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J. EVERSON

EXHIBIT A

May 18, 2012

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

IN RE: RISPERDAL LITIGATION : MARCH TERM, 2010
: NO. 296

Friday, May 18, 2012

Videotape Deposition of ALEX GORSKY, held at the law offices of DRINKER, BIDDLE & REATH, LLP, 105 College Road East, Princeton, New Jersey, beginning at approximately 10:00 a.m., on the above date, before LANCE A. BRUSILOW, Registered Professional Reporter, Certified Shorthand Reporter of the State of New Jersey, License No. 30XI00173800, and Notary Public, there being present.

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1 THE VIDEOGRAPHER: Good morning. We are
2 going on the record at 9:53 a.m. on Friday, May
3 18th, 2012. This begins volume one, tape one in
4 the videotape deposition of Alex Gorsky, taken by
5 the plaintiff In Re Risperdal litigation.

6 This case is filed in the Philadelphia
7 County Court of Common Pleas. This deposition is
8 taking place at the law office of Drinker, Biddle
9 & Reath at 105 College Road East in Princeton, New
10 Jersey.

11 My name is Jaime Scilla, videographer
12 representing brusilow+associates. The court
13 reporter is Lance Brusilow, also of
14 brusilow+associates.

15 Counsel, please identify yourselves and
16 state whom you represent, and will the court
17 reporter please swear in the witness.

18 MR. McCORMICK: Good morning. Brian
19 McCormick, from the Sheller firm, for the
20 plaintiffs.

21 MR. GOMEZ: Christopher Gomez, from the
22 Sheller firm, for the plaintiffs.

23 MR. SHELLER: Stephen Sheller, from the
24 Sheller firm, for the plaintiffs.

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1 MR. HARMAN: Matt Harman, plaintiffs.
 2 MR. MERVIS: Michael Mervis, Proskauer
 3 Rose, for Elsevier, Inc. and Excerpta Medica, Inc.
 4 MR. CAMPION: Tom Campion,
 5 Drinker-Biddle, for the defense.
 6 MS. WARREN: Lisbeth Warren, from
 7 Johnson & Johnson, for the Johnson & Johnson
 8 defendants.
 9 MR. POWERS: John Powers, Drinker,
 10 Biddle & Reath, for defendants.
 11 MR. MURPHY: Ken Murphy,
 12 Drinker-Biddle, for the defendants and the
 13 witness.
 14 ALEX GORSKY, having been first duly
 15 sworn, was examined and testified as follows:
 16 (EXAMINATION)

BY MR. McCORMICK:

18 Q. Good morning, Mr. Gorsky.
 19 A. Good morning.
 20 Q. I introduced myself earlier. My name is Brian
 21 McCormick. I represent a number of young men and boys
 22 who have been injured by the drug Risperdal and have
 23 brought lawsuits in the Philadelphia Court of Common
 24 Pleas.

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1 You're here for a deposition in this matter.
 2 Do you understand that?
 3 A. Yes, I do.
 4 Q. Mr. Gorsky, what is your current position with
 5 Johnson & Johnson?
 6 A. My current position is, I'm the chief
 7 executive officer of Johnson & Johnson.
 8 Q. And how long have you had that position?
 9 A. Since April 27th of this year.
 10 Q. Mr. Gorsky, have you had your deposition taken
 11 in a Risperdal-related matter in the past?
 12 A. Yes, I have.
 13 Q. Was that in the Texas Attorney General's case
 14 that was brought several years ago and then settled a
 15 couple months ago?
 16 A. Yes, it was.
 17 Q. And since that time have you had your
 18 deposition taken in any other matter?
 19 A. Yes, I believe I've had one deposition since
 20 that time.
 21 Q. What was that related to?
 22 A. I believe it was in regard to an average
 23 wholesale price issue with several different companies.
 24 Q. Okay. In preparation for your deposition

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1 today, Mr. Gorsky, did you review your deposition from
 2 2009 in the Texas case?
 3 A. I received -- I reviewed portion of it, yes.
 4 Q. Was there anything in that deposition that you
 5 would change now that you reread it again?
 6 A. Not in the portions that I re-read, no.
 7 Q. Mr. Gorsky, at one time were you the president
 8 of Janssen US?
 9 A. Yes, I was.
 10 Q. What was that time frame?
 11 A. I left that position -- I'm sorry, I'm just
 12 chronologically going backwards. I believe I left that
 13 position in approximately February of 2003, and I
 14 believe I assumed that position late in 2001.
 15 Q. Before that, were you the vice-president for
 16 sales and marketing for Janssen?
 17 A. Yes, I was.
 18 Q. And one of your responsibilities was for the
 19 CNS Division, correct?
 20 A. Yes, it was.
 21 Q. And part of that responsibility was the drug
 22 Risperdal. Is that right?
 23 A. Yes, it was.
 24 Q. And before that you were the vice-president of

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1 marketing for Janssen. Is that right?
 2 A. That's correct.
 3 Q. And in your responsibilities there you also
 4 had responsibilities for Janssen, right?
 5 MR. MURPHY: Objection to the form.
 6 MR. McCORMICK: I'll just rephrase it.
 7 BY MR. McCORMICK:
 8 Q. Mr. Gorsky, as the vice-president of marketing
 9 for Janssen, did you have responsibilities having to do
 10 with Risperdal?
 11 A. Those were part of my responsibilities, yes.
 12 Q. And before that you were the vice-president of
 13 the CNS Division for Risperdal. Is that correct?
 14 A. That's correct.
 15 Q. And during that time frame you also had
 16 responsibility for Risperdal. Is that right?
 17 A. Yes. Risperdal was part of my responsibility.
 18 Q. And as part of your responsibility did you
 19 expand Risperdal sales from \$500 million to \$800
 20 million in the United States?
 21 MR. MURPHY: Objection to the form. You
 22 may answer.
 23 THE WITNESS: The sales of Risperdal
 24 expanded during that time frame from \$500 million

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| <p style="text-align: right;">Page 9</p> <p>1 to \$800 million. 2 MR. McCORMICK: Okay. 3 BY MR. McCORMICK: 4 Q. And before you were the vice-president for the 5 CNS Division, were you a group director in the 6 psychiatry, neurology, allergy, analgesia and oncology 7 franchises? 8 A. Yes, I was. 9 Q. And when you were in that position did you 10 have any responsibility for Risperdal? 11 A. Risperdal was one of multiple responsibilities 12 I had at the time. 13 Q. So, Mr. Gorsky, from March of 1995, when you 14 became the group director in those franchises, until 15 you left Janssen in February of 2003, did you have 16 responsibilities related to Risperdal during that time 17 frame? 18 A. Yes, I did. Risperdal was one of the many 19 responsibilities I had during that time frame. 20 Q. And during that time frame was Risperdal 21 Janssen's largest product, sales product? 22 MR. MURPHY: Objection to form. You 23 may answer. 24 THE WITNESS: I don't recall</p> | <p style="text-align: right;">Page 11</p> <p>1 mothers, fathers, and all others who use Johnson & 2 Johnson's products? 3 A. Yes. As outlined in the first sentence, we 4 believe our first responsibility is to doctors, nurses, 5 patients, to mothers and fathers, and all others who 6 use our products and services. 7 Q. And as part of the credo, Mr. Gorsky, do you 8 believe that Johnson & Johnson's management must be 9 competent? 10 A. Yes, I do believe Johnson & Johnson's 11 management should be competent. 12 Q. And Johnson & Johnson's management's actions 13 must be just and ethical. Is that right? 14 MR. MURPHY: Does he believe that? 15 Q. Do you believe that, Mr. Gorsky? 16 A. Yes, I do believe that. 17 Q. Let me ask it a cleaner way: Mr. Gorsky, do 18 you believe that the actions of Johnson & Johnson's 19 management must be just and ethical? 20 A. Yes, I do believe that. 21 Q. Mr. Gorsky, did you believe that the Johnson & 22 Johnson Credo applied to Janssen Pharmaceutica during 23 the time frame of March of 1995 through February of 24 2003 when you worked at Johnson & Johnson -- at</p> |
| <p style="text-align: right;">Page 10</p> <p>1 explicitly, but not during that entire period of 2 time. I think at some point it was, but not 3 during that entire period. 4 (Exhibit Gorsky-01 was marked for 5 identification) 6 BY MR. McCORMICK: 7 Q. Mr. Gorsky, I'm going to mark as Exhibit 1 a 8 copy of -- 9 MR. McCORMICK: Ken, can you pass a copy 10 down to Mr. Mervis, please? 11 MR. MURPHY: Sure. 12 BY MR. McCORMICK: 13 Q. (Continuing) -- Mr. Gorsky, I've marked as 14 Exhibit 1 a copy of the Johnson & Johnson Credo. Do 15 you see that? 16 A. Yes, I do. 17 Q. And are you familiar with the Johnson & 18 Johnson Credo? 19 A. Yes, I am. 20 Q. And would you say that it's the overarching 21 philosophy that guides your business? 22 A. Yes, I would. 23 Q. And do you believe that your first 24 responsibility is to doctors, nurses, patients,</p> | <p style="text-align: right;">Page 12</p> <p>1 Janssen? 2 A. Yes, I did. 3 Q. And do all the Janssen employees realize that 4 the Johnson & Johnson Credo applies to them when 5 they're employed at Janssen? 6 MR. MURPHY: Objection, lack of 7 foundation. You may answer. 8 MR. McCORMICK: Let me ask it a 9 different way. 10 BY MR. McCORMICK: 11 Q. Mr. Gorsky, is the credo for Johnson & Johnson 12 distributed to the Janssen employees? 13 A. Yes, we distribute the credo to the Janssen -- 14 to the Johnson & Johnson employees and the Janssen 15 employees. 16 Q. Okay. And to the best of your knowledge, did 17 Janssen employees understand, as you do, that the credo 18 applies to the way they should conduct business? 19 A. To the best of my knowledge. And we give our 20 best efforts for all our employees to be knowledgeable 21 of the credo -- we hold several different sessions 22 through the year; we call them credo sessions -- where 23 we'll take an opportunity to review the credo, have 24 open discussions with our employees. They also take</p> |

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| <p style="text-align: right;">Page 13</p> <p>1 credo surveys, at least bi-annually, sometimes 2 annually. So, I think our best efforts are made. 3 And while I can never absolutely guarantee 4 that all of our employees fully understand each and 5 every aspect, it's a very important document as well as 6 philosophy that we try our best to follow. 7 Q. Okay. And when you say "we try our best to 8 follow," I just want to make sure that that goes down 9 not just to the Johnson & Johnson employees, but 10 Janssen employees. Is that correct? 11 A. Yes, that was the case when I was responsible 12 for Janssen. 13 Q. Okay. 14 (Exhibit Gorsky-02 was marked for 15 identification) 16 BY MR. McCORMICK: 17 Q. Mr. Gorsky, I've marked as Exhibit 2 a copy of 18 a memorandum in Support of United States' Motion to 19 Compel Johnson & Johnson Depositions in a civil action 20 currently pending in the United States District Court 21 for the District of Massachusetts. 22 Have you had a chance to review Exhibit 2? 23 A. No. I can take some time to do it. . . 24 Q. Please take the time and let me know when</p> | <p style="text-align: right;">Page 15</p> <p>1 think you met with Mr. Murphy, Mr. Powers and/or Ms. 2 Warren? 3 A. Ten hours, plus or minus. 4 Q. Mr. Gorsky, in relation to Exhibit 2, did you 5 know that the US government had filed a motion to 6 compel your deposition in this federal whistleblower 7 case in the United States District Court for the 8 District of Massachusetts? 9 A. Yes, I was. 10 Q. And did you know that your lawyers have 11 refused to allow you to appear for a deposition in that 12 case? 13 A. Yes, I'm aware that they did not feel it was 14 necessary. 15 Q. And do you agree with that decision? 16 MR. MURPHY: Objection, wholly 17 irrelevant. What's the basis for that, Brian? 18 MR. McCORMICK: He can answer. 19 MR. MURPHY: No. What is the basis for 20 that? Because it has nothing to do with this 21 litigation. 22 MR. McCORMICK: It certainly does. It's 23 Omnicare to Risperdal-related cases. There's 24 Risperdal kickbacks and the entire case is</p> |
| <p style="text-align: right;">Page 14</p> <p>1 you're finished. 2 A. Would you like me to read the entire document? 3 Q. You can glance at it and then I can direct you 4 to certain areas, or you can read -- I'm going to ask 5 you questions about pages six through eight, if you 6 would like to read those pages. 7 A. Okay. 8 Q. Mr. Gorsky, before we look at this document, 9 did you meet with your counsel before the deposition to 10 prepare? 11 A. Yes, I did. 12 Q. And who did you meet with? 13 A. I met with the gentlemen and the woman seat 14 here to my right. 15 Q. Mr. Powers or Mr. Murphy? 16 A. Both. 17 Q. And Ms. Warren? 18 A. Yes. 19 Q. And how many times did you meet with them? 20 A. I think we met on three separate occasions. 21 Q. And did you review documents during those 22 sessions? 23 A. Yes, I did review some documents. 24 Q. In total, Mr. Gorsky, how many hours do you</p> | <p style="text-align: right;">Page 16</p> <p>1 relevant. 2 MR. MURPHY: Omnicare? 3 MR. McCORMICK: Yes. 4 MR. MURPHY: Relative to this case? 5 MR. McCORMICK: Yes. 6 MR. MURPHY: How is it -- can we go off 7 the record? 8 THE VIDEOGRAPHER: Going off the record 9 at 10:09 a.m. 10 (There was a discussion held off the 11 record) 12 THE VIDEOGRAPHER: Stand by, please. 13 Back on the record at 10:15 a.m. 14 BY MR. McCORMICK: 15 Q. Mr. Gorsky, can you turn to page six of 16 Exhibit 2? 17 A. Yes, I'm at page six. 18 Q. Okay. Do you see the heading at the bottom in 19 bold with the letter B next to it? 20 A. Yes, I do. 21 Q. And it says "The United States' Request to 22 Depose Alex Gorsky"?</p> <p>23 A. Yes, I do. 24 Q. And can you turn to the next page, please,</p> |

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1 page seven? Look at the first full paragraph that
 2 starts with the words "From October 1998." Do you see
 3 that?

