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

W.C. et al. : MARCH TERM, 2013
:
vs. :
:
JANSSEN PHARMACEUTICALS, :
INC.; JOHNSON & JOHNSON; :
and JANSSEN RESEARCH & :
DEVELOPMENT, LLC : NO. 1803

MORNING SESSION

March 4, 2015

Courtroom 253, City Hall
Philadelphia, PA

BEFORE: HONORABLE VICTOR J. DiNUBILE, JUDGE,

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MR. WINTER: Your Honor, the next witness is someone from Janssen, Mr. DeLoria.

THE COURT: Yes.

MR. WINTER: On February 17th when we argued the in limine motions, you over our objection -- and I'm renewing an objection or a motion, Judge, at this point in time, I know what you ruled, but you said that plaintiffs can show that Janssen knew it, meaning Risperdal was being used off-label, and what they were doing as far as promotion, and then you went on to say plaintiffs can show what we were telling doctors in general.

I think given the record that now exists in the case, we object to any testimony that doesn't relate to the prescribers in this case, Your Honor.

THE COURT: See, I think it's not -- we're talking about the negligence issue, we're not talking causation, we're talking about negligence, what did Janssen know or have reason to know about the relationship

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between Risperdal and gynecomastia and high prolactin levels and what did they do. And that's all issues for the jury and therefore you don't limit it just to the doctors in question.

Now, for causation purposes and otherwise, you can argue that these doctors knew about it. Of course, Mr. Kline and Mr. Gomez is going to argue the opposite, but that's all fair game.

So I stand by my ruling.

MR. WINTER: Understanding that, Your Honor, we would object, and I don't want to have to stand up every time.

THE COURT: You don't have to. You've preserved this right, first of all, at the motion in limine and you've preserved that right again today. You don't have to object to each and every question.

MR. WINTER: Understanding that, Your Honor, to the extent Mr. Kline wants to start showing sales figures, dollars and cents in terms of sales of Risperdal, we vigorously object to that.

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THE COURT: Let me hear how that goes.
You may have a point. I have to hear it.

MR. WINTER: Thank you, Your Honor.

THE COURT: But the overall concept
I've ruled on.

MR. KLINE: Yes. And we plan to show
the business plan, which -- and it includes
information. I basically plan to walk them
through their own documents with a witness
who knows these documents and show what
they were thinking, what they knew, what
their objectives were. They say making
money is an objective. So we want to
discuss it.

THE COURT: I think -- I will -- if
you have specific objection, I'll rule on
it. I have to hear it.

MR. WINTER: Your Honor, if it's
negligence, what did we know and what did
we tell the doctors, that's what you said
they could ask about.

THE COURT: What they have reason to
know and what did you do about it.

MR. KLINE: What were they motivated

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to do. That's another issue.

THE COURT: Might be. Might be a motive. I'm not going to let you start delving into a lot of problems. What we're doing here is we have to balance the prejudicial aspect and the relevancy aspect to the point in question.

MR. KLINE: I don't have profits, I have sales because that shows what that meant to them and it gave the reason why they did what they did.

THE COURT: That may be relevant.

MR. KLINE: And this witness actually is in the middle of it.

THE COURT: I have to hear the individual question. I can't go -- I'm not going to go any further.

MR. KLINE: Okay.

MR. WINTER: Judge, understanding you're not going to go any further, you told us that we could not go into medical records relating to Mr. Cirba because there were things that we all know were in the records that could be prejudicial to him.

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THE COURT: Let me say this. The record speaks for itself, I don't have to summarize. I think you've gotten out Mr. Cirba's -- his mental health issues. So I don't see where you've been limited at all so far. So I think that summary may be incorrect. So you have to point to specifics.

MR. WINTER: Very well, Your Honor.

COURT CRIER: Jurors are now entering.

(Jury enters courtroom)

THE COURT: Good morning. Officially good morning. Ladies and gentlemen, thank you for your patience and courtesy. We're starting about an hour or so late due to a fire drill, I guess. I don't know if it was a fire drill, why we had it. I know there were fire engines around. But again thank you and we're ready to proceed.

Mr. Kline, you may proceed.

MR. KLINE: Your Honor, thank you.
Good morning.

Good morning, members of the jury.

THE JURY: Good morning.

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MR. KLINE: At this time plaintiffs call on cross-examination Carmen DeLoria from the Janssen Company.

THE COURT: Ladies and gentlemen, you haven't seen this live, but in a civil case one side can call the other side as of cross-examination. And of course, Janssen is a company, but the officials of the company who stand for the company like Mr. DeLoria is an adverse witness to Mr. Kline. So he can call him as of cross-examination and cross-examine Mr. DeLoria.

It can never be done in a criminal case and you know why, because under our constitutional rights you can't -- a defendant in a criminal case can't testify against himself or herself under Fifth, 14th Amendment rights and federal Constitution and applicable state provisions of our State Constitution. But it's done all the time in a civil case and that's what's happening here.

Now, you saw videotaped depositions where there were questions on both sides,

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but it's hard to pick up whether it was a cross-examination. It was more a discovery-type video deposition. It was a little harder to pick it up. But you'll see it here where Mr. Kline would have a right to pose leading questions and cross-examine Mr. DeLoria.

COURT CRIER: Stand for me for a moment, please. Just raise your right hand. State your full name and spell both your first and last name and your title.

THE WITNESS: Carmen DeLoria,
C A R M E N, D E capital L O R I A, and I am the Mood Disease Area Stronghold Commercial Leader.

COURT CRIER: Do you solemnly swear that the testimony you're about to give this Court and jury in the issue now being tried shall be the truth?

THE WITNESS: Yes.

COURT CRIER: Thank you, sir. Bring your chair up. Thank you.

THE WITNESS: Thank you.

...CARMEN DELORIA, after having been

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first duly sworn, was examined and testified as follows:

AS ON CROSS-EXAMINATION

BY MR. KLINE:

Q. Good morning, Mr. DeLoria.

A. Good morning.

Q. Testing. Having sat in that chair for part of two days, I know how awkward it is and a little uncomfortable. It was an experience for me. So if you would move as close to the microphone, it would be good I know for the jurors and good for everyone.

I'll start here. I'd like to have a conversation with you today. Are you prepared to do so?

A. Yes.

Q. Good. You are currently -- you are not speaking into the microphone. Would you tell the members of the jury and me your current position at the Janssen Pharmaceuticals.

A. Sure. So I work in the Global Marketing Division for Janssen Global Services, so I work on products that are not yet commercially on the market, and I work with our research and development colleagues in helping them to develop the drugs and

1 Carmen DeLoria - As on Cross

2 I do some of the marketing activities before the
3 drug actually gets on the market. So that's what
4 I'm currently doing.

5 Q. Okay. And you have been with Janssen I
6 believe since you graduated from college; is that
7 correct?

8 A. Yes.

9 Q. So at least as of now you're a lifer?

10 A. Yes.

11 Q. And it appears to me that you are, according
12 to a Curriculum Vitae or a resume which we have in
13 the litigation, you appear to be a graduate of
14 Rutgers, actually in pharmacy, you have a Bachelor's
15 of Science in pharmacy; correct?

16 A. Correct.

17 Q. In 1990 it appears, sir?

18 A. Yes.

19 Q. Okay. And it appears that you then went to
20 work at Janssen at that time and also it appears
21 that at some point in there you went on and got a
22 Master's Degree in public health?

23 A. That's correct.

24 Q. And that appears to be -- the Master of Public
25 Health appears to have come in 1998; is that

1 Carmen DeLoria - As on Cross

2 correct?

3 A. Yeah. I did that at night while I was working
4 still full time.

5 Q. Okay. Thank you. And it appears that way on
6 your CV. And then it appears that you made your way
7 up the ranks in the Janssen Company. You started
8 out as a Manager Associate in Medical Services and
9 you had that job for five years, '91 to '96?

10 A. Correct.

11 Q. And you right from the beginning were working
12 with and on the drug Risperdal; correct?

13 A. Yes, well, it was a couple years into the job
14 before I had any relationship, if you will, in terms
15 of dealing with the product. Once it was on the
16 market, because of the job that I was in, I would
17 answer questions from physicians and patients that
18 would have questions on our product. So that's when
19 I really started to become involved in it from that
20 perspective.

21 Q. Okay. Well, we know in this courtroom that
22 the drug was first approved in 1993. So were you
23 involved before or after Risperdal was approved as
24 an indication for adults in 1993?

25 A. For Risperdal. I would say it was probably

1 Carmen DeLoria - As on Cross

2 maybe about a year before then when we start to
3 build what we call database of responses. So we
4 know once a product is approved, we're going to get
5 questions. So there are a list of questions that we
6 predict we're going to get, how do you dose the
7 product, what are you indicated for, this for
8 example, so we would put together the standard
9 answers, we would call them, and we'd put them in a
10 database.

11 So I'm trying to remember back. I
12 probably helped in creating some of those standard
13 answers, which would have been about a year before
14 we would actually have launched the product.

15 Q. Okay.

16 A. In preparation of the launch.

17 Q. Preparation and launch. "Launch" meaning
18 launching the product after it's approved by the
19 FDA?

20 A. Correct.

21 Q. And of course there's some preparatory time
22 that goes into that. It's not like the FDA approved
23 the drug and no one in sales and marketing knew
24 about it?

25 A. Right.

1 Carmen DeLoria - As on Cross

2 Q. Okay. I got you. And it appears that you
3 then -- and at that period of time it says here that
4 you were an Associate in Medical Services. So in a
5 sentence or two, it's kind of the way I like to
6 always ask a question, in a sentence or two would
7 you please tell us what that job involved, that
8 first job at Janssen.

9 A. Yes. So the first job in Janssen is in some
10 companies they call it a Drug Information
11 Specialist. Most of the people that do this type of
12 job would have a pharmacy background or nursing
13 background. And my job again was to answer
14 questions from physicians, patients, nurses, or any
15 other health care practitioner that had questions
16 about our drug. And these would be for the drugs or
17 products that were on the market, and we had a
18 number of products that were on the market.

19 In addition to that, the other thing
20 that we became involved with is when the sales
21 training department was training new sales
22 representatives, I would go in and also help train
23 the sales representatives on our products and see if
24 they had any questions. So that in a nutshell was
25 what the job was.

1 Carmen DeLoria - As on Cross

2 Q. Thanks. A little more than two sentences, but
3 I appreciate it. And then tell me what you -- what
4 department were you in at that time? Was that part
5 of the Marketing Department?

6 A. It is not.

7 Q. Okay. And what department were you in at that
8 point?

9 A. Medical Affairs.

10 Q. Medical Affairs. Okay. Now, you then became
11 a sales rep; correct?

12 A. Correct. I hesitate for a second because I
13 did -- it was two days a week -- so it was what they
14 call a rotation. It was to get experience doing
15 something differently. So I did that two days a
16 week.

17 Q. Okay. Well, your resume says right on it, '95
18 to '96 sales rep, so you were a sales rep during
19 this period of time; correct, sir?

20 A. Correct.

21 Q. And you detailed -- and we've heard this term
22 actually, detailing. Detailing means going to
23 physicians' offices and giving them product
24 information? That's kind of a nutshell of it;
25 correct?

1 Carmen DeLoria - As on Cross

2 A. Yes.

3 Q. And at that time what you told us you did a
4 couple days a week, and I assume that's to broaden
5 your experience, broaden your basis of knowledge; is
6 that correct?

7 A. Correct.

8 Q. And it appears that you did that on drugs
9 other than Risperdal; correct?

10 A. Correct.

11 Q. Okay. That's how I read your resume.

12 A. Yes.

13 Q. Then moving along in your career at Janssen,
14 you then -- and during that whole period of time you
15 were in the Medical Affairs Department; correct?

