MR. KLINE:
20 Q. But Bockes to you --
21 MR. KLINE: Thank you, Mr. Winter. I
22 appreciate that.
23 BY MR. KLINE:
24 Q. -- "we currently have one prolactin reanalysis
25 project underway," correct?

1 A. Correct.
2 Q. Okay. And the date of it is January 10, '02.
3 Moving along, there is an e-mail dated
4 May 15, 2002, and it is from -- it's from Binder to
5 Pandina showing Table 21. When did you get Table
6 21, sir?
7 A. I don't recall.
8 Q. Sometime in 2001 -- I'm sorry, 2002?
9 A. Potentially. I don't even remember Table 21
10 until I'd seen some documents prior to this today.
11 Q. You've seen it in the litigation, it would be
12 fair to say, but you don't recall when you saw it in
13 2002?
14 A. That is correct.
15 Q. Would that be a fair statement?
16 A. Yes, correct.
17 Q. Covered.
18 Next, sir, there is -- there's an
19 e-mail to you dated June 11, 2002, and it -- I want
20 to show you a document marked June 11, 2002. It is
21 an e-mail from Mr. Pandina to you.
22 Briefly, while we get it out, who is
23 Mr. Pandina?
24 A. He was the medical affairs.
25 Q. And you interacted with him quite a bit on the

1 Risperdal matters; is that correct?
2 A. Yes, fair amount.
3 Q. And he sent an e-mail to you on that date,
4 actually just to you and to Irene Hsu, H-S-U.
5 Who is Irene Hsu?
6 A. Irene worked in my group and she worked in
7 managing the publication vendor and some other --
8 she had some other responsibilities, too.
9 Q. She worked for you, is that what I heard you
10 say?
11 A. Yes.
12 Q. And I want to see if you recognize a
13 document --
14 MR. KLINE: Do we have it handy,
15 Chris? If not, I'll have to pass.
16 MR. GOMEZ: Yeah.
17 MR. KLINE: P-68.
18 - - -
19 (Whereupon, Exhibit P-68 was marked
20 for identification.)
21 - - -
22 BY MR. KLINE:
23 Q. Sir, I'll hand it to you. If I may, I want to
24 display it, if there's no objection, to the jury.
25 It is from DeLoria -- it is from

1 Pandina to DeLoria, and it starts off with figure
2 one, prolactin observations. Do you see that?
3 A. Yes.
4 Q. Those prolactin observations, sir, did you --
5 were you told where they came from?
6 A. Well, in this -- this looks like it's some
7 kind of a poster presentation or a summary.
8 Q. Yes. They came from the data that was run in
9 May of 2001, which was just within the month before.
10 Does that sound familiar?
11 A. Yes.
12 Q. Okay. You said yes, correct?
13 A. Yes.
14 Q. Okay. Thank you. Next -- and hold on just
15 one second.
16 MR. KLINE: We're ready for the next
17 exhibit number, which is?
18 MR. GOMEZ: 69.
19 MR. KLINE: 69.
20 - - -
21 (Whereupon, Exhibit P-69 was marked
22 for identification.)
23 - - -
24 BY MR. KLINE:
25 Q. The jury has heard about a meeting that was at

1 the Palace Hotel in New York.
2 Were you at that meeting at the Palace
3 Hotel?
4 A. I was.
5 Q. You were?
6 A. I was, yes.
7 Q. They've heard a lot about it. I don't plan to
8 retread it. That will make everyone happy.
9 What I do want to talk about is a
10 meeting that was at The Mark Hotel in New York City.
11 Do you remember that meeting?
12 A. I do not.
13 Q. Okay.
14 A. Was it an advisory board?
15 Q. It was a child and adolescent national
16 advisory board. Do you recall it?
17 A. Yeah.
18 Q. Let's take the document out because it has you
19 as the first presentation on it.
20 A. Yes.
21 Q. Have you reviewed this document in advance of
22 today's testimony?
23 A. I believe I have. Once I see it, I can
24 confirm, but...
25 Q. Right in front of you, sir. We'll display it

1 to the jury. Are you familiar with it?
2 A. Yes.
3 Q. You were there, you presented?
4 A. Yes.
5 Q. You were -- you were like the first presenter,
6 correct?
7 A. Correct.
8 Q. The first order of business was by you at The
9 Mark Hotel, June 14th, '02, and to put it in
10 perspective, June 14, '02 is The Mark Hotel, C&A.
11 Now, who's present at this, lots of
12 people from outside of Janssen and Janssen people?
13 A. Yeah, there probably would have been maybe ten
14 advisors and some folks from Janssen, maybe 20
15 people altogether.
16 Q. Very briefly.
17 The first thing that's discussed at
18 the meeting, section 1, on page 3 is up on the very
19 top is the market overview by the chief marketing
20 person, correct, you? Correct?
21 A. Correct.
22 Q. And the discussion highlights the first
23 discussion, discussion highlight, first discussion
24 highlight was to "reanalyze the data, removing
25 18- to 19-year-old patients from the child and