4 A. Yes, I do.

5 Q. "From October 1998 to October 2001, Mr. Gorsky
 6 was Janssen's Vice-President of Marketing, and from
 7 October 2001 to early 2003 he was President of
 8 Janssen."

9 Did you agree with the government's allegation
 10 there?

11 A. Yes, I do.

12 Q. And then on the same page, Mr. Gorsky, do you
 13 agree --

14 A. Excuse me, just one slight correction.

15 Q. Sure.

16 A. It says "Mr. Gorsky was Janssen's
 17 Vice-President of Marketing." I was actually
 18 vice-president of marketing. But then for some interim
 19 period, I believe as you reviewed during the earlier
 20 resume, a description, I was actually vice-president of
 21 sales and marketing for Janssen before being president.

22 Q. Thank you for that clarification. Mr. Gorsky,
 23 the government next says that "During all of that time
 24 he was," meaning you, Mr. Gorsky, "responsible for

1 BY MR. McCORMICK:

2 Q. Do you recall dealing with Omnicare during
 3 this time frame, October of 1998 through early 2003?

4 A. I remember conversations around Omnicare and
 5 at least one meeting.

6 Q. Do you recall them as being a customer who
 7 purchased Risperdal?

8 A. It's difficult for me to say if they actually
 9 purchased Risperdal, again because of the reimbursement
 10 structure. The reason I'm saying that is because a
 11 wholesaler may actually pay us for the medication and
 12 then Omnicare may then actually purchase the drug from
 13 a wholesaler.

14 I don't remember the exact network through
 15 which they purchased it other than they were obviously
 16 involved.

17 Q. Okay. Mr. Gorsky, if we look at the next
 18 sentence in the motion, it says, "According to Mr.
 19 Gorsky's resume, he instituted Janssen's Health Care
 20 Compliance Program for regulatory and legal issues."

21 Do you see that?

22 A. Yes, I do.

23 Q. Do you agree with that?

24 A. Yes, I do. Throughout the period we had

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1 selling Risperdal, a drug whose biggest customer was
 2 Omnicare."

3 Do you agree with that statement, Mr. Gorsky?

4 A. I can't recollect that those facts are, in
 5 fact, completely true. I was responsible for aspects
 6 of Risperdal, not directly for the selling during
 7 different periods. And also, I don't remember if in
 8 fact Omnicare was the largest customer for Risperdal
 9 during that period.

10 Q. During that time frame did you track who or
 11 what were Janssen's customers who bought Risperdal?

12 MR. MURPHY: He personally?

13 MR. McCORMICK: Did Janssen track what
 14 customers were buying Risperdal.

15 THE WITNESS: I know we tracked who
 16 purchased Risperdal, but it's a very complicated
 17 system by which drugs are distributed. So, it's
 18 just a very complex system because you have
 19 multiple layers involved, wholesalers all the way
 20 down to the pharmacy and beyond that.

21 So, we received reports, but it wasn't
 22 necessarily indicative of who actually used the
 23 product.

1 guidelines in place for what we called healthcare
 2 compliance for sales and marketing of the products, but
 3 I know that in 2001 or early -- somewhere in that
 4 period -- I don't remember the exact dates because it
 5 was quite some time ago -- we did a very broad
 6 initiative around updating, ensuring that we were
 7 consistent with all the trade organization guidelines
 8 at the time, the latest legal and regulatory
 9 guidelines, which we took the entire company through an
 10 extensive training program.

11 Q. And you did that with Dave Mallegol? Is that
 12 right? Is that the right pronunciation of his name?

13 A. Dave Mallegol was one of the many people
 14 involved in that at the time. He was responsible -- I
 15 forget the exact position that he had, but it involved
 16 textbook training; it involved discussions, lectures,
 17 and actually written tests and validations afterwards.

18 Q. And was that something that Janssen didn't
 19 have before this time frame in 2001?

20 A. No, we had programs from the time that I
 21 started with Janssen back in 1988 that were revised
 22 through the process, but in that same time frame there
 23 were some pretty significant industry-wide initiatives
 24 that were launched.

5 (Pages 17 to 20)

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1 And really, as part of an effort to help set
 2 the standard for the industry, we put together a very
 3 comprehensive program, and Dave Mallegol was involved
 4 in that.

5 Q. Mr. Gorsky, turning back to Exhibit 2, do you
 6 see that two sentences down there is a sentence that
 7 says "He," meaning you, "met repeatedly with senior
 8 Omnicare executives" to discuss efforts to promote
 9 Risperdal?

10 Do you see that?

11 A. Where...

12 Q. Well, I tried to cut it short. Let's start
 13 again.

14 Mr. Gorsky, do you see there is a sentence
 15 after the sentence we just looked at that says Mr.
 16 Gorsky "regularly received Monthly Reports on J&J's
 17 Long Term Care Group, including reports which commented
 18 on Omnicare's efforts to promote prescribing of
 19 Risperdal and other J&J products?"

20 Do you see this?

21 A. Yes I do see that.

22 Q. Do you agree with that sentence?

23 A. I received monthly reports from all of our
 24 different groups. I don't recall the specific reports,

1 previously worked closely with J&J's Medical
 2 Development group (which was responsible for developing
 3 clinical trial data for Risperdal), he was," meaning
 4 you, "in a position to know why J&J chose not to inform
 5 Omnicare (or members of Janssen's own sales staff) that
 6 in January 1999, the Food and Drug Administration had
 7 warned J&J that marketing Risperdal as safe and
 8 effective in the elderly would be false and misleading
 9 because the drug had not been adequately studied in
 10 that population."

11 Did I read that correctly, Mr. Gorsky?

12 A. Yes, you did.

13 Q. And do you agree with that statement, Mr.
 14 Gorsky?

15 A. No, I would not.

16 Q. What's wrong with that statement, Mr. Gorsky?

17 A. I think throughout that time we felt that we
 18 were promoting Risperdal in an appropriate manner based
 19 upon its labeling at that time.

20 Q. And why did Johnson & Johnson choose not to
 21 inform its own sales staff about this 1999 FDA warning?

22 MR. MURPHY: Objection to the form of
 23 the question, lack of foundation. You may answer.

24 THE WITNESS: I don't recall the

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Page 24

1 but I'm sure that I received monthly reports regarding
 2 all of our different products.

3 Q. Okay. And in those monthly reports do you
 4 think there was a report talking about Omnicare and its
 5 efforts to promote the prescription of Risperdal?

6 A. I don't recall.

7 Q. Okay. And then do you see, Mr. Gorsky, the
 8 government's next allegation, where the federal
 9 government says that you met repeatedly with senior
 10 Omnicare executives to discuss those efforts?

11 Do you agree with that statement?

12 MR. MURPHY: Objection to the form. You
 13 may answer.

14 THE WITNESS: I don't recall the number
 15 of times that I met with the Omnicare officials
 16 during that time frame.

17 BY MR. McCORMICK:

18 Q. Do you think it was more than once?

19 A. I believe it was, but it's been some time ago,
 20 so I don't remember.

21 Q. Mr. Gorsky, let's skip a sentence and go down
 22 to the last sentence of this page that continues on to
 23 the next page and says the federal government alleges
 24 that "As Vice President of Marketing, and having

1 details of that letter.

2 BY MR. McCORMICK:

3 Q. Mr. Gorsky, did you know that J&J chose not to
 4 inform Omnicare of the same details of the January 1999
 5 FDA letter?

6 MR. MURPHY: Same objection. You may
 7 answer.

8 THE WITNESS: No, I was not aware.

9 BY MR. McCORMICK:

10 Q. Mr. Gorsky, let's look at the top of page
 11 eight. The second paragraph there reads the federal
 12 government says that you were "also involved in
 13 approving payments to Omnicare under the 2000
 14 Consulting and Services Agreement."

15 Do you see that?

16 A. Yes, I do.

17 Q. And is that true, that you would have been
 18 involved in approving payments to Omnicare?

19 A. I don't recall specifically approving
 20 payments, but in my role I likely would have been
 21 involved.

22 Q. And in this case isn't it the government's
 23 allegations that these payments to Omnicare were
 24 actually kickbacks?

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| <p>1 MR. MURPHY: Objection to the form of 2 the question, lack of foundation. You may answer. 3 4 THE WITNESS: I'm not familiar with all 5 of the details that are made in the court 6 document, but I do know that during that time 7 frame our contractual obligations to Omnicare were 8 reviewed by our legal counsel and were also quite 9 similar to contracts that we have with the 10 government in other areas regarding rebates, and 11 we felt that they were consistent and compliant 12 with all the appropriate guidelines and 13 regulations at that time. 14 BY MR. McCORMICK: 15 Q. Has anyone told you, other than your legal 16 counsel, that the government's allegations here are 17 that those payments that you made under the 2000 18 consulting agreement to Omnicare were kickbacks? 19 A. No, not that I'm aware of. 20 Q. Mr. Gorsky, did you know that Omnicare settled 21 its portion of this case years ago for approximately 22 \$100 million? 23 MR. MURPHY: Objection to the form of 24 the question. You may answer. THE WITNESS: I believe I did read</p> | <p>1 MR. MURPHY: Does he see the words? 2 BY MR. McCORMICK: 3 Q. Do you see where it says "OmniCare engaged in 4 'active intervention programs' to promote utilization 5 of Risperdal and other J&J drugs in order to qualify 6 for rebates and other payments from J&J"? 7 Do you see that, Mr. Gorsky? 8 A. Yes, I do. 9 Q. What is an active intervention program? 10 A. I'm not certain what exactly they're referring 11 to. 12 Q. Do you recall ever approving payments for 13 active intervention programs having to do with 14 OmniCare? 15 A. No, I do not. 16 MR. MURPHY: Are you done with the 17 document? 18 MR. McCORMICK: We are. 19 MR. MURPHY: For the record, I object 20 to the entire line of questioning regarding 21 Exhibit 2. 22 BY MR. McCORMICK: 23 Q. Mr. Gorsky, the OmniCare lawsuit in 24 Massachusetts involves allegations that Johnson &</p> |
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| <p>1 somewhere that Omnicare had come to a settlement 2 with the government. 3 BY MR. McCORMICK: 4 Q. Mr. Gorsky, getting back to the question I 5 just asked -- and you can just answer it yes or no -- 6 did the US government allege that you approved payments 7 that were kickbacks to Omnicare? 8 A. I have not read the entire document, so I'm 9 uncertain. 10 Q. During the next break -- why don't we take a 11 minute? -- we'll read through it and then see if you 12 can answer that question. 13 Let's turn to page twelve of the document, 14 please. Do you see the heading on this page that says 15 "Mr. Gorsky Should Possess Knowledge Of Relevant 16 Facts"? 17 A. Yes, I do. 18 Q. Let's turn to the top of page thirteen, 19 please. Do you see in the top paragraph, Mr. Gorsky, 20 the government talks about active intervention 21 programs? 22 MR. MURPHY: Where is that, counselor? 23 MR. McCORMICK: The top of page 24 thirteen.</p> | <p>1 Johnson illegally promoted and marketed the drug 2 Risperdal to Omnicare chain of nursing homes. Is that 3 correct? 4 A. Again, I'm not familiar with the entire 5 extent. I believe that's one of the issues that's 6 discussed. 7 Q. And another part of the case is that Johnson & 8 Johnson paid kickbacks to Omnicare to have its 9 physicians prescribe Risperdal in greater amounts than 10 they normally would. Is that correct? Do you 11 understand that to be part of the -- 12 A. I believe, from reviewing the document here 13 and some previous discussions, that's also part or one 14 of the allegations. 15 (Exhibit Gorsky-03 was marked for 16 identification) 17 BY MR. McCORMICK: 18 Q. Mr. Gorsky, I've handed you what I've marked 19 as Exhibit 3, which is a three-page document, an email 20 and an attachment. Will you take a minute to review 21 that document and let me know when you're finished? 22 A. Okay. 23 Q. Mr. Gorsky, have you had a chance to review 24 Exhibit 3?</p> |