16 A. Yes.

17 Q. Although there's a cross-over because you
18 spent two days a week in sales as a sales rep which
19 would be in Marketing; correct?

20 A. Sales and Marketing, yes.

21 Q. Oh, and that's a good point. The department
22 you just described to me is Sales and Marketing;
23 correct?

24 A. Right. They're run by two different people,
25 but generally it's referred to as Sales and

1 Carmen DeLoria - As on Cross

2 Marketing, but there's different reporting lines for
3 Sales and Marketing. So they are distinct, but the
4 larger group is Sales and Marketing, but the
5 reporting structures are completely different.

6 Q. Okay. Without getting into the complexities
7 of the Janssen Organization, would it be a correct
8 statement that Sales and Marketing are part of one
9 group and there is one individual, one person who is
10 in charge of that?

11 A. Yes.

12 Q. All right. And who is that individual, sir,
13 currently?

14 A. Currently, I have no idea. We have many
15 companies, so I'm not in a inline job. There is no
16 Sales and Marketing in my current job.

17 Q. All right. Let's move on. Quickly to go
18 through this. So you became -- you then moved up to
19 be the Director of New Product Development from '76
20 to -- from '96 to '98; is that correct?

21 A. Yes.

22 Q. And that was a promotion; correct?

23 A. Yes.

24 Q. And that involved -- that did not involve
25 Risperdal; correct?

1 Carmen DeLoria - As on Cross

2 A. Correct.

3 Q. And from -- and in '99 you were the Director
4 of Medical Marketing and Business Development, also
5 not involving Risperdal; correct?

6 A. Correct.

7 Q. And then you got another promotion as the
8 Senior Product Director of Gastroenterology, '99 to
9 '01; correct?

10 A. Yes.

11 Q. Now, all that period of time you were not
12 involved with Risperdal; correct?

13 A. Correct.

14 Q. Your involvement with Risperdal was early on
15 in the '93-ish period, 1993-ish period, and then you
16 were out of Risperdal it appears to me to be shortly
17 after that all the way through '01. Do I have it
18 about right?

19 A. That's correct.

20 Q. Okay. And now you come back into the
21 Risperdal world when you got -- when they gave you
22 the job of Senior Product Director CNS, meaning
23 central nervous system; correct?

24 A. Correct.

25 Q. Okay. And that appears to be '01 to '03, and

1 Carmen DeLoria - As on Cross

2 -- is that correct?

3 A. Yes.

4 Q. And there you were leading a team of ten
5 marketing managers and directors responsible for all
6 pre-launch commercialization activities for pending
7 new Risperdal indications; correct?

8 A. Yes.

9 Q. Okay. So you were a key person, a key point
10 person in Risperdal in '01 to '03. Would that be a
11 fair statement?

12 A. Yes, I mean as it relates to the activities
13 you've just mentioned, yes.

14 Q. Of course, as it relates to these activities,
15 not as it relates to some other activities, which
16 relate to testing of the drug and other things like
17 that.

18 A. Right. But also as it relates to the
19 promotional activities for Risperdal for approved
20 indications.

21 Q. Yes.

22 A. There was a separate Senior Product Director
23 who was responsible for those activities.

24 Q. Okay.

25 A. My activities were specifically for areas that

1 Carmen DeLoria - As on Cross

2 we were not approved indications, as well as new
3 formulations. So it was distinct.

4 Q. Okay. So what you were working on and what
5 we're interested here in this courtroom, you were
6 working on new -- you were working on new
7 indications, and of course that included children
8 and adolescents; correct?

9 A. Yes.

10 Q. And it included non-approved areas which also
11 would include children and adolescents on Risperdal;
12 correct?

13 A. Yes.

14 Q. And it says here on your resume, "Key areas of
15 responsibility." And, in fact, maybe we can -- so
16 we can follow along here, we're going to mark your
17 resume as Plaintiff's Exhibit No. 60, and I'm going
18 to hand it to you so it's convenient. But we'll
19 also display pieces of it, if we may.

20 A. Sure.

21 (Resume of Carmen DeLoria marked
22 Plaintiffs' Exhibit P-60 for
23 identification)

24 BY MR. KLINE:

25 Q. And we're now able to display the document

1 Carmen DeLoria - As on Cross

2 which was provided to us. Is this your Janssen CV?
3 I know we had it at a deposition, it's the personal
4 CV or Janssen CV or something else.

5 A. Yes.

6 Q. Okay. Which is the "yes" to?

7 A. That this is my CV.

8 Q. Okay. Prepared in connection with your work?
9 I guess that's my question.

10 A. Yes.

11 Q. Okay. Thanks. And I'm now on the '01 to '03
12 period which is where I, by the way, will focus some
13 significant part of my attention to that with you.
14 And you'll see here or everyone now will see under
15 key areas of responsibility, that included
16 development of promotional campaign. Do you see
17 that?

18 A. Yes.

19 Q. And we'll highlight it. Positioning. What's
20 positioning? Is that positioning of the drug in the
21 marketplace?

22 A. Yes. It's related to the messaging.

23 Q. The messaging?

24 A. Yes.

25 Q. And messaging is messaging?

1 Carmen DeLoria - As on Cross

2 A. Yes, messages.

3 Q. Yes.

4 A. That would be communicated.

5 Q. Right. A company has certain messages, but
6 not only companies, people, corporations, lots of
7 things have messages and messages means getting out
8 the message that you want people to hear; correct?

9 A. Correct.

10 Q. Okay. And forecasting, public relations,
11 market direction. I'm just reading the rest without
12 highlighting. Packaging, pricing, KOL development.
13 Okay. And on the last bullet point under Senior
14 Director, this is actually a description of your
15 job; correct?

16 A. Correct.

17 Q. Your job included oversight of medical --
18 oversight of medical marketing strategy; correct?

19 A. Correct.

20 Q. And a word there used, tactics; correct?

21 A. Correct.

22 Q. So you oversaw tactics for Risperdal; correct?

23 A. Yes, for some of the tactics.

24 Q. Okay. Well, certainly for the marketing
25 aspects; correct?

1 Carmen DeLoria - As on Cross

2 A. Well, as I mentioned before, any tactic that
3 was for promotion was handled by someone else.

4 Q. At that time who was that someone else?

5 A. At that time that would have been Riley Smith
6 and Daniel Bacon. Primarily Daniel bacon.

7 Q. Okay. All right. And it says here, and other
8 -- on the last line, other medical marketed related
9 activities. That was your job in '01 to '03;
10 correct?

11 A. Correct.

12 Q. And how much of your time did you spend on
13 Risperdal at that time? Almost all?

14 A. All.

15 Q. All?

16 A. All my time.

17 Q. Risperdal was your drug; correct?

18 A. Yes.

19 Q. All right. And so you were -- and how many --
20 and you had ten people working underneath you, ten
21 marketing managers working underneath you; correct?

22 A. Correct.

23 Q. And how many people working underneath them?

24 A. Well, that included the entire time.

25 Q. Pardon me?

1 Carmen DeLoria - As on Cross

2 A. That included the entire time. So all the
3 people working in this area was ten and then outside
4 of this group there was another at least ten plus
5 people that worked on Risperdal who reported to the
6 other gentlemen that I referred to earlier.

7 Q. Got it. But as to you, you oversaw ten
8 marketing managers and directors; correct?

9 A. Correct.

10 Q. For a -- and let me understand this, for a
11 drug which was -- and relating to the children and
12 adolescents market; correct?

13 A. No.

14 Q. Okay. Tell me.

15 A. Child and adolescent was one area.

16 Q. Okay.

17 A. The other was bipolar disorder, which we
18 eventually got indication for. The other area was
19 Risperdal CONSTA, which was a formulation that we
20 were developing of a long acting version which was
21 launched. In addition, Risperdal M tab, which was a
22 fast dissolving tablet which was later marketed.
23 The majority of individuals worked on those areas.
24 There was one person who reported to me who worked
25 on child and adolescents specifically. So the bulk

1 Carmen DeLoria - As on Cross

2 of these people did not work in child and
3 adolescents.

4 Q. Who was the person who worked directly for you
5 on that?

6 A. Joseph Lin.

7 Q. And his name appears on many e-mails that we
8 see, correct, that we see in this time period
9 relating to child and --

10 A. I assume there were some documents with his
11 name on it, absolutely.

12 Q. You reviewed documents in advance of
13 testifying in this courtroom today; correct?

14 A. Yes.

15 Q. Okay. Now, in addition, sir, let's see what
16 happens. From '03 to '05 you became the Senior
17 Product Director of Central Nervous System, that's
18 the title you had; correct?

19 A. Correct.

20 Q. And you stuck with the drug Risperdal in that
21 period; correct?

22 A. Correct.

23 Q. Once again, Risperdal was your only drug;
24 correct?

25 A. Correct.

1 Carmen DeLoria - As on Cross

2 Q. Okay. Risperdal to this day has never been
3 approved for ADHD; correct?

4 MR. WINTER: Objection, Your Honor.

5 THE COURT: I'll permit it.

6 Overruled.

7 BY MR. KLINE:

8 Q. Correct?

9 A. Correct.

10 Q. And Risperdal to this day has never been
11 approved for treatment of any kind of oppositional
12 defiant disorder; correct?

13 A. Correct.

14 Q. And when you were doing whatever your
15 activities were and whatever Janssen's activities
16 were in 2001 through 2006, they were being done when
17 the drug was not approved for use in children and
18 adolescents at all; correct? There was no usage --
19 I'll say a better question, I hope. There was no
20 approved use of -- no FDA approved use in the United
21 States of America for the drug Risperdal in children
22 and adolescents in the period 2001 through 2006;
23 correct?

24 A. Correct.

25 Q. In fact, the children's use that was then

1 Carmen DeLoria - As on Cross

2 permitted by the FDA was for the limited use for
3 autism in 2006, October 2006 to be exact, which went
4 into effect in -- effectively in '07; correct?

5 A. I don't know the exact date, but it was
6 eventually approved for --

7 Q. Autism?

8 A. Correct.

9 Q. Right. In 2000 -- while you were there --
10 strike that. One minute.

11 You were aware, Mr. DeLoria, were you
12 not, in order to do your job, that in 2000 Janssen
13 had gone to the FDA attempting in the first stages
14 of getting approval for the drug for something
15 called Conduct Disorder? You're aware of that fact;
16 correct.

17 A. Correct.

18 Q. And you're aware of the fact that the FDA
19 turned Janssen down; correct?

20 A. They did not approve it.

21 Q. Yes. Did not approve? I didn't hear.

22 A. They did not.

23 Q. Okay. And, in fact, in 2005 on the autism
24 disorder request, that was turned down as well at
25 that time; correct?

1 Carmen DeLoria - As on Cross

2 A. I don't know the specifics of that. I wasn't
3 working on that at the time.

4 Q. You weren't working at that time. Okay.
5 We'll move on.

6 To finish up, 2005 to the present, you
7 are the Director of Strategic Marketing for a
8 different drug; correct?

9 A. Right -- well, not to present. This is quite
10 old.

11 Q. Okay. Well, I have a resume that says to
12 present?

13 A. But I had that position -- this was a new
14 position that I had taken on within Global
15 Marketing, which is the group I'm in right now, and
16 that was a position I had once I left the Risperdal
17 marketing team. I took on this position here as
18 Director Strategic Marketing Carisbamate, which is
19 the name of the drug, and I did that for a few
20 years. I think it was two years or so.