1 adolescent market; advisors had arguments for and
2 against that" -- "this." Do you see that?
3 A. Apparently I'm on the wrong page.
4 Q. Discussion highlights, it's on the same page,
5 page 3.
6 A. Oh, okay. I see. On the bottom, okay. I was
7 looking at the top, okay.
8 Q. Do you see that?
9 A. Yes.
10 Q. And, sir, is that removing the 18- to
11 19-year-old patients, are you talking about removing
12 the under tens, or don't you remember?
13 A. I don't recall.
14 Q. And then let's look at something here.
15 You were copied, sir, on multiple
16 drafts of the pooled analysis. The jury has seen
17 them probably more than they want to, but they've
18 seen them a lot, correct? I shouldn't say correct
19 to that.
20 You saw the -- in realtime you were --
21 you were being copied, you in the marketing
22 department were being copied on the drafts, correct?
23 A. Correct.
24 Q. And, in fact, sir, did you see the e-mail
25 where you were copied on the first draft?

1 A. I may have. I'd have to see...
2 Q. Let's do that. Hopefully with dispatch. It's
3 Exhibit number -- I'm sorry, in the draft of INT-41.
4 I had a different point to make very quickly. Maybe
5 I can do it without a document.
6 It's correct, sir, that Joe Lin, who
7 worked for you, he is described in an e-mail from
8 you as the primary reviewer, primary reviewer for
9 all Risperdal child and adolescent publications.
10 Does that sound correct?
11 A. He was to be the reviewer, that is correct.
12 Q. And Lin, what's his background?
13 A. In terms of his educational background?
14 Q. Yeah.
15 A. He was in marketing.
16 Q. Marketing, like has a bachelor's in marketing?
17 A. I don't remember his degree.
18 Q. He's not a medically-trained person, correct?
19 A. Correct. It wasn't reviewing the manuscript
20 for medical accuracy.
21 Q. Yes. Let's display it for one moment.
22 MR. GOMEZ: P-70.
23 MR. KLINE: P-70.
24 - - -
25 (Whereupon, Exhibit P-70 was marked

1 for identification.)
2 - - -
3 BY MR. KLINE:
4 Q. Thank you very much for your cooperation in
5 all of this back and forth. From Carmen DeLoria to
6 Joe Lin and Karen Zimmerman. Who's Zimmerman?
7 A. She was involved in publication planning.
8 Q. "Karen, Joe is now the primary reviewer for
9 all Risperdal C&A publications." Do you see that?
10 A. Yes.
11 Q. And he would review the medical articles when
12 they came to the marketing department, correct?
13 A. Correct. There were a number of people who
14 would review it to look for -- make sure that it
15 made sense, there weren't any errors in the
16 publication, they were just another set of eyes, and
17 he was responsible for that.
18 MR. KLINE: Your Honor, I realize I'm
19 rushing. I can't do it in five minutes. I'm
20 just going to have to hold it over. I just
21 can't get it.
22 THE COURT: Very well.
23 This may be a good time to adjourn
24 anyway.
25 Ladies and gentlemen, I'm pretty sure

1 the courts are going to be closed tomorrow,
2 but, nonetheless, I'm taking the bull by the
3 horns, so to speak.
4 It looks like there's going to be an
5 awful lot of snow, and because of that
6 difficulty of you getting here, me getting
7 here, attorneys, witnesses, we'll adjourn until
8 Friday, 20 -- we'll try 25 after 9:00. Let's
9 see what the weather is. Do the best you can.
10 Have a pleasant day tomorrow, if you
11 can.
12 - - -
13 (Whereupon, the jury was excused
14 from the courtroom at 3:49 p.m.)
15 - - -
16 THE COURT: Off the record.
17 - - -
18 (Whereupon, a discussion was held
19 off the record.)
20 - - -
21 (Whereupon, the proceedings were
22 adjourned at 3:50 p.m.)
23 - - -
24
25

1 C E R T I F I C A T I O N

2 I hereby certify that the proceedings

3 and evidence are contained fully and accurately

4 in the notes taken by me on the trial of the

5 above case, and that this copy is a correct

6 transcript of the same.

7

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10 ___________________________
Danielle O'Connor, RPR, CRR
Official Court Reporter

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