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| <p style="text-align: right;">Page 29</p> <p>1 A. Yes, I have. 2 Q. And do you see that the cover email is to the 3 sales communications department on June 27th of 2001? 4 A. Yes, I do. 5 Q. And attached to it is a memo from you dated 6 June 20th of 2001, correct? 7 A. That's correct. 8 Q. And the subject line is "Policy on Promotion 9 of Products and Health Care Compliance," right? 10 A. That's correct. 11 Q. And at the bottom of the first paragraph there 12 is a sentence that reads, "Inappropriate promotion of 13 our products through homemade information or off-label 14 claims is not only illegal, but compromises the 15 reputation of Janssen, and of Johnson & Johnson, in 16 providing quality health care products and information 17 to providers and patients." Is that correct? 18 A. Yes, that is. 19 Q. And is this the policy that you discussed with 20 me earlier that was put in place in 2001 with Dave 21 Mallegol? 22 A. This is part of the policy that we put into 23 place. As I mentioned earlier, the entire policy 24 itself was very comprehensive in nature.</p> | <p style="text-align: right;">Page 31</p> <p>1 approved." Is that correct? It's the third bullet 2 point? 3 A. That's correct. 4 Q. And one of the other bullet points is 5 "Promoting products outside the Healthcare Compliance 6 Guidelines." That's a Class 1 violation, right? 7 A. That's correct. 8 Q. And then below that it says "Class 1 offense 9 might be sufficiently serious to warrant immediate 10 suspension without pay." Is that correct? 11 A. That's correct. 12 Q. And you signed off on this policy on promotion 13 of products and healthcare compliance in June of 2001, 14 correct? 15 A. Yes, I did. 16 Q. You can put that document aside, Mr. Gorsky. 17 (Exhibit Gorsky-04 was marked for 18 identification) 19 BY MR. McCORMICK: 20 Q. Mr. Gorsky, I've handed you what's been marked 21 as Exhibit 4, which is a two-page document. Can you 22 take a minute to review that and let me know when 23 you're finished? 24 A. Okay.</p> |
| <p style="text-align: right;">Page 30</p> <p>1 It included the policy itself, but also 2 training programs, testing/verification programs, as 3 well as ongoing surveillance and disciplinary programs 4 when there were things that were found that were 5 inconsistent with the policy. 6 So, this was one component of something that 7 was actually much more comprehensive. 8 Q. And this one went out to the sales force 9 because it talks about off-label marketing, right? 10 MR. MURPHY: Objection to the form. You 11 may answer. 12 THE WITNESS: I think what this talks 13 about is this off-label promotion, and it did go 14 out to -- it went to both the internal marketing 15 and sales departments, which were very different 16 departments. 17 MR. McCORMICK: Okay. 18 BY MR. McCORMICK: 19 Q. Turn to page two. It talks about various 20 violations and offenses. Is that right? 21 A. That is addressed in the second paragraph, 22 yes. 23 Q. And one of the Class 1 violations is 24 "Promoting products or indications that are not</p> | <p style="text-align: right;">Page 32</p> <p>1 Q. Mr. Gorsky, have you had a chance to review 2 Exhibit 4? 3 A. Yes, I have. 4 Q. And is that your initials up in the next -- 5 next to your name in the front line of the memo? 6 A. Yes, they are. 7 Q. This memo was sent out on February 8th, 2002? 8 A. Yes, that's the date of the memo. 9 Q. And it went out to a number of different 10 divisions or groups within Janssen, including the field 11 sales force and internal marketing and sales. Is that 12 right? 13 A. That's correct. 14 Q. And the subject line, similar to what we 15 looked at in Exhibit 3, is "Policy on Promotion of 16 Products and Health Care Compliance." Is that right? 17 A. That's correct. 18 Q. Right below there, the first paragraph of this 19 memo that you wrote, you refer to Janssen as a member 20 of the Johnson & Johnson Family of Companies. Is that 21 correct? 22 A. That's correct. 23 Q. Then if we go down to the third paragraph on 24 this page, you talk about the -- strike that.</p> |

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| <p>1 If we can down to the third paragraph of this 2 page, Mr. Gorsky, it says this policy -- or "It is a 3 policy that is built upon not only statutes and 4 guidelines, but our core value system, the Johnson & 5 Johnson Credo." Is that correct? 6 A. Yes. 7 Q. And that's the credo we talked about earlier? 8 A. Yes, it is. 9 Q. And this is an example of the questions I was 10 asking you earlier, where you believe that the Johnson 11 & Johnson Credo applied to the Janssen employees. Is 12 that right? 13 A. Yes. 14 Q. We skip a sentence there. There is another 15 sentence, that "Promotion within the approved labeling 16 has long been an integral part of that policy." Is 17 that right? Is that correct? 18 A. That's right. 19 MR. MURPHY: Is that what it says? 20 Q. Is that what it says, Mr. Gorsky? 21 A. Yes, that's what it says. 22 Q. At that time, in February of 2002, you were 23 telling the sales and marketing department that 24 off-label marketing was improper. Is that correct?</p> | <p>1 BY MR. McCORMICK: 2 Q. Mr. Gorsky, I've marked as Exhibit 5 a large 3 document that was previously marked during the 4 deposition of David Mallegol in the Texas litigation. 5 I'm not going to ask you to review every page, 6 but if you could glance through the document and let me 7 know when you're finished. 8 A. Okay. 9 Q. Mr. Gorsky, I know you haven't had a chance to 10 review every word of this document, but have you had a 11 chance to glance through Exhibit 5? 12 A. Yes, I have, just very topline. 13 Q. Exactly. Mr. Gorsky, are you familiar with 14 this document? 15 A. I don't remember it explicitly, but it looks 16 as though it was the full set of guidelines that were 17 prepared as part of our healthcare compliance policy. 18 And again, I don't know if this was something 19 that was considered a manual or used for one particular 20 event. I don't understand the entire context. 21 But it looks like it's a comprehensive 22 collection of our policies, examples of approved 23 processes, required paperwork and other examples, along 24 with Q&As, from my very brief preview.</p> |
| <p style="text-align: center;">Page 34</p> <p>1 A. We're stating just as it is here, "Promotion 2 within the approved labeling has long been an integral 3 part of that policy," and I think it's further outlined 4 on the next page exactly what that means. 5 Q. And on the next page is that paragraph at the 6 bottom of the page, "Our policy on out-of-label 7 promotion or violations." Is that correct? Is that 8 what you're talking about? 9 A. Well, what I was talking about is, actually 10 almost the entire content on this page further 11 clarified the comment that I referred to on the 12 previous page. 13 Q. Meaning that promoting a product for an 14 indication that's not approved would be a Class 1 15 violation, as we talked about in Exhibit 3, right? 16 A. Yes. And it goes into further detail about 17 copying or altering company-approved materials; or 18 promoting products for indications that are not 19 approved; or promoting products outside the healthcare 20 compliance guidelines. 21 Q. You can put that document aside, Mr. Gorsky. 22 A. Okay. 23 (Exhibit Gorsky-05 was marked for 24 identification)</p> | <p style="text-align: center;">Page 36</p> <p>1 Q. Mr. Gorsky, I want to ask you about some 2 examples that are provided in here. Can you turn to 3 the Bates label, the number in the bottom right-hand 4 corner that starts with JJPRD -- the last three digits 5 would be 971? So, it would be 8971. 6 A. Yes. Okay. 7 Q. Mr. Gorsky, I'm actually going to -- I 8 apologize. Can you turn to page 959? It's about ten 9 pages before this. 10 A. Okay. 11 Q. And the title of this section is "Guidance 12 Documents: Support of Continuing Medical Education 13 Activities." Is that correct? 14 A. That's correct. 15 Q. And then if we -- the fifth paragraph talks 16 about the FDA and its regulation of advertising and 17 promotion of drugs and biologics. Is that correct? 18 A. That's the first sentence. 19 Q. And part of that control would be over CMEs, 20 or continuing medical education, activities or 21 programs. Is that right? 22 MR. MURPHY: Objection to the form of 23 the question, lack of foundation, but you may 24 answer.</p> |

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1 THE WITNESS: I'm not sure I understand
 2 your question.
 3 BY MR. McCORMICK:
 4 Q. Okay. Did the FDA regulate what promotional
 5 activities could take place with or related to a CME?
 6 A. Well, as I remember, there were not
 7 promotional activities associated with certified
 8 medical education programs and --
 9 Q. Go ahead, I'm sorry.
 10 A. -- and I do not believe, although I can't be
 11 certain on this, that they were directly regulated by
 12 the FDA. I'm sure the FDA was involved, but I don't
 13 know how explicit that was.
 14 Q. Turn back to page 971, please.
 15 A. So, the numbers on the bottom, 97 --
 16 Q. The bottom right-hand corner.
 17 A. I'm sorry, it's a lot of documents. Okay.
 18 Q. Do you see at the top of this page it says
 19 questions and answers, right?
 20 A. Yes.
 21 Q. And these look like -- well, tell me what this
 22 page is.
 23 A. May I take a moment to review the previous
 24 page just so I understand the context?

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1 Q. Sure.
 2 A. It appears as though this section were the
 3 policies and guidelines that went through the policies,
 4 the procedures and considerations that would be
 5 assessed around CME programs, and this was a further
 6 initiative to help create deeper understanding of those
 7 by having a Q&A.
 8 Q. And look at question four, Mr. Gorsky. The
 9 question reads, "Is it okay for a speaker to discuss
 10 off label uses of product at CME activities?"
 11 Do you see that?
 12 A. Yes.
 13 Q. The answer is, "Yes, provided the CME activity
 14 is conducted in accordance with FDA guidelines, the CME
 15 activity would not be bound by promotional regulations.
 16 This type of independent activity is different from a
 17 promotional speaker program where speakers are
 18 contractually bound NOT to discuss off-label uses."
 19 Do you see that?
 20 A. Yes, I do.
 21 Q. And is that the way you understand the use of
 22 off-label promotion at a CME activity?
 23 MR. MURPHY: Objection to the form of
 24 the question. You may answer if you understand

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1 it.
 2 THE WITNESS: Your statement was not
 3 consistent with my understanding. What I said
 4 earlier is that promotional activities and CME
 5 programs were different types of programs.
 6 As outlined in this paragraph, this
 7 talks about -- as I mentioned earlier, I know that
 8 the FDA had some involvement in the CME
 9 guidelines, but that was considered separate and
 10 distinct from promotion versus other directly
 11 promotional programs.
 12 MR. McCORMICK: Okay.
 13 BY MR. McCORMICK:
 14 Q. Do you agree with the answer -- strike that.
 15 Do you agree that the answer provided to question four
 16 here is correct?
 17 A. I think in general terms, as I sit here today,
 18 it would be consistent. It's been some years since I
 19 reviewed all the specific outlines of the CME programs,
 20 but I would also assume that this document was
 21 rigorously reviewed by our regulatory and our legal
 22 team prior to its publication, who had extensive
 23 experience in that area.
 24 So I would assume, since they were the experts