21 Q. And then what?

22 A. Then from there I was in Marketing Excellent
23 which is basically a training department where I was
24 training other marketers on how to do marketing.

25 Q. Marketing Excellent, that's actually --

1 Carmen DeLoria - As on Cross

2 A. It's called Marketing Excellent.

3 Q. That's actually like a department?

4 A. Yes, it's a department. Many companies have
5 it. It's called Marketing Excellent.

6 Q. Okay. And then from there?

7 A. And from there I took another position within
8 Global Marketing working on -- trying to think of
9 the order here. I was working on Invega SUSTENNA.

10 Q. I missed the word you said.

11 A. Another position.

12 Q. Oh, within Global Marketing, I see.

13 A. Yes, on Invega SUSTENNA.

14 Q. A different drug?

15 A. A different drug.

16 Q. That's all we care about, whether it's
17 Risperdal or not.

18 A. It's not Risperdal.

19 Q. Okay. And so you left the Risperdal -- you
20 left Risperdal involvement when?

21 A. Would have been January -- February of 2005.

22 Q. Okay. Now, I have an exhibit, I know you're
23 familiar with it. We'll mark it as 61.

24 (Diagram entitled CNS Marketing

25 Franchise marked Plaintiffs' Exhibit P-61

1 Carmen DeLoria - As on Cross

2 for identification)

3 BY MR. KLINE:

4 Q. There's a document provided to us by Janssen
5 which is entitled "CNS Marketing Franchise." Do you
6 see that?

7 A. Yes.

8 Q. And I've seen that phraseology before. What
9 is a franchise?

10 A. A franchise is a word that sometimes people
11 use when there's more than one product in a
12 department, they'll call it a franchise. That's all
13 that meant.

14 Q. Okay. And CNS refers to central nervous
15 system; correct?

16 A. Correct.

17 Q. By the way, how much of your time in that '01,
18 '03 period did you spend, did you spend on child and
19 adolescent Risperdal issues?

20 A. Well, I would say overall in that two-year
21 time period, 20% or so. There was a period of a few
22 months before I hired Mr. Lin, who I referred to
23 before, where I've spent approximately half of my
24 time. Once he was hired, then I maybe spent 20% of
25 my time or so.

1 Carmen DeLoria - As on Cross

2 Q. But he spent 100% of his time?

3 A. He did.

4 Q. On child and adolescent?

5 A. Correct.

6 Q. Okay. And here also I see, just so we get a
7 sense of it, you're on the left-hand side near the
8 top, you're reporting to the -- directly to the
9 director of marketing for CNS, central nervous
10 system; correct?

11 A. Correct.

12 Q. Now, just a brief point on this.

13 MR. KLINE: If you can show the whole
14 chart, Corey.

15 BY MR. KLINE:

16 Q. And, Mr. DeLoria, I'll highlight it so he can
17 get a sense of where he is. I'm asking the witness
18 to say if you're -- are you in the highlighted box
19 there?

20 A. Yes.

21 Q. Okay. Now, CNS, briefly, Risperdal is a
22 powerful antipsychotic drug; correct?

23 A. It's an antipsychotic drug.

24 Q. Well, there's many documents that say it's a
25 powerful drug. Do you agree or disagree with that

1 Carmen DeLoria - As on Cross

2 statement?

3 A. You know, the word "powerful" I'm not sure
4 exactly what that means. It's a very subjective
5 term. Sometimes drugs that are potent are
6 considered -- it's an antipsychotic drug.

7 Q. All right. It's an antipsychotic drug and it
8 was -- its only indication in 2001 through 2003 to
9 use on label was to treat adult schizophrenics;
10 correct?

11 A. It was approved to treat schizophrenia.

12 Q. My question is a different one. Between 2001
13 and 2003 the only approved indication for the drug
14 was to the treatment of adult schizophrenics;
15 correct?

16 A. Correct.

17 Q. And this concept of CNS, CNS refers to central
18 nervous system, and the reason that this is the CNS
19 marketing franchise is that, is that drugs which
20 relate to antipsychotic drugs fall within this
21 category of central nervous system in the company;
22 correct?

23 A. Correct.

24 Q. In fact, the company at the time in 2001,
25 2003, this was viewed as a very important part of

1 Carmen DeLoria - As on Cross

2 the potential future of the company; correct?

3 A. Correct.

4 Q. And having a successful drug like Risperdal
5 was important to the Marketing Department; correct?

6 A. Correct.

7 Q. And it was also important -- also an important
8 component by 2001 were the sales of the drug to
9 children and adolescents off label; correct?

10 A. Well, we were aware that a portion of our
11 business was coming from child and adolescent. I
12 wouldn't say that that was the most important piece
13 of whatever business was coming in.

14 Q. I think we could agree -- let's try to agree
15 on everything we can possibly agree on. I think
16 you'd agree with me that it was a very important
17 part of the Risperdal future as of 2001, 2003,
18 namely, selling the drug to children and
19 adolescents, can we agree?

20 A. That we would eventually want to sell the drug
21 in children and adolescents, not that we were doing
22 --

23 Q. Would you agree? Would you agree with that?

24 A. Not the way you originally stated.

25 Q. Let's take the way I said it, if you may. You

1 Carmen DeLoria - As on Cross

2 were selling a lot of the drugs to children and
3 adolescents; correct? Twenty percent of the sales
4 were to children and adolescents?

5 A. We were not selling the drugs to child and
6 adolescent. It was being utilized for child and
7 adolescent.

8 Q. Okay. Let's take that.

9 A. But not selling.

10 Q. We'll go with you. It was being utilized. It
11 was being utilized in child and adolescent? Correct
12 so far?

13 A. Correct.

14 Q. And Janssen knew it; correct?

15 A. Correct.

16 Q. You weren't blind to the fact that this drug
17 was being widely used in children and adolescents;
18 correct?

19 A. Correct.

20 Q. In fact, Janssen was pleased with that fact;
21 correct?

22 A. I wouldn't use the word "pleased."

23 Q. Well, the documents that we're going to look
24 at, sir, would they not show that Janssen was very
25 pleased with the fact that the drug was being widely

1 Carmen DeLoria - As on Cross

2 used in children and adolescents?

3 A. We knew the drug was being utilized in child
4 and adolescent, and we were interested in getting an
5 indication in child and adolescent so we can
6 actually promote the drug in child and adolescent
7 knowing it was being used there. And the benefit
8 also of doing that is that physicians would know how
9 to use the drug appropriately because since we're
10 not approved, our sales representatives were not
11 able to go to explain to physicians appropriate --

12 Q. Sir, we're -- I'm sorry. Finish, please.

13 A. That's it.

14 Q. The fact of the matter is, sales
15 representatives were in offices of pediatricians,
16 pediatric psychiatrists, and pediatric neurologists
17 every day; correct?

18 MR. WINTER: Objection, Your Honor.

19 THE COURT: Well, I don't know. Do
20 you know that for a fact, Mr. DeLoria?

21 THE WITNESS: Well, I'll tell you what
22 I do know.

23 THE COURT: Very well.

24 THE WITNESS: What I do know is that
25 some of our sales representatives or most

1 Carmen DeLoria - As on Cross

2 did call on child and adolescent
3 psychiatrists, but child and adolescent
4 psychiatrists also treat adults. There's
5 very few child and adolescent psychiatrists
6 that only treat children. So, yes, we were
7 calling on them, but we were detailing them
8 or selling on the use of adults for adult
9 patients.

10 BY MR. KLINE:

11 Q. Let's see what we can agree on. You were
12 calling on adolescent and child psychiatrists;
13 correct?

14 A. Correct.

15 Q. Janssen was calling in this period of time
16 when the drug was not approved for children and
17 adolescent, you were calling on child and adolescent
18 neurologists; correct?

19 MR. WINTER: Objection, Your Honor.

20 THE COURT: Overruled.

21 BY MR. KLINE:

22 Q. Correct, sir?

23 A. I don't know specifically. If they were
24 treating adults, it's possible.

25 Q. And samples were being dropped off to child

1 Carmen DeLoria - As on Cross

2 and adolescent psychiatrists; correct?

3 A. I would assume so, they were treating adults,
4 sure.

5 Q. Do you know in this case whether samples were
6 being dropped off to child and adolescent
7 psychologists, psychiatrists?

8 A. In this example?

9 Q. In the William Cirba case involving the
10 Friendship House.

11 A. I don't know.

12 Q. Have you talked to the sales representative
13 that we've been promised to be able to see in this
14 case?

15 A. No.

16 Q. And, in fact, until 2004, sir, when there was
17 a change, the sales representatives, and you know
18 this, were bonused for sales that were made to
19 children and adolescents; correct?

20 MR. WINTER: Objection, Your Honor.

21 THE COURT: If he knows. Overruled.

22 THE WITNESS: The individual's bonus
23 was on their overall what they -- what
24 physicians were prescribing. They were not
25 specifically incentivized to child and

1 Carmen DeLoria - As on Cross

2 adolescent psychiatrists.

3 BY MR. KLINE:

4 Q. And that included, and that included the sales
5 that were to children and adolescents, you know
6 that; correct?

7 A. Well, that would have been included if they
8 were treating adults, sure.

9 Q. That's right, that's my question. Well, you
10 know that there are examples, you really know this,
11 sir, you know that there are examples of child and
12 adolescent psychologists -- I'm sorry, you know of
13 examples of child and adolescent psychiatrists who
14 were detailed, meaning sales representatives went to
15 those offices and those individuals were not
16 treating adults? You know of examples of that;
17 correct?

18 A. No, I don't know.

19 Q. Okay. Now, let's look, if we may, at some
20 business plans. Part of doing business is having
21 business plans; correct?

22 A. Yes. Business plans are common in all
23 businesses.

24 Q. And I want to start with one from August -- or
25 from July 29th, 2002, in a time frame that we're

1 Carmen DeLoria - As on Cross

2 interested in here. Have you reviewed it prior to
3 coming to court?

4 A. I have.

5 Q. You have, okay. And you reviewed a number of
6 the business plans, correct, in anticipation of
7 being questioned about them; correct?

8 A. I recall reviewing one, maybe two or three. I
9 don't know exactly.

10 Q. Certainly reviewed the July 29, '02, one;
11 correct, sir?

12 A. I believe I did.

13 MR. KLINE: We'll mark it P-62.

14 (Business Plan, July 29, 2002, marked
15 Plaintiffs' Exhibit P-62 for
16 identification)

17 BY MR. KLINE:

18 Q. There's an e-mail from you on the top of it.
19 I will hand it to the court officer who will provide
20 it to you and provide one to counsel.

21 A. Thank you.

22 Q. We'll also be displaying pages with some
23 call-outs and they'll be on the screen as well.

24 A. Okay.

25 Q. Now, we'll put up Exhibit No. P-62 and it is a

1 Carmen DeLoria - As on Cross

2 document -- is this document essentially a slide
3 show, sir?

4 A. It is.

5 Q. It's a Power Point presentation?

6 A. Correct.

7 Q. And that Power Point presentation was made
8 where?

9 A. This would have been presented to the Janssen
10 Board.

11 Q. It was presented -- I was distracted. It was
12 presented to the Janssen Board of Directors?

13 A. They're just referred to as the Board, the
14 Janssen Board.

15 Q. Well, who is the Board?

16 A. The Board would be the president of the
17 company. It would be the person in charge of
18 regulatory affairs, person in charge of medical,
19 public relations, et cetera. It would be the head
20 of different departments.

21 Q. It's a very higher up meeting, can we agree?
22 If the president of the company is there, it's a
23 higher up meeting?