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1 in that area, that it would be correct.
 2 Q. That would have been my next question: Based
 3 on the amount of review and analysis that would have
 4 gone into preparing a healthcare compliance manual, you
 5 would assume that this answer is correct. Is that
 6 right?
 7 A. Yes. I mean, I relied on my regulatory and
 8 legal experts, who, to the best of my knowledge, were
 9 well regarded and frequently sought in the industry, to
 10 help develop and refine these policies and procedures.
 11 Q. Let's look at question seven: "Are Janssen
 12 employees permitted to review the CME program materials
 13 prior to the conduct of the first presentation
 14 session?"
 15 Do you see that?
 16 A. Yes, I do.
 17 Q. And the answer that is provided by your
 18 regulatory and legal and healthcare compliance --
 19 strike that.
 20 The answer that is provided by Janssen's
 21 regulatory, legal and healthcare compliance employees
 22 is, "No. Company employees should not be involved in
 23 reviewing or otherwise influencing the content of CME
 24 programs. After the commencement of the CME activity,

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| <p>1 all materials are reviewed pursuant to the SOP for 2 Medical Review."</p> <p>3 Did I read that correctly?</p> <p>4 A. Yes, you did.</p> <p>5 Q. And my same question: Based on the fact that 6 this was probably, as I think you said, rigorously 7 reviewed and analyzed by your healthcare compliance, 8 regulatory and legal and whoever else, would you agree 9 that that answer is probably correct at the time it was 10 written?</p> <p>11 A. Yes, I would.</p> <p>12 Q. Okay.</p> <p>13 THE VIDEOGRAPHER: Excuse me, counsel, 14 five minutes.</p> <p>15 MR. McCORMICK: Thanks, Jaime.</p> <p>16 BY MR. McCORMICK:</p> <p>17 Q. Mr. Gorsky, can you turn to the next page?</p> <p>18 A. 972?</p> <p>19 Q. 972, yes.</p> <p>20 A. Yes.</p> <p>21 Q. Mr. Gorsky, at the top of page 972 there is a 22 question eight: "A CME Provider has requested support 23 for a CME activity in an area of interest to Janssen. 24 This CME Provider also has a division that is working</p> | <p>1 A. Yes, I do.</p> <p>2 Q. Mr. Gorsky, can you turn to page 9009, please?</p> <p>3 A. Yes.</p> <p>4 Q. Mr. Gorsky, do you see that the heading of 5 this section is "Guidance Document: Entertainment, 6 Gifts and Promotion"?</p> <p>7 A. Yes, it is.</p> <p>8 MR. McCORMICK: Hang on for one second.</p> <p>9 Why don't we go off the record here, take a break?</p> <p>10 And then we'll come back. I don't want to get 11 started in the middle of something.</p> <p>12 We'll take a break, Mr. Gorsky, and let 13 Jaime change the tape, get a walk around and then 14 we'll come back to the table. Okay?</p> <p>15 THE WITNESS: Okay.</p> <p>16 MR. McCORMICK: Thank you.</p> <p>17 THE VIDEOGRAPHER: Off the record at 18 10:59 a.m. This is the end of tape one.</p> <p>19 (A brief recess was taken)</p> <p>20 THE VIDEOGRAPHER: Stand by, please.</p> <p>21 Back on the record at 11:06 a.m. This is tape two.</p> <p>22 BY MR. McCORMICK:</p> <p>23 Q. Mr. Gorsky, we're back from our first break. 24 Do you understand you're still under oath?</p> |
| Page 42 | Page 44 |
| <p>1 with the Janssen brand supporting speaker programs. 2 Can we interact with the CME Provider's speaker program 3 support team on this CME activity since we have a good 4 working relationship?"</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes, you did.</p> <p>7 Q. And the answer to number eight, which was 8 again probably put together by your regulatory and 9 compliance and legal team, says, "No. There must be a 10 clear firewall established between the two groups. It 11 is inappropriate for a promotional support group to 12 discuss or be involved with any CME activity. All CME 13 activities must be free from commercial bias. Clearly, 14 using promotional staff compromises this standard. It 15 is the responsibility of the CME Provider to ensure 16 clear separation of promotional and CME staff groups."</p> <p>17 Did I read that correctly, Mr. Gorsky?</p> <p>18 A. Yes, you did.</p> <p>19 Q. And based on the fact that this answer was 20 probably rigorously reviewed and analyzed by your 21 regulatory, legal and compliance and any other 22 department involved before it was put into a compliance 23 manual, do you assume that this answer was correct at 24 the time it was written?</p> | <p>1 A. Yes, I do.</p> <p>2 Q. We were looking at the healthcare compliance 3 guidelines, and I think we were on page 9009 of the 4 document.</p> <p>5 The title of this section of the guidelines is 6 "Guidance Document: Entertainment, Gifts and 7 Promotions." Do you see that, Mr. Gorsky?</p> <p>8 A. Yes, I do.</p> <p>9 Q. The first sentence of the overview for this 10 section says that Janssen abides by two different sets 11 of guidelines. What are those guidelines?</p> <p>12 A. It states that "Janssen abides by the American 13 Medical Association's [AMA] and Pharmaceutical and 14 Research Manufacturers of America's [PhRMA] Guidelines 15 on Gifts to Physician's from Industry."</p> <p>16 I don't remember the specifics of each one of 17 those, but I know that both organizations established 18 guidelines and recommendations for promotional 19 practices on entertainment, gifts and promotions as 20 outlined here on several different occasions through 21 the 1990s and 2000s, and we wanted to ensure that ours 22 were consistent with those guidelines, as far as I can 23 remember.</p> <p>24 Q. And the next sentence states that "Although</p> |

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1 these guidelines apply only to physicians, Janssen
 2 applies the same principles in their dealings with
 3 other health care professionals." Is that correct?

4 A. That's correct, that's what it says.

5 Q. Would that include nurses in a doctor's
 6 office?

7 A. I'm assuming it would include all healthcare
 8 professionals.

9 Q. Can you turn to page 9012, please? Again,
 10 we're looking at the questions and answers that are
 11 pertinent to this section: Entertainment, gifts and
 12 promotions. Is that correct?

13 A. That's correct. It's consistent, I believe,
 14 with what we did before, where there were policies and
 15 procedures, and then this is a Q&A attempting to
 16 further clarify.

17 Q. So, these would be sample questions you would
 18 get from a sales representative into the compliance
 19 department, right?

20 MR. MURPHY: Objection to the form of
 21 the question. You may answer.

22 MR. McCORMICK: Let me see if I can
 23 rephrase.

24 BY MR. McCORMICK:

1 Q. The question-and-answer section, Mr. Gorsky,
 2 would be representative questions or samples of
 3 questions that may come from a Janssen sales
 4 representative into the compliance department. Is that
 5 correct?

6 A. I'm speculating some, but -- as I haven't
 7 reviewed the entire document, but from here it would
 8 appear as though this could be used by a number of
 9 different people, anyone involved directly or
 10 indirectly with the promotion of our products.

11 Q. Let's look at question four, Mr. Gorsky. The
 12 question reads, "Can Janssen pay for a physician or
 13 hospital's Holiday party?"

14 The answer states, "No. This is a gift and
 15 gifts may not be provided to physicians or groups
 16 unless they primarily entail a patient benefit and are
 17 of modest value."

18 Did I read that correctly?

19 A. Yes, did you read it correctly.

20 Q. Similar to the other questions and answers we
 21 discussed, based on your assumption that this
 22 compliance manual would have gone through a rigorous
 23 review by Janssen's regulatory, legal and compliance

1 departments, you would assume that this answer is
 2 correct as of the time it was written. Is that
 3 correct?

4 A. That's correct.

5 Q. Let's look at question number six, Mr. Gorsky.
 6 The question reads, "Can a sales representative conduct
 7 a 'Dash'N Dine' pizza program or a Dash program that
 8 offers items other than meals, such as clothing, shoes,
 9 gift certificates, wine, etcetera?" The answer reads,
 10 "No. All Dash programs are prohibited."

11 Did I read that correctly?

12 A. Yes, you read it correctly.

13 Q. Mr. Gorsky, based on our previous review of
 14 these documents and your assumption that these
 15 questions and answers have gone through a rigorous
 16 review by your regulatory, legal and compliance
 17 departments, do you assume that the answer to the
 18 question provided there was correct as of the time it
 19 was written?

20 A. Yes.

21 Q. You can put that document aside, Mr. Gorsky.
 22 (Exhibit Gorsky-06 was marked for
 23 identification)

24 BY MR. McCORMICK:

1 Q. The question-and-answer section, Mr. Gorsky,
 2 would be representative questions or samples of
 3 questions that may come from a Janssen sales
 4 representative into the compliance department. Is that
 5 correct?

6 A. I'm speculating some, but -- as I haven't
 7 reviewed the entire document, but from here it would
 8 appear as though this could be used by a number of
 9 different people, anyone involved directly or
 10 indirectly with the promotion of our products.

11 Q. Let's look at question four, Mr. Gorsky. The
 12 question reads, "Can Janssen pay for a physician or
 13 hospital's Holiday party?"

14 The answer states, "No. This is a gift and
 15 gifts may not be provided to physicians or groups
 16 unless they primarily entail a patient benefit and are
 17 of modest value."

18 Did I read that correctly?

19 A. Yes, did you read it correctly.

20 Q. Similar to the other questions and answers we
 21 discussed, based on your assumption that this
 22 compliance manual would have gone through a rigorous
 23 review by Janssen's regulatory, legal and compliance

1 BY MR. McCORMICK:

2 Q. Mr. Gorsky, I'm going to hand you what I've
 3 marked as Exhibit 6, which is a chain of emails from
 4 November of 2001. The first Bates label it's JJRE
 5 03856494.