24 A. Yes, sure.

25 Q. Okay. And it appears that this would have

1 Carmen DeLoria - As on Cross
2 gone through a number of drafts because you're
3 saying, you are saying to a number of people,
4 "Attached is the final CNA business plan
5 incorporating Janet's comments."

6 MR. KLINE: And let's display the
7 covering e-mail.

8 BY MR. KLINE:

9 Q. I assume that you transmitted this
10 electronically; is that correct, Mr. DeLoria?

11 A. Yes.

12 Q. And so you have an e-mail and behind the
13 e-mail you have a Power Point presentation; correct?

14 A. Correct.

15 Q. When was the meeting? I know when the meeting
16 was, it was July 29th, 2002; correct?

17 A. Right.

18 Q. Okay. And this document, sir, would reflect
19 knowledge we now know of the people at the meeting
20 including the president of Janssen; correct?

21 A. Correct.

22 Q. You'll have to speak into the mic.

23 A. Correct.

24 Q. Thanks. Again, I know it's awkward. I can
25 attest to it.

1 Carmen DeLoria - As on Cross

2 And I just want to see if you can
3 search your memory for who else was there at that
4 meeting. I now know -- the president of Janssen USA
5 was there?

6 A. Correct.

7 Q. Okay. Who else?

8 A. The -- I'm trying to remember what they called
9 him at the time. It would have been the
10 vice-president of the CNS business unit or
11 franchise, which was Janet Vergis.

12 Q. Is that the Janet Vergis to --

13 A. That's who I'm sending this e-mail to, so she
14 was basically my boss' boss.

15 Q. Okay. Let's just look at that. The e-mail --
16 go ahead, tell me who else was there that you can
17 recall.

18 A. Sure. It would have been the head of the
19 other business unit, which would have been for an
20 algesia or pain management. And then as I said, the
21 other individuals before, regulatory or medical,
22 maybe public relations, all the other departments.

23 Q. And was this -- was this on July 29th of 2002,
24 did this take place in a -- at a conference room
25 table? Did it take place in a classroom-type

1 Carmen DeLoria - As on Cross

2 setting? Give us a feel so when we look at it, we
3 know what it looked and felt like.

4 A. Sure. It was a simple conference room. We
5 normally have a U-shaped table with everyone sitting
6 around and then in the front of the room would be
7 the team presenting the slides to the Board and then
8 we would just respond to any questions that people
9 would have.

10 Q. And where did it take place?

11 A. Right in our building. Right at the Janssen
12 building.

13 Q. The Janssen building in Pennsylvania or the
14 one across the river?

15 A. In Titusville, New Jersey.

16 Q. Okay. And it says here in the e-mail -- let's
17 see who is on the e-mail chain. You are sending the
18 final cut. So this is what was presented; correct?

19 A. This is the final business plan.

20 Q. Right.

21 A. Correct. Sending it to Janet and Ronald.

22 Q. And we know Janet is your boss' boss. What
23 was her title, vice-president of something or other?

24 A. Yes, she's the vice-president. Probably the
25 CNS business unit.

1 Carmen DeLoria - As on Cross

2 Q. Okay. And who is Ronald Kalmeijer?

3 A. Kalmeijer. So Ronald was my supervisor,
4 that's who I reported to.

5 Q. Okay. So it's to your boss, to your boss'
6 boss. And who is Aida Rivera?

7 A. Aida, she's our secretary at the time.

8 Q. Okay. The most important person on this
9 e-mail by any doubt?

10 A. Yes.

11 Q. Now, it says, "Attached is a final business
12 plan and" -- oh, and who is the president of Janssen
13 at the time who was at this meeting?

14 A. Alex Gorsky, I believe.

15 Q. Alex Gorsky; is that correct?

16 A. Yes.

17 Q. Mr. Gorsky is still at Janssen, isn't he, or
18 is he over at Johnson & Johnson?

19 A. He's with Johnson & Johnson.

20 Q. It says, "Janet, please note," and then you
21 attached this thing. Okay. I'd like to talk to you
22 about the business plan. This is -- if we can look
23 at the first page of P-62. It's Risperdal, paren
24 Risperidone, child and adolescent and other new
25 business, 2003 Business Plan, July 29, 2002. And

1 Carmen DeLoria - As on Cross

2 before we turn the page, sir, this business plan is
3 a business plan solely related to child and
4 adolescent business -- I mean there's a few
5 additional things here, but it's basically a child
6 and adolescent business plan, not an overall
7 business plan for the drug Risperdal; correct?

8 A. This was primarily for child and adolescent.

9 Q. And of course, we have now a business plan in
10 2002 for a drug which is not approved by the FDA;
11 correct?

12 A. Correct.

13 Q. Now, let's look at the child and -- next page.
14 I just want to work our way right through this. And
15 this was presented in this fashion; correct?

16 A. Correct.

17 Q. And who presented, by the way, sir?

18 A. I believe I most likely presented this.

19 Q. Okay. And you have -- I'm sure that the whole
20 team, this whole team was there; correct?

21 A. No.

22 Q. Okay. Because you were presenting to the
23 Board and so the whole team wouldn't necessarily be
24 there; correct?

25 A. Correct.

1 Carmen DeLoria - As on Cross

2 Q. Who from the team was there, do you recall
3 quickly?

4 A. From this list?

5 Q. Yes.

6 A. Tom Gibbs.

7 Q. That's who was at the meeting.

8 A. And maybe George Gharabawi from Medical
9 Affairs. That's probably it.

10 Q. Now, we had a discussion earlier about the
11 number of prescriptions that -- the amount of usage
12 of this drug. The next table shows us how much of
13 Risperdal, how many prescriptions of Risperdal were
14 being used. And let's look at this table. It's
15 entitled "APS TRX Volume Growth, Child and
16 Adolescent Market." Do you see it?

17 A. Yes.

18 Q. And, sir, for the prior year, 2001 -- in 2001,
19 those prescriptions are in thousands, which means
20 that in 2001 there were 1,106,000 prescriptions of
21 Risperdal; correct?

22 A. I don't know what the axis is on -- is it in
23 thousands?

24 Q. Yes, it is. Look at it. You presented it, so
25 I would like your help on this.

1 Carmen DeLoria - As on Cross

2 A. I certainly presented this over a decade ago.

3 Q. You know how to read axes. You see it's in
4 thousands, right, on the left axis? Sir, the left
5 axis.

6 A. I see what you're saying, but it seems to me
7 that the bars are in line with the vertical axis, so
8 there's telling you there's 1,106, it's exactly the
9 same number that's on the axis. You can't imply
10 that there's three zeros to be added on that. It's
11 just the exact --

12 Q. Sir, are you suggesting to us that there were
13 only a thousand prescriptions of the drug sold, not
14 a million prescriptions? Is that your testimony?

15 A. My testimony is I don't know if that's
16 thousands or not. That's my testimony. Maybe there
17 was a million, maybe there was a thousand, I don't
18 know.

19 Q. Sir, who made this chart?

20 A. Someone in our Market Research Department.

21 Q. Okay. You approved it, you and Janet, your
22 boss' boss approved it; correct?

23 A. Correct.

24 Q. And you can't tell us sitting in a courtroom
25 under oath that that's not thousands in the

1 Carmen DeLoria - As on Cross

2 left-hand column?

3 A. Well, if you asked me the day I presented
4 this --

5 Q. Is that your testimony, that you cannot tell
6 us?

7 MR. WINTER: Judge, Judge --

8 BY MR. KLINE:

9 Q. Here is a simple question.

10 THE COURT: Pose it and then proceed.

11 MR. KLINE: Thank you.

12 BY MR. KLINE:

13 Q. You cannot tell us today that those numbers
14 are in the thousands?

15 A. I don't know.

16 Q. You went over this before you testified, sir?

17 MR. WINTER: Objection, Your Honor.

18 THE COURT: Sustained.

19 BY MR. KLINE:

20 Q. Are you suggesting to the jury, sir, you're
21 suggesting to the jury under oath that there were
22 only 1,106 prescriptions of Risperdal to children
23 and adolescents, is that what you're telling the
24 jury under oath?

25 A. I'm not suggesting that. I just simply stated

1 Carmen DeLoria - As on Cross

2 I don't know if there's three zeros here. If you
3 tell me it's a million and you verify it, I just
4 don't know.

5 Q. I can tell you -- you know who Ivo Caers is?

6 A. Yes.

7 Q. I can represent to you that he told us two
8 weeks ago that it was in the millions.

9 MR. WINTER: Objection, Your Honor.

10 THE COURT: Sustained.

11 MR. KLINE: I'll read the testimony.

12 THE WITNESS: I'm not going to agree
13 to something that I don't know.

14 BY MR. KLINE:

15 Q. Who is Ivo Caers, sir?

16 MR. WINTER: Your Honor, can the
17 witness finish his answer, please?

18 THE COURT: Mr. DeLoria, do you have
19 anything else you want to add?

20 THE WITNESS: No.

21 BY MR. KLINE:

22 Q. Let's move on. As of 2002 there's a chart
23 that -- the next slide, sir. By the way, if I may,
24 if I may, sir, what did you tell your colleagues
25 when you presented this chart that day in the

1 Carmen DeLoria - As on Cross

2 U-shaped conference room?

3 A. Well, I would have -- I can't tell you exactly
4 what I said other than the fact that I would have
5 reported or reviewed -- are you referring to this
6 slide or the slide before?

7 Q. Yes -- no, the first slide.

8 A. Okay. Sorry, I thought you changed the slide.

9 I would have just reported the change
10 in the volume. TRX stands for total prescriptions
11 and I would have reported what the volume trends
12 were for the market as well as for Risperdal.

13 Q. And if someone raised their hand and said, Mr.
14 DeLoria, what does 1106 referred, to what would you
15 have answered?

16 MR. WINTER: Objection, Your Honor.

17 THE COURT: Sustained.

18 BY MR. KLINE:

19 Q. Okay. According to the second chart, it says
20 that there was one two six three by five O two. Do
21 you see that chart?

22 A. Yes.

23 Q. Next chart that was demonstrated, this is in
24 the order that was presented to us. I assume it's
25 in the order that was presented to the group,

1 Carmen DeLoria - As on Cross

2 including the president. Would that be correct?

3 A. Yes. Unless we went out of order, I would
4 assume that that's correct.

5 Q. According to this, sir, antipsychotic share in
6 child and adolescent market. It appears, sir, that
7 Risperdal had 52.5% of the child and adolescent
8 market; is that correct?

9 A. Yeah, that was the projection, yes.

10 Q. And if you go to the next slide --

11 MR. KLINE: Actually let's go to three
12 two three nine, please, Corey, three two
13 three nine.

14 BY MR. KLINE:

15 Q. There's a description which says, "Child and
16 Adolescent, Opportunities and Requirements." Do you
17 see that?

18 A. Yes.

19 Q. And then if you go to the next slide, which is
20 3240, we have the key publication dates. Do you see
21 that?

22 A. Yes.

23 Q. And, sir, there is a description of six
24 studies. Do you see RIS-41 there, sir?

25 A. Yes.

1 Carmen DeLoria - As on Cross

2 Q. You're familiar with RIS-41; correct?

3 A. Yes.

4 Q. In fact, sir, you were copied on drafts of the
5 manuscript of RIS-41, something we'll be discussing
6 in a while; correct?

7 A. Yes.

8 Q. And it indicates that there was a publication
9 date for the fourth quarter 2002. Do you see that?

10 A. Yeah. That was the estimate of when we
11 thought it would be submitted.

12 Q. Do you know when it was actually published,
13 sir?

14 A. I do not.

15 Q. Lessons learned is the next.

16 A. Yes.

17 Q. Now, the lessons learned is information that
18 you've gathered from a variety of sources; correct?

19 A. Correct.

20 Q. And this would include information that you've
21 received anecdotally, information you received
22 formally, information you've received in a lot of
23 different fashions; correct?