6 Can you take a minute to review that document
 7 and let me know when you're finished?

8 A. Yes. Okay.

9 Q. Mr. Gorsky, have you had a chance to review
 10 Exhibit 6?

11 A. Yes, I have.

12 Q. And do you see that you sent an email, on page
 13 two of this document, on or around November 2nd of
 14 2001?

15 A. Yes, I did.

16 Q. And the signature line shows that you were the
 17 president of Janssen at that time. Is that correct?

18 A. That's correct.

19 Q. And you're checking on meeting dates for Joe
 20 Scodari. Is that right?

21 A. That's correct.

22 Q. Who is Joe Scodari?

23 A. At that time Joe Scodari was the company group
 24 chairman, I believe, for North America Pharmaceutical

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| <p style="text-align: right;">Page 49</p> <p>1 Group.</p> <p>2 Q. And Mr. Gorsky, in your email to a number of</p> <p>3 individuals at Janssen, you were asking for ideas on</p> <p>4 growth opportunities. Is that correct?</p> <p>5 A. That's correct.</p> <p>6 Q. And these growth opportunities should be what</p> <p>7 you call investment opportunities that generate topline</p> <p>8 growth in the 2002 and 2003 time frame, right?</p> <p>9 A. Yes.</p> <p>10 Q. And would selling Risperdal or having --</p> <p>11 strike that. Would increasing the sales of Risperdal be</p> <p>12 a growth opportunity in 2001?</p> <p>13 MR. MURPHY: Objection to the form of</p> <p>14 the question. You may answer.</p> <p>15 THE WITNESS: I'm not sure exactly what</p> <p>16 you're meaning by the question.</p> <p>17 MR. McCORMICK: Okay.</p> <p>18 BY MR. McCORMICK:</p> <p>19 Q. Mr. Gorsky, let's look at page one and the</p> <p>20 email that Ms. Vergis forwarded. She forwarded your</p> <p>21 email to a number of other individuals. Is that right?</p> <p>22 A. Based upon the tracking of the email, yes.</p> <p>23 Q. And at that time do you recall that Ms. Vergis</p> <p>24 was the vice-president of the CNS franchise for</p> | <p style="text-align: right;">Page 51</p> <p>1 called growth opportunities?</p> <p>2 MR. MURPHY: Objection to the form of</p> <p>3 the question. You may answer.</p> <p>4 THE WITNESS: You know, I don't</p> <p>5 remember specifically other than as reflected on</p> <p>6 this email.</p> <p>7 MR. McCORMICK: Okay.</p> <p>8 BY MR. McCORMICK:</p> <p>9 Q. Then do you see in the very latest of the</p> <p>10 emails in the email chain Gahan Pandina forwards the</p> <p>11 email chain, including your original email about growth</p> <p>12 opportunities, to Georges Gharabawi and his email</p> <p>13 reads, "Would this be an appropriate forum to discuss</p> <p>14 the J&J center idea with Dr. Biederman?"</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes, you did. That's what the email states.</p> <p>17 Q. Okay. Did you know who Dr. Biederman was in</p> <p>18 November of 2001?</p> <p>19 A. I don't know if I knew who Dr. Biederman was</p> <p>20 in 2001. I know of Dr. Biederman. I just don't</p> <p>21 remember the exact time when I came to know him.</p> <p>22 (Exhibit Gorsky-07 was marked for</p> <p>23 identification)</p> |
| <p style="text-align: right;">Page 50</p> <p>1 Janssen?</p> <p>2 A. I don't remember her exact title, but I think</p> <p>3 that is consistent with what I remember.</p> <p>4 Q. Okay. And then the email that Ms. Vergis</p> <p>5 forwards, which is your forward, if you track along</p> <p>6 here, was forwarded then by Ramy Mahmoud to a number of</p> <p>7 other individuals. Is that correct?</p> <p>8 A. Yes.</p> <p>9 Q. And Mr. Mahmoud talks about "money on the</p> <p>10 table." Do you see that?</p> <p>11 A. The opening sentence says "Remember 'money on</p> <p>12 the table'?" I'm not sure what. . .</p> <p>13 Q. Do you recall before November of 2001 taking</p> <p>14 part in activities or exercises that were referred to</p> <p>15 as "money on the table" when you were at Janssen?</p> <p>16 A. I vaguely remember from time to time during</p> <p>17 the course of the year their management may provide the</p> <p>18 opportunity for additional investment in different</p> <p>19 areas of the business that was called a "money on the</p> <p>20 table" exercise, but I don't remember the specific</p> <p>21 exercise.</p> <p>22 Q. Would that be similar to the email or the</p> <p>23 exercise that you're talking about here that you</p> <p>24 forwarded to individuals and then were forwarded on</p> | <p style="text-align: right;">Page 52</p> <p>1 BY MR. McCORMICK:</p> <p>2 Q. Mr. Gorsky, I'm handing you what's been marked</p> <p>3 as Exhibit 7. It's a one-page document, a letter dated</p> <p>4 December 7, 2001 from Joseph Biederman to Kent Bockes</p> <p>5 Please take a minute to review it and let me know when</p> <p>6 you're finished.</p> <p>7 A. Okay.</p> <p>8 Q. Mr. Gorsky, in December of 2001 do you recall</p> <p>9 that Kent Bockes was a product director in the CNS</p> <p>10 franchise?</p> <p>11 A. I mean, I recall Kent Bockes, but I don't</p> <p>12 recall what exactly his role was at that time.</p> <p>13 Q. Did Mr. Bockes ever discuss this letter with</p> <p>14 you, which is a request for an educational grant in the</p> <p>15 amount of \$500,000 from Dr. Joseph Biederman of</p> <p>16 Massachusetts General Hospital?</p> <p>17 A. I don't recall.</p> <p>18 Q. Do you recall in or around the time frame</p> <p>19 November/December 2001 discussions surrounding an</p> <p>20 educational grant for the creation of a center for</p> <p>21 child and adolescent psychiatry research at</p> <p>22 Massachusetts General Hospital in partnership with Dr.</p> <p>23 Biederman?</p> <p>24 A. I don't recall a specific conversation around</p> |

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| <p>1 a grant. I recall discussions regarding Dr. Biederman, 2 who was considered to be one of the top researchers -- 3 I believe he was out of Harvard and Massachusetts 4 General Hospital -- particularly in child and 5 adolescent psychiatry and that there were ongoing 6 discussions with him, but I don't remember the 7 specifics.</p> <p>8 Q. You can put that aside, Mr. Gorsky.</p> <p>9 MR. McCORMICK: I'm marking as Exhibit 8 10 a document with the Bates label JJRIS 00302772. 11 It's a PME Request Form. Take a minute to review 12 it and let me know when you're finished.</p> <p>13 (Exhibit Gorsky-08 was marked for 14 identification)</p> <p>15 THE WITNESS: Okay.</p> <p>16 BY MR. McCORMICK:</p> <p>17 Q. Mr. Gorsky, have you had a chance to review 18 Exhibit 8?</p> <p>19 A. Yes.</p> <p>20 Q. And you see that it's a PME Request Form. Is 21 that correct?</p> <p>22 A. Yes, that's what it says at the top of the 23 form.</p> <p>24 Q. What does PME stand for, if you recall?</p> | <p>1 A. That would have been Ortho-McNeil 2 Pharmaceutical Company, another subsidiary of Johnson & 3 Johnson.</p> <p>4 Q. And before you approved this \$500,000 5 expenditure of which Janssen was responsible for 6 \$200,000, did you discuss the plan for the child and 7 adolescent research center with anyone before approving 8 it?</p> <p>9 A. I don't recall if I had a specific discussion 10 on this particular program. This would have been one 11 among many programs that would have come across my 12 desk.</p> <p>13 (Exhibit Gorsky-09 was marked for 14 identification)</p> <p>15 BY MR. McCORMICK:</p> <p>16 Q. Mr. Gorsky, I've marked as Exhibit 9 a 17 three-page document entitled "Educational Grant Letter 18 of Agreement." Take a minute to review that and let me 19 know when you're finished.</p> <p>20 A. Okay.</p> <p>21 Q. Mr. Gorsky, have you had a chance to review 22 Exhibit 9?</p> <p>23 A. Yes, I have.</p> <p>24 Q. And do you see on page three there is a</p> |
| Page 54 | Page 56 |
| <p>1 A. I don't remember exactly. It went through a 2 number of iterations over the years. If it was product 3 management expenses -- I don't remember.</p> <p>4 Q. Okay. Toward the bottom do you see your name 5 typed?</p> <p>6 A. Yes, I too.</p> <p>7 Q. And then is that your signature next to your 8 name?</p> <p>9 A. Yes, it is.</p> <p>10 Q. And it's got a date there, 12/16/01?</p> <p>11 A. Yes, it does.</p> <p>12 Q. You were approving a \$500,000 expenditure for 13 a child and adolescent research center, Massachusetts 14 General Hospital. Is that correct?</p> <p>15 A. The grant, as I read it, was for \$500,000. 16 However, it also says that "OMP and McNeil will each be 17 contributing \$150,000 to this project (Thus, our total 18 expenditure will be \$200,000 with 300K coming back to 19 us)."</p> <p>20 Q. Meaning that Janssen would put out the first 21 \$500,000, but OMP and McNeil would pay \$300,000 back to 22 Janssen. Is that right?</p> <p>23 A. I'm assuming that was the case, yes.</p> <p>24 Q. And what's OMP?</p> | <p>1 signature block there with your name printed?</p> <p>2 A. Yes.</p> <p>3 Q. Is that your printing or handwriting?</p> <p>4 A. I don't believe it is.</p> <p>5 Q. Do you recall ever signing this Educational 6 Grant Letter of Agreement for \$500,000 for the MGH 7 Center for Pediatric Mania?</p> <p>8 A. No, I do not.</p> <p>9 Q. But you had previously, in Exhibit 8, approved 10 the \$500,000. Is that correct?</p> <p>11 MR. MURPHY: Objection to form of the 12 question. You may answer if you understand it.</p> <p>13 THE WITNESS: I think what I had 14 approved in the previous document was the request, 15 a grant total of \$500,000, with Janssen being 16 responsible for \$200,000. And also I'll just note 17 on it there was not yet a signed contract in 18 place.</p> <p>19 BY MR. McCORMICK:</p> <p>20 Q. Is Exhibit 9 the contract that would have been 21 signed?</p> <p>22 MR. MURPHY: Objection to the form of 23 the question. You may answer.</p> <p>24 THE WITNESS: I don't know.</p> |

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1 BY MR. McCORMICK:

2 Q. So, are you saying the bribe to Massachusetts
3 General Hospital was only 200,000, not 500,000?

4 MR. MURPHY: Did you say "bribe"?

5 MR. McCORMICK: (No response)

6 MR. MURPHY: Did you say "bribe"?

7 MR. McCORMICK: Yes.

8 MR. MURPHY: Objection to the form of
9 the question, argumentative. You may answer.10 THE WITNESS: I would disagree with
11 that statement.12 MR. McCORMICK: All right, you can put
13 that exhibit aside.14 (Exhibit Gorsky-10 was marked for
15 identification)

16 BY MR. McCORMICK:

17 Q. Mr. Gorsky, I've marked as Exhibit 10 an email
18 chain from March of 2002. Can you take a minute to
19 review it and let me know when you're finished?

20 A. Okay.

21 Q. Mr. Gorsky, have you had a chance to review
22 Exhibit 10?

23 A. Yes, I have.

24 Q. And do you see that you are the recipient and

1 that right?

2 A. I can't speculate on that because of the heavy
3 volume that I get, and it would depend on the exact
4 nature and content of the forward on the other email.5 Q. Well, looking at the email now, do you see
6 that Mr. Pandina -- Dr. Pandina is talking about a
7 meeting, a pediatric -- strike that.8 Looking at the email now, Mr. Gorsky, do you
9 see that Gahan Pandina is talking about a meeting that
10 they had with Dr. Biederman and then a pediatric
11 seminar that Dr. Biederman gave after that meeting?12 A. Yes, that's what it appears to be referring
13 to.14 Q. And it says that Dr. Biederman gave or
15 attended and participated in a three-day educational
16 seminar in child psychopharmacology and pediatric
17 bipolar disorder the day immediately after he met with
18 Janssen at Janssen's offices, right?19 A. This sentence, as I read it, says "This
20 meeting began the day immediately after our meeting
21 with him here at Janssen last week."22 Q. Later on in the email Gahan Pandina notes that
23 Dr. Biederman was not perceived to be aligned with any
24 company in particular.

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1 then the sender of two of the emails in this email
2 chain?

3 A. Yes, I do.

4 Q. And do you see the email from Gahan Pandina,
5 who was the assistant director of CNS clinical
6 development, on March 22, 2002 and the subject line
7 reads "Feedback regarding MGH pediatric seminar"?

8 Have you had a chance to review that email?

9 A. Yes, I have.

10 Q. And then you receive an email -- or that email
11 is forwarded to you by Ramy Mahmoud later on that day.
12 Is that correct?

13 A. That's correct.

14 Q. Okay. Was it your custom and practice in
15 March of 2002 that if you received an email and it
16 forwarded another email, you would have reviewed both
17 those emails?18 A. I can only speculate because I would literally
19 receive hundreds of emails, so I may or may not have
20 been able to read the entire content of the email.21 Q. Well, you can't specify every example, of
22 course, but would it have been your practice that, if
23 you had received an email that was forwarded to you,
24 you would have tried to review the earlier email? Is

1 Do you see that?

2 MR. MURPHY: What line are you at,
3 counsel?

4 MR. McCORMICK: Sixth line.

5 THE WITNESS: As I read that statement,
6 it says, "He was very balanced in his approaches
7 to treatment, and not perceived to be aligned with
8 any company in particular."

9 MR. McCORMICK: Okay.

10 BY MR. McCORMICK:

11 Q. And do you see the last sentence or last
12 paragraph in Mr. Pandina's email? It says, "I think
13 this is a clear example of the utility of partnering
14 with a group such as MGH, who has the potential of
15 reaching and having a significant impact upon the field
16 of child and adolescent psychiatry with these types of
17 professional activities in non-sponsored venues"?

18 Do you see that?

19 A. Yes, I do.

20 Q. By that, does -- strike that. By that Mr.
21 Pandina means that Massachusetts General Hospital and
22 Dr. Biederman will give Johnson & Johnson good cover
23 when they speak about Risperdal for pediatric use. Is
24 that correct?

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| <p>1 MR. MURPHY: Objection to the form of 2 the question, lack of foundation and calls for 3 speculation, but you may answer.</p> <p>4 THE WITNESS: No, I would not draw that 5 conclusion. As I read the paragraph now, again it 6 talks about there being a three-day educational 7 seminar, that it was a very balanced review; and 8 it actually talks not about judging the validity 9 of the diagnosis of pediatric mania, given the 10 lack of data in this area at the time.</p> <p>11 So, I couldn't draw the conclusion that 12 you made in your statement.</p> <p>13 BY MR. McCORMICK:</p> <p>14 Q. Well, based on the documents we just reviewed 15 before, it looked like there had been some thought 16 towards a research center being run by Dr. Biederman at 17 Massachusetts General Hospital. Is that correct? In 18 this time frame?</p> <p>19 A. In the earlier documents it did talk about an 20 educational grant in support of a -- it was called 21 Child and Adolescent Research Center, but in the same 22 documents it talks about the clear direction around 23 where those funds could be used and should not be used 24 and their context based upon Exhibit 9.</p> | <p>1 recall, I don't recall our exact labeling at that time. 2 It was over ten years ago. And how it was worded, I 3 just don't have recall of that right now.</p> <p>4 Q. And in reviewing documents in preparation for 5 this deposition or preparing for the Texas deposition 6 and having your deposition taken there, you did not 7 realize or come to know that Risperdal did not become 8 approved for any pediatric use until October of 2006?</p> <p>9 A. I was aware as we prepared for this in 2006. 10 What I can't say with certainty sitting here today is 11 exactly what the label articulated prior to that 2006. 12 And there was considerable and ongoing discussion with 13 the FDA around various aspects of our label at that 14 time.</p> <p>15 Q. Mr. Gorsky, I think you just agreed with me 16 that Risperdal was approved or indicated by the FDA for 17 a pediatric use in October 2006. Is that right? The 18 first time.</p> <p>19 A. I don't remember the -- I don't have recall. 20 I wasn't at Janssen in 2006, nor in the preparation for 21 this did I read the specific labeling received in 2006.</p> <p>22 What I've testified is that I don't recall 23 what was specifically in our label at this time 24 regarding the use in child and adolescents.</p> |
| Page 62 | Page 64 |
| <p>1 Q. Well, we'll look at where the funds were used 2 later, but that research center was eventually formed 3 and operated. Is that correct?</p> <p>4 A. I don't know.</p> <p>5 Q. Okay. You don't recall attending any meetings 6 regarding the Massachusetts General Hospital center 7 that Dr. Biederman was running with funds from Johnson 8 & Johnson or Janssen?</p> <p>9 A. I recall meeting Dr. Biederman, but I can't 10 recall the exact context of that meeting.</p> <p>11 Q. And then Ramy Mahmoud forwards that email to 12 you with a note that says, "A great way to get the word 13 out to a big part of the child and adolescent 14 prescribing community...very more that we do this kind 15 of thing and do it right...and it would appear that we 16 are definitely off on the right track on this 17 one...Ramy."</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. And then your response is -- well, strike 21 that.</p> <p>22 In March of 2002 was Risperdal approved for 23 any pediatric use, Mr. Gorsky?</p> <p>24 A. I don't recall. And when I say I don't</p> | <p>1 Q. Respectfully, Mr. Gorsky, are you really going 2 to expect the jury to believe that you don't know that 3 prior to October of 2006 there was no pediatric 4 approval or indication by the FDA for Risperdal?</p> <p>5 MR. MURPHY: Objection to the form of 6 the question, argumentative, but you may answer 7 the question, sir.</p> <p>8 THE WITNESS: No, that's not what I 9 said. I said that I didn't know the exact 10 language. And I was clearly made aware and as I 11 prepared for here because I had left the company 12 four years or approximately three years prior to 13 the labeling, the exact labeling being received.</p> <p>14 I don't know what was included and I 15 don't have -- the label itself is a document that 16 is multiple pages; has, you know, several 17 different sections. I don't remember exactly what 18 it said about use in children and adolescents.</p> <p>19 BY MR. McCORMICK:</p> <p>20 Q. I'm not --</p> <p>21 A. That's. . .</p> <p>22 Q. And I'm not trying to trick you; I really am 23 not. And I'm not trying to -- it's just going to make 24 this day a lot longer if we can't come -- I'm not</p> |

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| <p style="text-align: right;">Page 65</p> <p>1 asking you about the entire label, Mr. Gorsky, and I'm 2 not trying to argue with you. I know Mr. Murphy is 3 about to object and say I'm arguing with you. 4 I'm just trying to ask you that in this time 5 frame of March of 2002, whether Risperdal was approved 6 for any pediatric use. Not anything else, just 7 pediatric use, child and adolescents.</p> <p>8 A. And what I'm saying is, I don't recall. There 9 are several ways that that language can be in the 10 label: Something not being recommended, has not been 11 studied. There's a whole number of factors that can be 12 in there, and I just don't recall that specific 13 language.</p> <p>14 Q. Well, the language I'm talking about is 15 whether Risperdal was approved by the FDA for the use 16 in child and adolescents in 2002.</p> <p>17 A. It did not have the specific indication, 18 obviously, that was achieved in 2006 in 2002.</p> <p>19 Q. Okay. So here, then, where Ramy Mahmoud is 20 talking about a great way to get out word to our child 21 and adolescent prescribing community, he's actually 22 celebrating a way for Janssen to promote Risperdal 23 off-label to the children and adolescent community. Is 24 that right?</p> | <p style="text-align: right;">Page 67</p> <p>1 a front to prescribe or promote Risperdal off-label to 2 the child and adolescent market?" 3 MR. MURPHY: Does he recall doing that? 4 MR. McCORMICK: Right. 5 THE WITNESS: I don't recall having 6 that conversation, but I would assume that Ramy 7 and the other people included on this were very 8 well-versed with our promotional policy and 9 guidelines, and as physicians within that group 10 would have been particularly sensitive to those. 11 MR. McCORMICK: Okay.</p> <p>12 BY MR. McCORMICK: 13 Q. Did you ever say to Ramy Mahmoud or Pandina -- 14 strike that. 15 Do you recall ever saying to Ramy Mahmoud or 16 Pandina, "We need to stop and think about this. If Dr. 17 Biederman's talking about Risperdal and we're giving 18 him \$500,000 as an educational grant, he has a conflict 19 of interest"? 20 A. I don't recall having that specific 21 conversation, but I've had multiple conversations with 22 all our employees about ensuring that all of our 23 activities, promotional and non-promotional, were 24 consistent with our guidelines and regulations.</p> |
| <p style="text-align: right;">Page 66</p> <p>1 MR. MURPHY: Objection to the form of 2 the question, mischaracterizes the evidence. You 3 may answer.</p> <p>4 THE WITNESS: No, I disagree with that 5 statement. I think in the note from Gahan 6 Pandina, again it talks about the validity of the 7 diagnosis of pediatric mania and the condition. 8 In Ramy's note, specifically which I 9 would assume I would have reviewed since I passed 10 it on, it says, "A great way to get the word out 11 to a big part of the child and adolescent 12 prescribing community...very important that we do 13 this thing and do it right," which I would take to 14 be reinforcing, ensuring that we're doing it in 15 the right way. So no, I would not draw the same 16 conclusion.</p> <p>17 BY MR. McCORMICK: 18 Q. And then you just stated that you responded to 19 the email and said "Great to see that our partnering 20 with institutions and KOLs," right? 21 A. Yes, that is the way I responded. 22 Q. And do you recall at that time stopping Ramy 23 Mahmoud or Gahan Pandina and saying, "We can't use 24 Massachusetts General Hospital and/or Dr. Biederman as</p> | <p style="text-align: right;">Page 68</p> <p>1 And in fact, I think in the earlier document 2 the request that was clearly outlined, that there 3 should be no collusion on those matters in the same 4 way, where there was a specific grant request. 5 Q. Mr. Gorsky, I want to make sure I understand. 6 We looked at Ramy Mahmoud's email where he forwards 7 Gahan Pandina's email. And sitting here today you 8 don't have any problem with the way Ramy Mahmoud 9 phrased this email or the way he's approaching this 10 relationship between J&J and Dr. Biederman or 11 Massachusetts General Hospital. Is that right? 12 MR. MURPHY: Objection to the form of 13 the question. Phraseology is one thing, but what 14 do you mean by "approaching"?</p> <p>15 MR. McCORMICK: The language of the 16 email.</p> <p>17 BY MR. McCORMICK: 18 Q. Do you stand by the language of the email, Mr. 19 Gorsky?</p> <p>20 MR. MURPHY: Does he stand by it? 21 MR. McCORMICK: Yes. 22 MR. MURPHY: You may answer if you can. 23 THE WITNESS: I don't know what you 24 mean by "stand by it."</p> |

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1 BY MR. McCORMICK:

2 Q. Did you ever write back to Ramy Mahmoud or
 3 Gahan Pandina and say, "I think your email has some
 4 off-label promotional problems if we're using Dr.
 5 Biederman and Massachusetts General Hospital for an
 6 improper purpose"?

7 A. I don't recall. However, if I refer back to
 8 the previous document where there was a request for a
 9 grant, there were multiple statements talking about the
 10 importance of "No promotional activities will be
 11 permitted in the same room or obligate path as the
 12 Program"; requiring objectivity and balance; requiring
 13 limitations on data; and actually discussion of
 14 unapproved uses saying institutions will require that
 15 presenters disclose when a product is not approved.

16 And assuming that as a background, while I
 17 can't account for every conversation that may have been
 18 had by the different employees, following that to this
 19 document where Ramy made the statement "It's very
 20 important that we do this thing and do it right," I
 21 would have felt that he was following our recommended
 22 guidelines and procedures.

23 Q. And I can understand you want to concentrate
 24 on that second clause. The first clause, though -- "A

1 And I think they even talk in here about the
 2 importance of having the right kind of scales to ensure
 3 the appropriate diagnosis and treatment of these
 4 children. And I believe that was the overall intent of
 5 Dr. Mahmoud's email.

6 Q. I mean, in fact you actually said "great."
 7 You seem pleased with the way that this relationship is
 8 going -- is that right? -- if you look at your email?

9 A. I can just conclude, from having read Ramy's
 10 portion, that yes, supporting a cause to better
 11 understand this very difficult condition and treatment
 12 in children did represent good partnering.

13 (Exhibit Gorsky-11 was marked for
 14 identification)

15 BY MR. McCORMICK:

16 Q. Mr. Gorsky, I've handed you what we've marked
 17 as Exhibit 11, which is an email and an attachment.
 18 The first Bates label on the page is JJRE 02310614.

19 Will you take a minute to review that document
 20 and let me know when you're finished.

21 A. Okay.

22 Q. Mr. Gorsky, have you had a chance to review
 23 Exhibit 11?

24 A. Yes, I have.

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1 great way to get the word out to a big part of the
 2 child and adolescent prescribing community" -- is what
 3 concerns me, because at the time Risperdal was not
 4 indicated and approved for any pediatric or child and
 5 adolescent use, and Mahmoud and Pandina both appear to
 6 be presenting this relationship with Dr. Biederman and
 7 Massachusetts General Hospital as the opportunity to
 8 get the word on Risperdal out to this community.

9 MR. MURPHY: That's a statement.

10 Q. Is that correct?

11 MR. MURPHY: You just gave him your
 12 interpretation.

13 BY MR. McCORMICK:

14 Q. Did you agree with my interpretation?

15 A. No, I do not agree with your interpretation.

16 Q. And in fact, you -- I'm sorry.

17 A. Can I continue my statement?

18 Q. Of course.

19 A. There is a range of items they're talking
 20 about, and this is a category where this represented a
 21 significant area of unmet medical need for the
 22 appropriate treatment of children and diagnosis of
 23 these children, with prescribing completely being a
 24 separate issue.

1 Q. This is an email from Gahan Pandina in April
 2 of 2000 -- strike that.

3 Mr. Gorsky, Exhibit 11 is an email from Gahan
 4 Pandina to you and a number of other individuals on
 5 April 2nd of 2002 and then an attachment. Is that
 6 correct?

7 A. That's correct.

8 Q. And at the time in April of 2002 you were the
 9 president of Janssen Pharmaceutica. Is that right?

10 A. That's correct.

11 Q. The re line discusses a J&J-Massachusetts
 12 General Hospital meeting executive summary for a
 13 meeting that occurred at Janssen on March 14th of 2002.
 14 Is that right?

15 A. That's correct.

16 Q. Okay. And do you see on page three of this
 17 document, or page 616 Bates label, you attended this
 18 meeting on behalf of Janssen?

19 A. As I said earlier, I think I remember meeting
 20 Dr. Biederman at this and attending part of this
 21 session, but I don't remember exactly which portions I
 22 attended or would have been present for.