24 A. Correct.

25 Q. And, again, you reviewed this prior to it

1 Carmen DeLoria - As on Cross

2 going up in front of an audience that included the
3 president of the company; correct?

4 A. Correct.

5 Q. And one of the lessons learned, the top
6 left-hand bullet --

7 MR. KLINE: And, Corey, we will
8 highlight them as we go along and then take
9 down the highlighting that's there.

10 BY MR. KLINE:

11 Q. So the first bullet point is "Child and
12 adolescent market is becoming increasingly
13 competitive. Increased comfort with newer agents."
14 Was that one of the lessons learned?

15 A. Yes.

16 Q. And the second lesson learned was that
17 prolactin, among other things, continued to be an
18 important issue; correct?

19 A. Correct.

20 Q. And you, sir, even though you are trained as a
21 pharmacist and now operating in a business capacity,
22 you knew that there were problems with the
23 perception of Risperdal in increasing prolactin;
24 correct?

25 A. I wouldn't word it that way. We were aware

1 Carmen DeLoria - As on Cross

2 that there was some misperceptions of what some
3 physicians thought about some of our adverse events
4 based on what other companies, our competitors, were
5 saying about it, and that's what this is referring
6 to.

7 Q. I want to take you up on two words you used in
8 there, "adverse events." There were adverse events
9 being reported about Risperdal relating to prolactin
10 increase; correct?

11 A. Well, prolactin is --

12 Q. Yes or no?

13 A. Well, I have to specify specifically to
14 respond to be accurate. There were adverse events
15 reported with Risperdal when patients were on
16 Risperdal that potentially could have been related
17 to prolactin, but prolactin elevation itself is a
18 lab finding. So that's why I just wanted to be
19 specific.

20 Q. You knew the competitors were saying bad
21 things about Risperdal; correct?

22 A. Correct.

23 Q. And you knew that doctors, some doctors
24 believed bad things about Risperdal, correct, as it
25 related to prolactin?

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2 A. I would say some, most likely.

3 Q. Well, you thought it enough to write this
4 bullet point, "Competitors are driving negative
5 safety and tolerability perceptions for Resperidol."

6 And the example that's picked is what, sir?

7 A. Prolactin.

8 Q. Were there any other examples picked by you?

9 A. No.

10 Q. And there was another problem, which was that
11 the child and adolescent market growth are
12 flattened; correct?

13 A. Correct.

14 Q. Now, is this a standard way that you would set
15 up a format like this, sir, lessons learned?

16 A. In terms of that and implications?

17 Q. Yes.

18 A. I would say at the time that was fairly
19 standard, yes.

20 Q. Okay. You've given other presentations with
21 this kind of format, would that be correct?

22 A. I don't really do this anymore in terms of
23 lessons implications.

24 Q. Back then?

25 A. So back then this was a standard.

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2 Q. Here are the implications, one, generation and
3 dissemination of current and future data is
4 essential; correct?

5 A. Correct.

6 Q. And the second item is, and let's highlight
7 this one, dissemination of reanalysis of safety
8 databases is critical; correct?

9 A. Correct.

10 Q. And you were aware that there was going to be
11 a reanalysis of five CBD studies; correct?

12 A. Yes, I was aware of that.

13 Q. Right. That's why it's in here, because it
14 relates directly to what you know was being -- was
15 going to be done; correct?

16 A. Correct. There were other reanalyses that
17 were going on other than that, but, yeah, that would
18 have likely have been one of the ones that was being
19 referred to here.

20 Q. Sir, you know that the important safety
21 analysis that was being done as it pertained to
22 prolactin safety was the reanalysis that eventually
23 got published as Findling; correct?

24 A. Correct, but this bullet point isn't
25 necessarily just referring to prolactin was my

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2 point.

3 Q. Yes. As it relates to prolactin, it was the
4 reanalysis of the five studies that was the
5 important study; correct?

6 A. Correct.

7 Q. Now you did a SWOT analysis, S W O T,
8 analysis. And SWOT analysis talks about the
9 strengths of the drug, the opportunities, the
10 weaknesses, and the threats. That's what SWOT is,
11 strengths, weaknesses, opportunities, and threats;
12 correct?

13 A. Correct.

14 Q. All right. By the way, all of this is being
15 talked about for a drug that's not even approved for
16 use in children and adolescents; correct?

17 A. Correct.

18 Q. So you have strengths, which we see in front
19 of us, and opportunities, which we see in front of
20 us. We see threats in front of us. And we see
21 weaknesses in front of us; correct?

22 A. Correct.

23 Q. As to the weaknesses, the first bullet point
24 is safety perceptions, and the first among that are
25 listed there is prolactin; correct?

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2 A. Correct.

3 Q. And that is a bullet point that precedes lack
4 of awareness of appropriate dosage; correct?

5 A. Correct.

6 Q. Okay. Now, under the next topic Key Issues,
7 Key Issues, one key issue is physician misperception
8 of Risperdal safety profile driven primarily by
9 increasing competitive market; correct?

10 A. Correct.

11 Q. Okay. Now, let's look at that if we may for a
12 minute. Increasing competitive market. Okay. In
13 order for there to be a competitive market, there
14 has to be a competition; correct?

15 A. Correct.

16 Q. And you were competing for a market share;
17 correct?

18 A. Well, we were competing for a market share
19 within adults, however, that would, I'll use the
20 word spill over, in terms of the perceptions beyond
21 that. But when we're referring to competitive
22 market, we're referring to adults.

23 Q. This isn't talking about adults here at all,
24 is it, sir?

25 A. No.

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2 Q. In fact, there was a competitive market to get
3 a market share of the children and adolescents that
4 were being used off label in these various
5 antipsychotic drugs between and among the pharma
6 companies; correct?

7 A. No.

8 Q. Well, sir, let me just leave it at this.
9 Physician misperception primarily driven by
10 increasingly competitive market. Was there an
11 increasingly competitive market? We're going to see
12 documents in a minute about it. Was there an
13 increasingly competitive market about to try to get
14 a share for Risperdal among children and adolescents
15 in 2001 through 2003, yes or no?

16 A. No, not the way you were phrasing it.

17 Q. Well, let's see what you were saying in the
18 boardroom, okay. Let's continue. Key issues. Key
19 issues and strategies. Now, you had a strategy
20 about this drug which was not approved for FDA use
21 yet; correct?

22 A. Correct.

23 Q. And you had -- when you have strategies, what
24 does the word "strategy" mean to you, sir?

25 A. I'll use the word "plan." I don't know of a

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2 simple way to define what your strategy would be,
3 your approach.

4 Q. Okay. Bear with me, sir. Would you agree
5 with the Merriam Webster definition so we can talk
6 about this in terms of strategy, "A careful plan or
7 method for achieving a particular goal"? Would you
8 agree, a careful plan or method for achieving a
9 particular goal? Is that a fair statement what a
10 strategy would be, sir?

11 MR. WINTER: Your Honor --

12 THE COURT: Are you objecting?

13 MR. WINTER: Yes, Your Honor.

14 THE COURT: Overruled.

15 THE WITNESS: I would agree with that.

16 BY MR. KLINE:

17 Q. Good. And then you have core strategies. So
18 now we have a -- now we have a careful plan or
19 method for achieving a goal and then we have a core
20 to it. And, sir, a core strategy would be an
21 essential or a -- a strategy, can we agree?

22 A. It was a key strategy. I don't think we had
23 noncore strategies.

24 Q. Well, some strategies you would agree with me
25 would be noncore and some would be core?

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2 A. I believe these are our only strategies. I
3 don't recall other strategies.

4 Q. Sir, the word "core" was used; correct?

5 A. Correct.

6 Q. And core, the definition of core is the
7 central or most important part of something;
8 correct?

9 A. Correct.

10 Q. So we have the central most important part of
11 the plan, that's what we have with a core strategy;
12 correct?

13 A. These are strategies.

14 Q. They're your core strategies, can we agree to
15 that?

16 A. They are only strategies, that's what I'm
17 trying to explain. There's not core and noncore.
18 The word core was just selected. We could have said
19 key strategies, we could have said all our
20 strategies.

21 Q. Who picked "core strategy," sir?

22 A. I may have picked it.

23 Q. Are you disavowing the word "core strategy"
24 here?

25 A. I'm disavowing the characterization --

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2 Q. Who used the word, sir, please?

3 A. I used the word.

4 Q. Okay.

5 A. But you're reading into what I may have been
6 thinking at the time is my point. These were our
7 strategies.

8 Q. Yes. When you say reading into them, using
9 the dictionary?

10 A. Well, I don't know if there's a need to go
11 into a dictionary.

12 THE COURT: I think we've covered

13 this.

14 BY MR. KLINE:

15 Q. Let's go on. Let's see what the core strategy
16 was. A core strategy. This is a core strategy of
17 the company; correct?

18 A. Correct.

19 Q. Known to the president that day; correct?

20 A. Correct.

21 Q. A core strategy was to establish Risperdal,
22 look at number three, establish Risperdal as having
23 a favorable risk/benefit ratio relative to other
24 compounds; correct?

25 A. Correct.

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2 Q. Core strategy?

3 A. Correct.

4 Q. And when you have a core strategy, those
5 things that you do, you then do things to implement
6 the core strategy; correct?

7 A. Correct.

8 Q. And we saw that one of the things that was
9 going to be done was reanalyze data; correct?

10 A. Correct.

11 Q. And there were to be strategic initiatives.
12 Again, this is all as of July 29, 2002. Strategic
13 initiatives, sir. All right. So we have, "Use of
14 psychotropic medications remains controversial." Do
15 you see that?

16 A. Yes.

17 Q. One of your goals was to educate the public
18 and educate -- really educate the doctors so that it
19 became less controversial to use antipsychotics,
20 correct, in children and adolescent?

21 A. It was to educate the community.

22 Q. Yes. And there were a whole series of things
23 that Janssen was prepared to do which are in front
24 of the jury, like partnered with advocacy to
25 increase awareness and to create demand and need for

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2 data; correct?

3 A. That's what it says, correct.

4 Q. Now, for strategic initiatives, sir, an
5 initiative is to act or take charge before others do
6 so. Is that how you were using initiative?

7 A. No.

8 Q. And you see one of the things that you were --
9 you have here is this thing about what you were
10 calling physician misperception of risk safety
11 profile. Do you see that?

12 A. Yes.

13 Q. Okay. Do you know, by the way, and you may or
14 may not know, do you know whether any physicians
15 outside of Janssen ever saw those multiple drafts of
16 the article that became published as the Findling
17 study? Do you know?

18 A. I believe the authors would have seen it.
19 They were not Janssen employees.

20 Q. Okay, the authors. How about anyone else,
21 other physicians who were prescribing the drug,
22 would they have seen those drafts?

23 A. A draft of a publication?

24 Q. The drafts.

25 A. No, we would never be able to show someone

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2 something that's off label.

3 Q. Yes. And how about -- you're familiar with
4 what Table 21 is, aren't you? You know what Table
5 21 is?

6 A. I've seen --

7 Q. You what?

8 A. I've seen Table 21.

9 Q. You've seen Table 21, yes. Do you know if
10 Table 21 was being shared with physicians nationwide
11 back in 2001, 2002, 2003?

12 A. They would not have seen it.

13 Q. Do you know that document, do you know, sir
14 that document has never been turned over to the FDA,
15 are you aware of that fact?

16 MR. WINTER: Objection, Your Honor.

17 THE COURT: Sustained.

18 MR. KLINE: Was it the form, sir? Was
19 it the form, Your Honor?

20 THE COURT: I think you're going a
21 little far --

22 MR. KLINE: Okay. I'll ask a
23 different witness. I'll ask Mr. Caers when
24 he comes.
25

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2 BY MR. KLINE:

3 Q. And you see under this, it says -- here is the
4 strategy, the strategy on physician misperception,
5 the number one strategy, which we're highlighting,
6 is to neutralize, neutralize safety and tolerability
7 concerns. Do you see that?

8 A. Yes.

9 Q. You would agree with me, sir, that none of
10 these words are being chosen by accident; correct?

11 A. I mean these are just words that were chosen
12 to make our points across.

13 Q. Words used to get your points across, is that
14 what I heard you say?

15 A. Yes. I mean there wasn't a 20-minute debate
16 on what word to use there amongst the team.

17 Q. They were words that you believed accurately
18 and correctly described what you were telling your
19 colleagues up to the top people in the company;
20 correct?

21 A. Yes, these are the words we selected, sure.

22 Q. Okay. The next thing that is said -- and,
23 sir, can we at least agree, and I'm sorry to put us
24 all through this, but neutralize, sir, is to render
25 ineffective or harmless by applying an opposite

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2 force? Is that how you were using it?

3 A. I was using it in the sense of trying to get
4 the misperceptions corrected, and that's what I
5 meant by neutralize.

6 Q. Did you ever say one way we can correct the
7 misperceptions about the safety is to, since you had
8 seen it, to share Table 21 with physicians next time
9 that sales reps go into doctors' offices? Did you
10 ever suggest that?

11 A. No, that would have been off label. We didn't
12 give that kind of direction to our reps to promote
13 off label.

14 Q. Okay. And the next thing that it said is, and
15 here we have database, data sets. One data set,
16 sir, was the RIS-41 study, that was a data set;
17 correct?

18 A. Correct.

19 Q. And one data set was the combined five studies
20 of which RIS-41 was one, in the pooled analysis;
21 correct?

22 A. Correct.

23 Q. And one of the goals here, one of the goals
24 here was to leverage -- you see the word? Can we
25 highlight the word "leverage" -- leverage the

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2 current data sets; correct?

3 A. Correct.

4 Q. Okay. Now, leverage is a term that you know;
5 correct?

6 A. Correct.

7 Q. And leverage means using something to its
8 maximum advantage; correct?

9 A. Correct.

10 Q. And so the goal here was to use the current
11 data sets to their maximum advantage; correct?

12 A. Correct.

13 Q. Now, the next slide says, "Use of psychotropic
14 medications in children is controversial." Correct?

15 A. Correct.

16 Q. And two slides down, three -- ending in 248,
17 it says, "Physician misperception of Risperdal
18 safety profile." And there it says the goal is,
19 "Establish Risperdal as having a favorable
20 risk/benefit ratio relative to our compounds."

21 Correct?

22 A. Correct.

23 Q. That was a strategy; correct?

24 A. Correct.

25 Q. And the strategy was to make the drug come out

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2 with a favorable risk/benefit ratio; correct?

3 A. Well, the strategy was to establish that based
4 on the data that was generated, correct.

5 Q. Yes. Right. Take the data that you have and
6 then establish it as having a favorable risk/benefit
7 ratio, that's what you told this group, that's what
8 you're telling this jury; correct?

9 A. Correct.

10 Q. And here's how it was going to be done. Again
11 we see the word "leveraging" again. Leveraging the
12 current data sets and generating new data to address
13 identified gaps; correct?

14 A. Correct.

15 Q. So one of the things that was going to be done
16 here, and in fact what you knew was in the process
17 of being done, because we're going to see e-mails
18 that you have, including one that says excellent --
19 you've seen the excellent e-mail, haven't you?

20 A. Yes.

21 Q. You -- one of the things that was being done
22 here was the reanalysis of the five pooled studies
23 was underway; correct?

24 A. Correct.

25 Q. It was important to everybody who was

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2 interested in this drug being successful at the
3 Janssen Company; correct?

4 A. Well, it was important as far as it relates to
5 seeking an indication and ensuring that we had the
6 data out there in regard to this prolactin question
7 because we did get questions from physicians about
8 it.

9 Q. No, sir, this doesn't talk about the prolactin
10 and the physicians. That was 15 slides earlier.
11 This talks about leveraging the database sets, and
12 what my question to you is, was the -- strike that.
13 I'm going to move on. I'm being repetitious and I
14 apologize.

15 Key tactics number one. The key tactic
16 -- now, we see core strategy. Now we have key
17 tactic. Key tactic, number one. By the way, if
18 you're going to have key tactic number one and key
19 tactic number two, the most important of the two is
20 going to become number one, can we agree?

21 A. No, these are not necessarily in any priority.

22 Q. Not necessarily in order?

23 A. They're very rarely put in order.

24 Q. Okay. But it might be; correct? You just
25 don't remember?

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2 A. It might be. It's a key tactic.

3 Q. Don't you usually when you have key tactics
4 and you're thinking most important, next important,
5 third important, you put the top one first? Don't
6 you usually do that, sir, usually?

7 A. It depends. Not in terms of tactics because
8 these are your key tactics, you're requesting that
9 these key tactics be done.

10 Q. So if you had five key tactics, you might put
11 the most important one as number five; is that
12 correct?

13 A. I didn't say that. You asked me if number one
14 was the most important. I'm responding to you to
15 say we did not specifically put these in priority
16 order. I'm not suggesting it might at the time been
17 priority.

18 Q. Think back. Think back. Sir, you don't have
19 amnesia about this; correct?

20 A. No.

21 Q. You do have a recollection of this; correct?

22 A. I have a recollection of putting together the
23 business plan.

24 Q. You have a recollection of being there;
25 correct?

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2 A. Correct.

3 Q. You have a recollection that these are all
4 statements that you made; correct?

5 A. Correct, and I have a recollection that I did
6 not put them in priority order because that was not
7 something that was routinely done.

8 Q. Okay. Well, then let's look at key tactic one
9 anyway. Key tactic one, "Reanalysis and
10 dissemination of the CDMR database addressing,"
11 among other things with the first one, "prolactin."
12 Correct?

13 A. Correct.

14 Q. And of course that reanalysis was underway at
15 this time; correct?

16 A. I believe so.

17 Q. In fact, sir, Table 21 had already come back
18 in May of 2002; correct?

19 A. I don't have the specific time. If that's
20 what you say. I don't have the exact timing.

21 Q. This is July of 2002. I'll represent to you
22 to refresh your recollection that the Table 21 was
23 in -- was published -- was available in May of 2002.
24 Now, sir, if that's correct, then the -- this
25 statement here is after Table 21 was known to the

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2 company; correct?

3 MR. WINTER: Objection, Your Honor.

4 THE COURT: Overruled.

5 BY MR. KLINE:

6 Q. Correct, sir?

7 A. Apparently so.

8 MR. KLINE: Now, Your Honor, will we
9 be working straight through?

10 THE COURT: Yes.

11 MR. KLINE: Through whenever we have a
12 lunch break?

13 THE COURT: Yes. Around quarter of
14 1:00.

15 MR. KLINE: Okay.

16 THE COURT: Is that all right, ladies
17 and gentlemen, if we -- if you want to take
18 a break, let me know. Just raise your
19 hand.

20 You want a break?

21 MR. KLINE: Just -- everyone can sit
22 in place if they want.

23 THE COURT: All right. Let's take a
24 brief break.

25 (Jury leaves courtroom)

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2 (Short recess)

3 -----

4 COURT CRIER: Everyone may be seated.

5 Court is now back in session.

6 MR. KLINE: Your Honor, thanks.

7 BY MR. KLINE:

8 Q. Mr. DeLoria, you recall our discussion about
9 sales calls to child psychiatrists, child
10 neurologists, do you recall that?

11 A. Yes.

12 Q. I'd like to turn in this very document to
13 Exhibit 3272, ending in 3272, Bates number. This is
14 the JJRE document saying, "Confidential, produced in
15 litigation pursuant to protective order." Do you
16 see it?

17 A. Yes.

18 Q. This was part of that presentation on July
19 29th; correct?

20 A. Correct.

21 Q. And what you presented was that there are
22 5,192 child psychiatrists. I assume that's in the
23 United States, sir?

24 A. Yes.

25 Q. And 3,307 had received a sales call in the

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2 last 12 months?

3 A. Correct.

4 Q. Child psychiatry, sir, is a subspecialty of
5 psychiatry; correct?

6 A. Correct.

7 Q. Physicians in child psychiatry generally tend
8 to specialize in that field; correct, sir?

9 A. Tend to specialize in child psychiatry.

10 Q. Yes. That means they treat children and
11 adolescents; correct?

12 A. Correct.

13 Q. And 63.7% of them were visited by Janssen by a
14 sales representative in the 12 months before this
15 meeting; correct?

16 A. Correct.

17 Q. And, sir, if you see right down below,
18 Risperdal had a 42% market share and sales of \$132
19 million?

20 A. Correct.

21 Q. In child and adolescents?

22 A. Written by those physicians.

23 Q. Yes.

24 A. Correct.

25 Q. Just written by the psychiatrists, the child

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2 psychiatrists?

3 A. Right, but my only point was that what that
4 means is that \$132 million of sales came out of
5 those specific physicians. You don't know what they
6 were prescribing it for who, but it was that dollar
7 amount for those physicians above, correct.

8 Q. Yes. The dollar amount for the child
9 psychiatrists, the \$132 million of these -- of just
10 the child psychiatrists portion of the prescribing
11 market for child and adolescent Risperdal; correct?

12 MR. WINTER: Objection, Your Honor.

13 THE COURT: I think it's been covered.

14 MR. KLINE: Okay.

15 THE COURT: I'll sustain.

16 BY MR. KLINE:

17 Q. And this is all off label; correct?

18 A. No.

19 Q. Why, because there might have been a few
20 adults thrown in?

21 A. Because the child and adolescent psychiatrists
22 also treat adults. Many of these patients continue
23 to see their child and adolescent psychiatrists
24 through adulthood and some of them also in addition
25 to their regular practice actually prescribe in

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2 other institutions. So my only point is, yes, some
3 of them are certainly child and adolescent patients
4 on it, my only point is I could not tell you what
5 percent.

6 Q. Can you try to find that percent?

7 A. I don't recall.

8 Q. Now, sir, remember our discussion earlier?

9 You know, sir, you know sir, sitting here today that
10 a very large majority of child psychiatrists
11 patients are children and adolescents; correct?

12 MR. WINTER: Objection, Your Honor.

13 THE COURT: Overruled.

14 BY MR. KLINE:

15 Q. You know that, sir?

16 A. Yes, but that's not what you said before.

17 Q. Yes. Now, going back to the figure, sir, can
18 we agree that if child psychiatrists alone in this
19 period accounted for \$132 million of sales, that the
20 prescription numbers that we were looking at on the
21 bar graphs are likely in millions? Can we agree,
22 sir?

23 MR. WINTER: Objection, Your Honor.

24 THE COURT: Sustained.

25

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2 BY MR. KLINE:

3 Q. Now, the psychiatrists, if we go to the
4 exhibit ending with 266, the psychiatrists are the
5 leaders that were targeted for children and
6 adolescent usage in Risperdal by Janssen; correct?

7 A. Can you say that again, please?

8 Q. Yes. The child and adolescent psychiatrists,
9 the child psychiatrists were your principal market;
10 correct? That's where you targeted your efforts,
11 generally speaking; correct?