23 Q. Well, this is a meeting summary, so we're
 24 assuming that what is in here is correct. Is that

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| <p>1 right?</p> <p>2 A. Yes. What I'm saying, though, is: Whether I</p> <p>3 was just there for the introduction/welcome or some of</p> <p>4 the other areas, I don't recall.</p> <p>5 Q. Okay, and we'll get there. I'm just asking if</p> <p>6 your name is listed as an attendee and then you</p> <p>7 presented as the introduction and welcome at 8:30. Is</p> <p>8 that right?</p> <p>9 A. Yes, that's what the document states.</p> <p>10 Q. All right. It looks like Dr. Biederman as</p> <p>11 well as two other individuals from Massachusetts</p> <p>12 General Hospital attended the meeting.</p> <p>13 A. Yes, that's what it states in here.</p> <p>14 Q. Would you assume that Johnson & Johnson paid</p> <p>15 for their travel costs to come to this meeting?</p> <p>16 A. I don't know.</p> <p>17 Q. If we turn to the next page, page 617? Do you</p> <p>18 see the overview heading about halfway through the</p> <p>19 page?</p> <p>20 A. Yes, I do.</p> <p>21 Q. The third sentence says, "Three</p> <p>22 representatives from MGH were present, along with a</p> <p>23 number of representatives from J&J sister companies."</p> <p>24 Do you see that?</p> | <p>1 MR. MURPHY: Objection to the form of</p> <p>2 the question. You may answer if you understand</p> <p>3 it.</p> <p>4 THE WITNESS: I can't speculate on</p> <p>5 that.</p> <p>6 BY MR. McCORMICK:</p> <p>7 Q. Do you know if Risperdal was being prescribed</p> <p>8 by doctors around the country for pediatric bipolar</p> <p>9 disorder in March of 2002?</p> <p>10 A. I would assume that there was use of Risperdal</p> <p>11 in that patient population in 2002.</p> <p>12 Q. So, if more children are diagnosed and then</p> <p>13 treated for pediatric bipolar disorder, then where</p> <p>14 before, as a result of this meeting at MGH, with</p> <p>15 support from Janssen, in March of 2002, you would</p> <p>16 assume that, then, more prescriptions for Risperdal</p> <p>17 would be written after that meeting. Is that correct?</p> <p>18 MR. MURPHY: Would he assume that?</p> <p>19 MR. McCORMICK: Yes.</p> <p>20 THE WITNESS: I can't speculate on</p> <p>21 that.</p> <p>22 BY MR. McCORMICK:</p> <p>23 Q. Can you turn to the top of page 618, please?</p> <p>24 It says "Planned re-analysis" -- is that correct? -- on</p> |
| Page 74 | Page 76 |
| <p>1 A. Yes, I do.</p> <p>2 Q. And the sister companies would have been</p> <p>3 Ortho-McNeil Pharmaceutical and McNeil Consumer that we</p> <p>4 talked about earlier?</p> <p>5 A. If I look forward, there were people from</p> <p>6 Johnson & Johnson Pharmaceutical Research and</p> <p>7 Development as well as McNeil Consumer as well as</p> <p>8 Ortho-McNeil. I'm not familiar with those individuals.</p> <p>9 Q. Down at the bottom of that page there is a</p> <p>10 heading "Initial Center Activities." Do you see that?</p> <p>11 A. I do.</p> <p>12 Q. And it says "With support of Janssen, an</p> <p>13 international meeting was held at MGH on Saturday March</p> <p>14 9, 2002 focused on diagnosis and treatment of pediatric</p> <p>15 bipolar disorder."</p> <p>16 Did I read that right?</p> <p>17 A. Yes, you did.</p> <p>18 Q. And a meeting that would have discussed or</p> <p>19 focused on the diagnosis and treatment of pediatric</p> <p>20 bipolar disorder would have been beneficial to Janssen</p> <p>21 at the time, because if more children are diagnosed and</p> <p>22 treated for pediatric bipolar disorder, then I would</p> <p>23 assume the amount of Risperdal being sold would also go</p> <p>24 up. Is that correct?</p> | <p>1 the top?</p> <p>2 A. Yes, it does.</p> <p>3 Q. Talking about the re-analysis of certain data</p> <p>4 in a JPI database. Is that right?</p> <p>5 A. That's what it states in the memo, yes.</p> <p>6 Q. What's JPI?</p> <p>7 A. Janssen Pharmaceutica, Incorporated.</p> <p>8 Q. And if you read that section, it looks like</p> <p>9 Massachusetts General Hospital is working with JPI to</p> <p>10 review data and publish the numbers of various disease</p> <p>11 states. Is that correct?</p> <p>12 A. Can you give me a moment to review?</p> <p>13 Q. Of course.</p> <p>14 A. It does talk about doing a review of a</p> <p>15 database, talking about relating to validating the</p> <p>16 DSM-4 conduct disorder as a sub type, and then also the</p> <p>17 second analysis related to aggression.</p> <p>18 I'm not certain of the exact content of the</p> <p>19 database, if this was a general database, what the</p> <p>20 database may have been involved with.</p> <p>21 And at that time there was very little</p> <p>22 information around these conditions in children and</p> <p>23 adolescents during a time when there was an increasing</p> <p>24 recognition of a need to -- that this was increasing in</p> |

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1 its occurrence in physician offices.

2 So, again, I'm not sure if this was -- what I
 3 do remember is trying to better understand exactly what
 4 the nature of the disease in adolescents and children
 5 was versus adults and in better understanding the
 6 overall condition.

7 Q. And better understanding the overall condition
 8 would lead to more diagnoses of pediatric bipolar
 9 disorder, which would then, in turn, lead to more
 10 prescriptions for antipsychotic drugs including
 11 Risperdal. Is that right?

12 MR. MURPHY: Objection to form, lack of
 13 foundation. You may answer it.

14 THE WITNESS: I can't speculate. I
 15 think at this time those recognition -- that many
 16 of these children were suffering debilitating
 17 illness and there was little in the way of
 18 literature on the appropriate diagnosis, I believe
 19 as this was referred to, and on the appropriate
 20 treatment based on the physicians' understanding
 21 of the patient and the different options that were
 22 available to them as well as the patient.

23 BY MR. McCORMICK:

24 Q. Do you see down below the two bullet points

1 still under oath?

2 A. Yes, I do.

3 Q. Let's turn to page 619, please. Do you see
 4 there is a heading about two-thirds of the way down
 5 which says "Consultation regarding studies for FDA
 6 labeling in child BPD"? Do you see that?

7 A. Give me just a moment, please.

8 Q. Sure.

9 A. Which paragraph?

10 Q. About halfway down the page, "Consultation --
 11 A. I do. I'm sorry.

12 Q. That's okay. And the first paragraph of this
 13 section says, "In relationship to acquiring FDA
 14 labeling in child BPD, two key factors were
 15 identified." Is that correct?

16 A. Yes, that is what it states.

17 Q. And BPD would be bipolar disorder?

18 A. I believe so, yes.

19 Q. And "The first step was to establish evidence
 20 in support of the diagnosis of BPD in children, that
 21 BPD is a distinguishable and reliably identifiable
 22 disorder with a poor prognosis that can be moderated by
 23 treatment." Is that right?

24 MR. MURPHY: Is that what it states?

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1 there it talks about safety data?

2 A. Could you show me where...

3 Q. It's a JPI database. There are two bullet
 4 points and the paragraph says, "Safety data was also
 5 highlighted as a key area of importance for
 6 publication."

7 A. Yes, I do see that.

8 Q. And then one of the safety areas that's
 9 discussed there is prolactin. Is that right?

10 A. It says, "Safety areas include prolactin (in
 11 publication), cardiovascular" and a number of other
 12 items.

13 MR. McCORMICK: Before we start a new
 14 section, why don't we take a break and go off to
 15 change a tape?

16 THE VIDEOGRAPHER: Going off the record
 17 at 12:03 p.m. This is the end of tape two.

18 (A brief recess was taken)

19 THE VIDEOGRAPHER: Stand by, please.
 20 Back on the record the at 12:10 p.m. This is tape
 21 three.

22 BY MR. McCORMICK:

23 Q. Mr. Gorsky, we're back from a break. We're
 24 still looking at Exhibit 11. You understand you're

1 Q. That what it states.

2 A. That's what it states, yes.

3 Q. That step, then, would be to gain recognition
 4 of bipolar disorder in children as an identifiable
 5 mental disorder. Is that right?

6 MR. MURPHY: Objection to the form,
 7 lack of foundation. You may answer.

8 THE WITNESS: I'm not sure what you
 9 mean by that question.

10 BY MR. McCORMICK:

11 Q. What do you think the first step here under
 12 the first factor means? What's that sentence mean to
 13 you?

14 A. As it's read, that the first factor was to
 15 "establish evidence in support of the diagnosis of
 16 BPD," bipolar disorder, "in children, that bipolar
 17 disease is a distinguishable and reliably identifiable
 18 disorder with a poor prognosis that can be moderated by
 19 treatment."

20 It then goes on to say that "The second would
 21 be to have the FDA acknowledge that this would be a
 22 treatable diagnostic entity that could result in filing
 23 more [sic] clear cost-benefit related to treatment to
 24 be established."

20 (Pages 77 to 80)

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| <p>1 Q. Okay. And I'm going to try to interpret that 2 in English so I understand it. I believe the first 3 step would be that BPD in children has to be identified 4 as a disorder that actually exists. Is that right? 5 A. The way that I would -- that it is 6 distinguishable and a disorder that they can require -- 7 identifying these disorders as indicated in DSM-4, they 8 have very specific criteria to ensure ultimately that 9 the right diagnosis is achieved as well as the right 10 treatment plan. 11 So, the way that I would read that is, yes, it 12 was to provide consistent and clear guidelines to 13 physicians who might be treating these children. 14 Q. Okay. The second step, if I'm trying to 15 interpret again in plain English, would be that to get 16 labeling for the FDA for this type of disorder, the FDA 17 has to acknowledge that the disease itself is treatable 18 in some fashion. Is that right? 19 A. That's what this statement says, yes, that it 20 would be treatable -- that it would be a treatable 21 diagnostic entity. 22 Q. And then there were discussions between J&J 23 and the Massachusetts General Hospital about the need 24 for a trial in the treatment of bipolar disorder in</p> | <p>1 Is that right? 2 A. Again, I don't remember if I was present for 3 that part of the discussion, because if it was a 4 day-long meeting and getting into this level of detail, 5 I'm just not certain. 6 But it appears that they talked about, to your 7 earlier point, what were the defining characteristics 8 of the disease that could be used for diagnosis, then 9 they also talked about what were the various designs 10 that should be taken to treat these children who may 11 also be on other medications that could be prescribed, 12 and also it goes on to note that apparently they had 13 conducted a trial with another medication in this same 14 population. 15 Q. And then the next sentence actually says, "It" 16 was agreed" between all those parties that we 17 previously identified "that the trial would need to be a 18 randomized, double blind, multicenter trial. . ." 19 Is that correct? 20 A. Yes, it does. It says, "In order to 21 provide -- I'm not sure why it's read that way. It's a 22 bit confusing. 23 Q. Okay. Turn to page 623, please, Mr. Gorsky. 24 The last heading on this page is "Plan for Center</p> |
| Page 82 | Page 84 |
| <p>1 children -- for children between the ages of six and 2 twelve years. Is that right? 3 MR. MURPHY: Where are you reading, 4 sir? 5 MR. McCORMICK: The next paragraph. 6 THE WITNESS: That's what the sentence 7 says in the paragraph, yes. 8 BY MR. McCORMICK: 9 Q. Then it says Johnson & Johnson and 10 Massachusetts General Hospital and various J&J 11 companies, including Ortho-McNeil and Janssen, 12 discussed various designs of what that trial would look 13 like, correct? 14 A. As it goes on to say, "Various designs were 15 discussed, including a comparison with psychosocial 16 intervention...and a crossover design with a stimulant 17 medication," and it's for children with ADHD. 18 Q. So, sometime during that meeting the 19 individuals at the meeting -- and you may or may not 20 have been there at that time, but the individuals from 21 Massachusetts General Hospital, from Janssen, from 22 Johnson & Johnson PRD, from McNeil Consumer, from 23 Ortho-McNeil -- all discussed how this particular 24 trial, the treatment of BPD in children, would look.</p> | <p>1 Activities." Do you see that? 2 A. Yes, I do. 3 Q. And the paragraph reads, "The tables on the 4 following two pages outline the specific initiatives 5 and timelines corresponding to the key areas and 6 initiatives mentioned below. The first table is a list 7 of specific activities of interest to J&J and 8 timeliness related to these activities. The second 9 table -- 10 A. Excuse me, it says "timelines." 11 Q. "Timelines," excuse me, "and timelines related 12 to the activities. The second table is a list of 13 potential research activities provided by MGH as part 14 of the original MGH proposal." 15 Did I read that correctly, except for my 16 "timeliness" and "timelines"?" 17 A. Yes. 18 Q. So, if we turn the page to the first table, 19 which is page 624, as it described in this executive 20 summary, this is a list of specific activities of 21 interest to J&J. Is that right? 22 A. It looked as though they were of interest to 23 both organizations, yes. 24 Q. Doesn't this sentence actually say the first</p> |