12 A. Are you referring to sales representatives or
13 promotional efforts? That's not what I'm clear --

14 Q. Let's take both. Sales representatives.

15 A. No, our sales representatives are not
16 targeting child and adolescent patients. They were
17 calling on child and adolescent psychiatrists that
18 also saw adults, that's why I'm not exactly sure
19 where you're going.

20 Q. Was there a list kept, sir, that you can show
21 me that all of these child and adolescent
22 psychiatrists were also seeing adults? Do you have
23 a list, like do you have that data?

24 A. Me personally?

25 Q. Yes.

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2 A. I don't personally have that list.

3 MR. KLINE: If we can put the last one

4 up before we're there. If we can go back.

5 BY MR. KLINE:

6 Q. This is a business plan that deals with child
7 and adolescents, correct, not with adults? That's
8 what the business plan says; correct?

9 A. Correct.

10 Q. You are aware of the fact there's a separate
11 board certification for child psychiatry; correct?

12 A. Correct.

13 Q. Sir, there's a document in this sales plan
14 which I'd like to also review with you which is
15 entitled "Risperdal Versus." You did a Risperdal
16 versus a number of other drugs and before we put it
17 up, let's talk generally about it. There's
18 discussion which we've already seen about
19 competition among the various antipsychotic drugs
20 made by different manufacturers for the child and
21 adolescent market; correct?

22 A. I think we discussed this before.

23 Q. Yes. I just want to get us back in context.

24 A. Right. Well, the reason why I'm bringing this
25 up is the way you phrased, there was not active

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2 competition for child and adolescent patients.

3 Q. Yes.

4 A. So to that extent I don't agree with the
5 statement. It was a competitive market, without
6 question, but we weren't actively competing with
7 other pharmaceutical companies to try to get these
8 child and adolescent patients.

9 Q. Okay. Let's agree with this. It was a
10 competitive market? Let's see all the areas we can
11 agree on. It was competitive market; correct?

12 A. Correct.

13 Q. And you were assessing where you stood
14 Risperdal versus the various other products;
15 correct?

16 A. Yes, that's correct.

17 Q. You actually did a survey; correct?

18 A. Which survey are you referring to?

19 Q. Well, did you do any surveys?

20 A. Did many surveys.

21 Q. Okay. Let's look at the document which is --
22 which ends in 275. One of the drugs -- one of the
23 drugs that was also being used off label was
24 Zyprexa; correct?

25 A. Correct.

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2 Q. And, by the way, Janssen would prefer to sell
3 a tablet of Risperdal versus -- who made Zyprexa?

4 A. Ely Lily.

5 Q. -- Lily sell a tablet of Zyprexa? If you had
6 your choice and someone were using it off label,
7 you'd prefer Risperdal to be chosen rather than
8 Zyprexa; correct?

9 A. Correct. If it was appropriately being used.

10 Q. And so what you did here, Risperdal versus
11 Zyprexa for child and adolescent disorders, here is
12 a list of the psychiatrists. Now, there's Risperdal
13 better, Zyprexa better. Tell me what this chart
14 shows.

15 A. Show --

16 Q. As you presented it that day.

17 A. Yes. So basically these types of charts are
18 created to show a physician's -- so physicians are
19 asked to track basically -- or I should say plot
20 what their perceptions are of particular side
21 effects or efficacy comparing two products, and then
22 it's plotted on a graph and then you can kind of
23 see, for example, physicians thought that Risperdal
24 was better as it relates to low weight gain, Zyprexa
25 was better as it refers to depression efficacy. So

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2 that's essentially how you read this chart. It was
3 what physicians' perceptions were on the product.

4 Q. Right. How about the one in the middle,
5 physicians' perceptions was that Zyprexa was better
6 as to prolactin; correct?

7 A. Correct.

8 Q. And Zyprexa was one of the competitive drugs;
9 correct?

10 A. Correct.

11 Q. And another competitive drug was Seroquel;
12 correct?

13 A. Correct.

14 Q. Being used in children and adolescents off
15 label; correct?

16 A. Correct.

17 Q. And let's look at this one, the next exhibit
18 which is 276. Seroquel was perceived as better as
19 to prolactin and Risperdal as well; correct?

20 A. Correct.

21 Q. And let's look at Geodon, another competitive
22 drug being used off label for children and
23 adolescents; correct?

24 A. Correct.

25 Q. And Geodon was seen as better as to prolactin;

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correct?

A. Correct.

Q. And then there were charts that were done for '01, '02, just the psychiatrist -- I'm sorry, the others were just psychiatrists apparently too, I misspoke. And let's look very briefly at Exhibit 278 and you have Risperdal versus Zyprexa for '01, '02, and once again that chart shows Zyprexa better for low prolactin; correct?

A. Correct.

Q. And Risperdal versus Seroquel and the next exhibit number, 279, for the period '01 versus '02. This is testing, these last two charts are testing if perceptions changed at all in the period, in the period from '01 to '02; correct?

A. Correct.

Q. And you're actually gauging how physicians feel about Risperdal versus competitive drugs in children and adolescents; correct?

A. Correct.

Q. For a drug that's not even approved by the FDA for that use; correct?

A. That's correct.

Q. You're actually doing physicians' surveys to

1 Carmen DeLoria - As on Cross

2 see if they thought Risperdal was better than
3 Zyprexa; correct?

4 A. Correct.

5 Q. You did a survey to see -- and you actually
6 asked the physicians is Risperdal better than the
7 other drugs that we've mentioned; correct?

8 A. Correct.

9 Q. And this was gathering what you and what
10 Janssen believed were important information about a
11 -- about prescribing habits of doctors who can't
12 even prescribe the drug to an indication which is
13 approved by the FDA unless they happen to have an
14 adult patient; is that correct?

15 MR. WINTER: Objection, Your Honor.

16 THE WITNESS: No, that's not a correct
17 statement at all. You just said that
18 physicians are not allowed to write for
19 products off label?

20 BY MR. KLINE:

21 Q. You're not allowed to promote the drug off
22 label, that's really what I wanted to get to. I
23 misstated the question. Let me try again. Okay.
24 Let me try again.

25 You are -- maybe I can do it simply.

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2 You are in this chart and the chart before it, you
3 are tracking physician prescribing data; correct?

4 Correct so far?

5 A. We're tracking their perceptions on the
6 product.

7 Q. And was this a survey?

8 A. Yes, it was.

9 Q. And who conducted the survey?

10 A. Janssen.

11 Q. And did that involve going to how many
12 physicians?

13 A. I don't know specifically here the number. It
14 doesn't say.

15 Q. What department was that done in, sir?

16 A. Market Research.

17 Q. Market Research. So the Market Research
18 Department of Janssen in 2001 and again in 2002 were
19 tracking these perceptions of doctors as to the
20 drugs; correct?

21 A. Correct.

22 Q. Okay. Now, this was one of a number of
23 business plans, this one being July of 2002;
24 correct?

25 A. Correct.

1 Carmen DeLoria - As on Cross

2 Q. But actually the business planning for the
3 drug went back for the adolescent market, the child
4 and adolescent market to plans that were earlier;
5 correct?

6 A. Correct. There was a business plan that was
7 in place for what would be the eventual approval.
8 So the business plans were put in place in order to
9 make us prepared for what would eventually be the
10 autism launch.

11 Q. Sir, is there anything in that business plan
12 that we saw that talked about the autism launch or
13 based on -- that indicates that it's based on
14 something for future approval?

15 A. All of our business plans were based under the
16 premise that we were seeking, which we were,
17 indication which originally was the conduct disorder
18 and then eventually ended up being autism. But
19 these business plans are in place for the sole
20 purpose that we are moving forward with an
21 indication and the tactics and the strategies that
22 you saw are tactics and strategies that are not only
23 shorter term but also longer term and this is why
24 we're tracking this.

25 Q. Let's see what we can agree on. You can agree

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2 with me -- let's not debate whether you were
3 thinking about long term. You'd agree with me what
4 you just said is that there is information in these
5 which deal with short-term strategies, can we agree?

6 A. Agree.

7 Q. You just said it?

8 A. Agree.

9 Q. Now, when was the first time -- I have one in
10 front of me, but I want to see if you saw one
11 earlier. When is the first -- I'm going to start
12 again. There is a business plan which is -- which
13 was for the drug Risperdal covering all aspects of
14 the drug. That would be adult use in schizophrenia
15 as well as children and adolescents; correct?

16 A. Are you saying that prior to me arriving on
17 the team or --

18 Q. At any time.

19 A. From what I recall, there was always a
20 separate business plan for the schizophrenia adults
21 and this was for the nonschizophrenia adults. I
22 don't recall them ever being one. There may have
23 been.

24 Q. What I would like to get at is when did you
25 first -- when did Janssen first start a separate

1 Carmen DeLoria - As on Cross

2 business plan for the child and adolescent market?

3 A. I believe the year prior to me coming into the
4 team there may have been a business plan from what I
5 recall, that might have been the earliest year.

6 Q. A child and adolescent business plan would
7 have first been in 2000; correct?

8 A. Yes, because if you recall, we were pursuing
9 the conduct disorder indication, so that would have
10 been at that time.

11 Q. Okay. So when you came -- I'm now looking
12 at -- the first business plan that was under when
13 you were there was the July '01 business plan, a
14 year earlier than the one we've been looking at;
15 correct?

16 A. Yes, yes.

17 Q. All right. And I have some pieces of that
18 plan which I'd like to discuss with you. This is a
19 plan also with which you're familiar; correct?

20 A. Correct.

21 Q. It was presented to the Board; is that
22 correct?

23 A. Correct.

24 Q. The president of the company was there as
25 well; correct?

1 Carmen DeLoria - As on Cross

2 A. Correct.

3 Q. And you were there; correct?

4 A. Correct.

5 Q. And this plan -- let's look at -- this is a
6 year earlier. And, by the way, let's look at who
7 did the presentation. Apparently the presentation
8 was not done by you, it was done by Kent Bockes; is
9 that correct?

10 A. Kent Bockes.

11 Q. Okay. And who is he related to you? Boss?
12 Underling? Boss' boss? Who is he?

13 A. So he is someone who was working on that
14 pediatric or the child and adolescent business plan.
15 He reported to me for a short period of time and
16 then was replaced by Mr. Lin who I referred to
17 previously.

18 Q. Okay. And he's listed as the Product
19 Director. He's in Marketing; correct?

20 A. Correct.

21 Q. Paul Mullen?

22 A. Market Research.

23 MR. KLINE: By the way, let's mark it
24 as Exhibit 63 and we'll display this page
25 that we're talking about here.

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2 (Business Plan, July 2001, marked
3 Plaintiffs' Exhibit P-63 for
4 identification)

5 BY MR. KLINE:

6 Q. I'll briefly hand it to you. And we'll also
7 have it displayed, Mr. DeLoria, so it's convenient.
8 So Bockes we know who he was. Mullen briefly?

9 A. Market Research.

10 Q. And Mahmoud, who is he?

11 A. He was the head of Medical Affairs for CNS.

12 Q. Now, this is just rolling back a year earlier,
13 there's some a little bit different information here
14 and some additional information. Would you agree?

15 A. I'm sorry, once again.

16 Q. I said there's some different information and
17 some earlier information in this document. You've
18 reviewed it; correct?

19 A. I don't recall the contents, but I'm sure it
20 was slightly different because it's a year earlier.

21 Q. Okay. I just want to go through some of the
22 things that are here. On the -- on Page 725, a
23 goal, number three, was that Risperdal would serve
24 as a springboard for a J&J pediatric
25 psychopharmacology franchise. Do you see that?

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2 A. Yes.

3 Q. And, by the way, did -- maybe I can sort this
4 out. You participated in this, correct? Did you
5 write it?

6 A. I don't believe I wrote it, but I would have
7 reviewed it.

8 Q. Okay. And if we can look as of 2001 next
9 slide, which is 726, children comprised as of 2001
10 21% of the use of Risperdal; correct?

11 A. Correct.

12 Q. So to put it in context, you have a
13 pharmaceutical company who has a drug which one out
14 of every five prescriptions is sold off label;
15 correct?

16 MR. WINTER: Objection, Your Honor.

17 THE COURT: Overruled.

18 BY MR. KLINE:

19 Q. Correct, sir? Do you need the question read
20 back?

21 A. Correct.

22 Q. And everyone who is in the room knew that
23 fact, one out of five prescriptions goes to someone
24 who is a child or an adolescent for which the drug
25 was not approved; correct?

1 Carmen DeLoria - As on Cross

2 A. Correct.

3 Q. And 45% of it went to children between the
4 ages of seven and 12, 45% of that 21%?

5 A. That was the estimate.

6 Q. That's so we can go through this, of the 21%
7 piece of the pie, 5% were with kids under six,
8 correct so far?

9 A. Yes.

10 Q. 45% was kids between the ages of seven and 12,
11 and 50% is kids between the ages of 13 and 19;
12 correct?

13 A. Correct.

14 Q. And you, sir, knew, and you knew that other
15 folks knew -- let me ask it this way. Everyone in
16 the room knew that these were children with
17 significant disabilities; correct?

18 A. I mean these were the children that were
19 deemed by the child and adolescent psychiatrists to
20 have, you know, a serious you could say mental
21 illness or some type of a disorder that require the
22 use of an antipsychotic product.

23 Q. Yes, a drug -- every one of these children,
24 some doctor made a decision that they would give a
25 drug which was an adult schizophrenia drug off label

1 Carmen DeLoria - As on Cross

2 to that child; correct?

3 A. Correct.

4 Q. By definition, a child who has -- a child who
5 has a significant disability; correct?

6 A. Correct.

7 Q. Children who, as you would see it, I think we
8 can agree on this, are the most vulnerable in
9 society; correct?

10 A. Children are vulnerable by definition, I guess
11 you can say.

12 Q. I didn't ask you by definition. These are
13 among the most vulnerable of all children; correct?

14 A. I don't know.

15 Q. Now, let's look at this chart and see if this
16 chart will be a better one to help us with. This is
17 No. 727. Antipsychotic sales for child and
18 adolescent market. Sir, in 1997 -- let me step
19 back. Let me take this down for a moment. Let's
20 have a discussion.

21 When you came on board on Risperdal,
22 did you go back and review the history of the drug?

23 A. I don't recall specific review of the drug at
24 the time.

25 Q. No? Did you attempt to learn everything you

1 Carmen DeLoria - As on Cross

2 could about the drug?

3 A. Well, as part of the job, sure.

4 Q. Did you or didn't you? What did you do to
5 educate yourself?

6 A. I don't know if you can learn everything about
7 the drug. But to educate myself?

8 Q. Yes.

9 A. Ask questions. I mean I knew a lot about the
10 drug already, I worked at the company. I mentioned
11 before I'd spent a few years answering questions
12 about the product.

13 Q. Okay.

14 A. So I was well aware of how the product was
15 being used.

16 Q. Do you know what a new drug application is?

17 A. Yes.

18 Q. Did you go back and look at the NDA, the new
19 drug application?

20 A. No. That's several hundred thousand pages.

21 Q. Yes. The submissions to the FDA are millions
22 of pages; correct?

23 A. If that's what you say. I know it's hundreds,
24 thousands, maybe over a million. I'm not in the
25 regulatory department, so I actually don't know.

1 Carmen DeLoria - As on Cross

2 Q. Okay. Now, did you -- were you familiar in 20
3 -- you were familiar when you came on board, 2001;
4 correct?

5 A. Correct.

6 Q. Were you familiar with the attempt by Janssen
7 to get approval for conduct disorder in 2000?

8 A. Correct.

9 Q. Had you become familiar with that generally to
10 do your job, did you learn a little bit about it?

11 A. Well, yeah, I mean I know that they had
12 submitted for the specific indication you're
13 referring to. I did not read the submission, but I
14 was aware of the submission.

15 Q. Did you see the documents that went back to
16 1997 when the FDA had refused to allow dosing
17 information to be put into the label?

18 A. I don't recall seeing it, but I'm aware of
19 what you're referring to.

20 Q. Okay. Do you recall seeing the document from
21 the FDA that said as of 1997 there was meager safety
22 data?

23 A. I don't recall.

24 Q. Okay. Well, let's look at the chart that we
25 have in front of us. By 2000 -- and, by the way,

1 Carmen DeLoria - As on Cross

2 none of these antipsychotics were being used for
3 indications approved in the label as to children and
4 adolescents; correct?

5 MR. WINTER: Objection, Your Honor.

6 MR. KLINE: I'll withdraw it. I'll
7 just stick with Risperdal.

8 BY MR. KLINE:

9 Q. Sir, in 2000, the drug was for the child and
10 adolescent market share, the drug was 178 -- \$178
11 million drug; correct?

12 MR. WINTER: Objection, Your Honor.

13 THE COURT: I think you've made your
14 point that there were sales of the drug and
15 so forth. I think -- I'm going to sustain
16 the objection as to this.

17 MR. KLINE: Your Honor, if I may, the
18 point is the increase and then we have
19 additional motive testimony, so I would
20 respectfully request that these numbers
21 which are in front of the jury be allowed.

22 MR. WINTER: Objection, Your Honor.

23 THE COURT: Sustained. I think you
24 could say there were sales, there were
25 increase in sales, and you've already laid

1 Carmen DeLoria - As on Cross

2 -- that's as far as I'll let you go.

3 MR. KLINE: I cannot show the numbers,
4 is that the Court's ruling?

5 THE COURT: Yes.

6 MR. KLINE: I will of course abide by
7 it, but I just want to know.

8 THE COURT: Yes.

9 BY MR. KLINE:

10 Q. Sir, then I will ask percentage increases.

11 THE COURT: I'll permit that.

12 MR. KLINE: Okay. What I'll do is
13 I'll take the calculator at the lunch hour,
14 Your Honor, and come back to this.

15 THE COURT: Or generalization.

16 MR. KLINE: No, I'd rather try to be
17 specific.

18 THE COURT: Very well.

19 BY MR. KLINE:

20 Q. Let's look at Exhibit 728. Sir, the drug, the
21 share that Risperdal had in the antipsychotic
22 market, that's among the competition, was 53.9%;
23 correct?

24 A. Correct.

25 Q. And both this document and other documents

1 Carmen DeLoria - As on Cross

2 which you're aware of, sir, will demonstrate that
3 Janssen Pharmaceuticals cared an awful lot about
4 keeping that share, correct, not having that share
5 decrease, can we agree?

6 A. Well, we were interested in generating data so
7 we can have an indication within this area. We were
8 also interested, as we said before, in correcting
9 the misperceptions in general about the product as
10 it related to adverse events.

11 Q. None of that was my question, sir. My
12 question, sir, and I've heard both of those things
13 that you've said now about five times, but my
14 question is a different one, respectfully. My
15 question doesn't have to go to what you said many
16 times that you were interested in an approval, that
17 you wanted to get information. My question is, you
18 were interested in preserving your share? That's a
19 very specific question. Can we agree?

20 MR. WINTER: Your Honor, I object to
21 that question. It is a speech.

22 THE COURT: Well, all right.

23 MR. KLINE: A question has about five
24 words in it.

25 THE COURT: Mr. DeLoria, just answer

1 Carmen DeLoria - As on Cross

2 that part of it.

3 BY MR. KLINE:

4 Q. I will repeat the question so we only have a
5 question. You were interested in preserving this
6 53% share and the documents, not only this one, but
7 other documents show it; correct?

8 A. We were interested in preserving the share.

9 Q. Now, the share, of course, was for -- strike
10 that. We've covered that.

11 Let's go to 729. 729 is a pie chart
12 which shows us the -- if we go back to 728 for a
13 moment, please. And, by the way, on 728 of Exhibit
14 63 the 2001 business plan, sir, Risperdal by the
15 chart that's in front of the jury, it shows that in
16 2001 Risperdal dominated the off label child and
17 adolescent market for antipsychotics; correct?

18 A. It had the highest market share, correct.

19 Q. I didn't hear the words you said.

20 A. It had the highest market share.

21 Q. Well, maybe you will and maybe you won't
22 agree, but Risperdal dominated the market, you have
23 50% and everybody else is 20 or lower. Can you
24 agree that you dominated the market?

25 MR. WINTER: Objection, Your Honor.

1 Carmen DeLoria - As on Cross

2 THE COURT: Sustained. You can make
3 that argument to the jury.

4 MR. KLINE: Okay.

5 THE COURT: If you wish.

6 BY MR. KLINE:

7 Q. I will do it by percentages. Risperdal had
8 53%, and what's the next line down, sir?

9 A. 20%.

10 Q. And who had that?

11 A. Zyprexa.

12 Q. And what's the next line underneath that, the
13 one that's going down?

14 A. Seroquel.

15 Q. Seroquel is going down. And then there is an
16 under 10% that is creeping up. What is that?

17 A. It was conventional. It's hard to see from
18 here. It looks like the conventionals are going
19 down, then Seroquel is at about 10% in the triangle.

20 Q. Now, we have the document ending in Bates 729.

21 And this pie chart looks at something different.

22 And again, all of this -- all of this so we're

23 clear, I think you'd agree, everything in this

24 document is knowledge to Janssen up to the level of

25 the president of the company, everything that we're

1 Carmen DeLoria - As on Cross

2 going over here; correct?

3 A. This was presented to the president, correct.

4 Q. Antipsychotic use in child and adolescent
5 patients. This document shows for Risperdal. Let's
6 look at the right side to the Risperdal. Of the use
7 in child and adolescent patients, 13% of it was
8 being used for ADHD; correct?

9 A. Correct.

10 Q. And now there was a chart where you were on
11 Page -- on 731, this chart that day in July of 2001
12 there was an assessment being made of the key
13 markets for child and adolescents; correct?

14 A. Yes, this was looking at key markets. It says
15 we were considering what indications we could pursue
16 in addition to the indication that we had. We're
17 always looking for what opportunities would make
18 most sense to invest in.

19 Q. Yes. Yes. But I'm interested in something
20 different. I'm interested in the fact that it
21 doesn't say prevalence of key and child adolescent
22 markets in the future, does it?

23 A. It does not, but I wrote it along with or at
24 least was part of the team and I can tell you that
25 whenever we put these plans together, these are

1 Carmen DeLoria - As on Cross

2 plans that are from now into the future.

3 Q. Yes. And including now because you were
4 selling a lot of the drug at the time?

5 A. We weren't selling, it was being used at the
6 time.

7 Q. Oh, when you say, "We weren't selling it,"
8 sir, there is a consumer on the other end paying
9 money for the drug; correct?

10 A. Correct.

11 Q. Someone goes to a pharmacy and there's money
12 exchanged; correct?

13 A. Correct.

14 Q. That's a sale; correct?

15 A. It's a sale, but we're not selling it. You're
16 implying that we're promoting it by using the word
17 "selling." That's your implications.

18 Q. Is it?

19 A. Without question.

20 Q. Did I ask the word "promoting"?

21 A. You didn't, but you're using the word
22 "selling."

23 THE COURT: I think you can make that
24 argument to the jury.

25 With that let's adjourn for lunch. Be

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back at 2:00.

(Luncheon recess)

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