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| <p>1 table is a list of specific activities of interest to 2 J&J?</p> <p>3 A. Yes, but I'm assuming you didn't have both 4 these parties together, so that they were talking about 5 how they would collaborate on these various activities.</p> <p>6 Q. Okay. Well, it's curious you can interpret 7 this sentence that way, but on other -- that's fine, 8 we'll go forward.</p> <p>9 Table 1 then lists a number of center 10 objectives, doesn't it?</p> <p>11 A. Yes, it does.</p> <p>12 Q. To the left column? It says epidemiology and 13 diagnosis. Is that right?</p> <p>14 A. Yes, it does.</p> <p>15 Q. So, one of the specific activities of interest 16 to J&J was the description of symptom course of 17 pediatric bipolar disorder, correct?</p> <p>18 A. I'm confused on the tables. Let me just refer 19 back, because it appears as though there are two 20 different tables: One that's the MGH center goals and 21 objectives, which would be Table 1; and the second is 22 the proposed Johnson & Johnson Child and Adolescent 23 Pediatric Research Institute.</p> <p>24 In the paragraph it states, "The first table</p> | <p>1 Q. Then down at the bottom, let's look at numbers 2 twenty-nine and thirty. It talks about -- number 3 twenty-nine is "Development of Bipolar Disorder CME 4 Program." Is that right?</p> <p>5 A. Yes.</p> <p>6 Q. Number thirty is the implementation of a 7 bipolar disorder CME program, right?</p> <p>8 A. Yes, that's what's stated.</p> <p>9 Q. You can put Exhibit 11 aside, Mr. Gorsky. But 10 looking at Exhibit 11 and the previous emails, was the 11 goal of Janssen or Johnson & Johnson providing this 12 money to Massachusetts General Hospital for Johnson & 13 Johnson to get back a deliverable or something for 14 their investment?</p> <p>15 A. I think -- obviously there were mutual goals 16 of both organizations in this case. And I think that 17 the goal, as outlined on two charts, of understanding 18 this disease and in supporting and gaining information 19 and knowledge about how to appropriately study these 20 medications, again in an area where there was, as I 21 remember, little to no data on the use of drugs that 22 were being used in this category, that that was an 23 intended objective and something that would be 24 requested in return.</p> |
| <p style="text-align: center;">Page 86</p> <p>1 is a list of specific areas of interest to Johnson & 2 Johnson," so I'm just -- that relates to my comment. 3 Do you understand my confusion?</p> <p>4 Q. Yes, I see what you're saying. They're 5 reversed.</p> <p>6 A. Right.</p> <p>7 Q. Table 1 is Table 2.</p> <p>8 A. That's fine.</p> <p>9 Q. I'm glad you pointed that out. Let's turn to 10 625, he then, and look at the tables for the J&J 11 interests.</p> <p>12 A. Okay.</p> <p>13 Q. Okay? And one of the -- looking at the list of 14 specific activities of interest to J&J, the first one 15 is "Efficacy of Risperidone for Pediatric's Bipolar 16 Disorder."</p> <p>17 Do you see that?</p> <p>18 A. Yes, I do.</p> <p>19 Q. And another particular specific activity that 20 the center's going to carry out for J&J's interest is a 21 "Pediatric Bipolar Risperidone PK Study," right?</p> <p>22 A. Yes.</p> <p>23 Q. Number two?</p> <p>24 A. Yes.</p> | <p style="text-align: center;">Page 88</p> <p>1 Q. Was using Massachusetts General Hospital and 2 Dr. Biederman a back-door way for Johnson & Johnson to 3 disseminate information supporting the use of 4 antipsychotics, and particularly Risperdal, in the 5 treatment of mental disorders in the child and 6 adolescent population?</p> <p>7 MR. MURPHY: Objection to the form of 8 the question. You may answer.</p> <p>9 THE WITNESS: No, I don't think so. I 10 think that the use of Dr. Biederman and 11 Massachusetts General Hospital and Harvard, I 12 think two of probably the more esteemed academic 13 centers in this therapeutic category, let alone 14 the world, was an attempt -- and Dr. Biederman is 15 a key opinion leader -- was an attempt to get the 16 very best minds and the very best clinical 17 information developed so that we could meet better 18 criteria around diagnosis and treatment of this 19 particular population.</p> <p>20 BY MR. McCORMICK:</p> <p>21 Q. Let me ask it this way, Mr. Gorsky. I mean, 22 at the very least, Johnson & Johnson expected or hoped 23 that investing in Dr. Biederman and Massachusetts 24 General Hospital and this center would lead to wider</p> |

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| <p>1 diagnosis and treatment of child and adolescent mental 2 disorders. Is that right?</p> <p>3 MR. MURPHY: Objection to the form of 4 the question. You may answer.</p> <p>5 THE WITNESS: As outlined, I believe, 6 in these documents, I think our goal was to, yes, 7 have better diagnostic criteria for children who 8 are in need of treatment and to have better 9 therapeutic options for children who are in need 10 of treatment, and have them go through the 11 appropriate clinical development and testing and 12 methodology relevant to other types of therapy 13 that are available. I think those were shared 14 goals.</p> <p>15 BY MR. McCORMICK:</p> <p>16 Q. Was one of those shared goals a hope or 17 expectation by Janssen/Johnson & Johnson that Dr. 18 Biederman or Massachusetts General Hospital would be 19 able to come up with objective medical proof of mental 20 disorder in children and adolescents?</p> <p>21 A. I think, as reflected in these documents, it 22 was to try to improve the criteria that were used for 23 diagnosis -- that was clearly outlined, if I remember 24 correctly, in that -- which again was something that</p> | <p>1 THE WITNESS: Just give me a moment? 2 MR. McCORMICK: Yes, of course. Take 3 your time. You're in charge.</p> <p>4 THE WITNESS: Okay, I've gone through 5 about the first four or five pages.</p> <p>6 MR. McCORMICK: All right.</p> <p>7 BY MR. McCORMICK:</p> <p>8 Q. Mr. Gorsky, can you turn to page 861, which is 9 the -- well, strike that. Let's stay on the first 10 page.</p> <p>11 You see this document is called "Annual Report 12 2002: The Johnson & Johnson Center for Pediatric 13 Psychopathology at the Massachusetts General Hospital"?</p> <p>14 A. Yes, it does.</p> <p>15 Q. And the director is Joseph Biederman, M.D., 16 whom we've spoken about a couple times today, right?</p> <p>17 A. Yes.</p> <p>18 Q. Let's turn to page 861, please, Mr. Gorsky, 19 which is it is executive summary of the annual report.</p> <p>20 The first sentence of the overview says that 21 "The mission of the Center is...a strategic 22 collaboration between Johnson & Johnson and the 23 Pediatric Psychopharmacology Research Program at the 24 Massachusetts General Hospital." Is that correct?</p> |
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| <p>1 appeared to be needed in the field at the time versus 2 what the standard of practice was.</p> <p>3 Q. All right.</p> <p>4 (Exhibit Gorsky-12 was marked for 5 identification)</p> <p>6 BY MR. McCORMICK:</p> <p>7 Q. Mr. Gorsky, we've marked as Exhibit 12 a 8 multipage document that contains Bates labels 9 J-TXPandina 01859. It was previously marked as a 10 deposition exhibit in the deposition of Gahan Pandina 11 in the Texas litigation.</p> <p>12 It's a multipage document, so I would ask that 13 you glance through it until you feel comfortable and 14 let me know you're finished, then I will direct you to 15 certain areas that we're going to talk about.</p> <p>16 MR. MURPHY: Do you want to tell him 17 where it is you're going to talk about so he can 18 go there?</p> <p>19 MR. McCORMICK: Probably just the first 20 four or five pages.</p> <p>21 MR. MURPHY: Okay.</p> <p>22 THE WITNESS: Give me a moment, 23 please?</p> <p>24 MR. McCORMICK: Excuse me?</p> | <p>1 A. Yes, that's what it says.</p> <p>2 Q. It doesn't say Janssen or McNeil or 3 Ortho-McNeil. It says collaboration between Johnson & 4 Johnson and MGH, right?</p> <p>5 A. That's correct.</p> <p>6 Q. Okay, then let's move down to the next 7 paragraph.</p> <p>8 A. Can I make one statement to clarify that 9 comment?</p> <p>10 Q. Usually not, but sure, go ahead.</p> <p>11 A. The only reason I'm clarifying is because I 12 believe there were some people out of Johnson & 13 Johnson's Research Foundation that may have been 14 coordinating some of these trials as well, so there are 15 different entities that are involved here, hence the 16 name Johnson & Johnson.</p> <p>17 Q. Okay. Let's turn to the next paragraph, Mr. 18 Gorsky. It says, "An essential feature of the Center 19 is its ability to conduct research satisfying three 20 criteria..."</p> <p>21 Did I read that right?</p> <p>22 A. Yes.</p> <p>23 Q. And if we look at the third criteria, it says 24 "it will move forward the commercial goals of J&J." Is</p> |

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| <p>1 that correct?</p> <p>2 A. Well, there are several other criteria 3 mentioned before that.</p> <p>4 Q. Right, and your counsel can ask you about that 5 later. I'm just asking you, is one of the three 6 criteria the fact that "it will move forward the 7 commercial goals of J&J"?</p> <p>8 A. Yes.</p> <p>9 Q. So, this annual report from the Johnson & 10 Johnson Center For Pediatric Psychopathology from 2002 11 admits that information and research from this 12 supposedly unbiased research center is to benefit the 13 business of sales for Johnson & Johnson. Is that 14 correct?</p> <p>15 MR. MURPHY: Objection to the form of 16 the question. You may answer.</p> <p>17 THE WITNESS: It states that one of the 18 criteria among several others is to move forward 19 the commercial goals of J&J.</p> <p>20 BY MR. McCORMICK:</p> <p>21 Q. And commercial goals would include sales of 22 pharmaceuticals. Is that right?</p> <p>23 A. Yes, it would.</p> <p>24 Q. Okay. And then if we look at the next</p> | <p>1 they might prescribe.</p> <p>2 BY MR. McCORMICK:</p> <p>3 Q. The next says, "Considering that nearly all 4 psychiatric -- strike all that. I apologize.</p> <p>5 Mr. Gorsky, let's look at the next sentence, 6 where it says "Considering that nearly all psychiatric 7 medication use in children is off label. . ."</p> <p>8 Do you see that?</p> <p>9 A. Yes, I do.</p> <p>10 Q. And that would include Risperdal because in 11 2002, I think we've already agreed, Risperdal was not 12 approved for use in children and adolescents. Is that 13 right?</p> <p>14 A. Based upon our earlier conversation, it did 15 not have the specific indication at that time, that's 16 correct.</p> <p>17 I would think it's important to highlight, 18 however, that physicians do have the option of treating 19 patients with the medication that they feel is best 20 suited for a particular condition.</p> <p>21 Q. I understand that, but just because a doctor 22 can prescribe a drug off-label doesn't mean that 23 Janssen or Johnson & Johnson can promote it off-label, 24 correct?</p> |
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| <p>1 sentence from the annual report, it says "We strongly 2 believe that the Center's systematic scientific inquiry 3 will enhance the clinical and research foundation of 4 child psychiatry and lead to the safer, more 5 appropriate and more widespread use of medications in 6 children."</p> <p>7 Did I read that correctly?</p> <p>8 A. Yes, you did.</p> <p>9 Q. So, one of the hopes or one of the -- strike 10 that. One of the goals of this center's inquiry is to 11 lead to the more widespread use of medications in 12 children. Is that right?</p> <p>13 A. In addition to the areas that you mentioned 14 before, such as the safer, more appropriate and more 15 widespread use of medication in children, yes.</p> <p>16 Q. Okay. And if there is a more widespread use 17 of medication in children for mental disorders, I think 18 it would be a safe assumption, wouldn't it, that 19 antipsychotics would be prescribed to treat some of 20 those mental disorders? Is that right?</p> <p>21 MR. MURPHY: Objection to the form of 22 the question. You may answer.</p> <p>23 THE WITNESS: I can't speculate, not 24 knowing exactly what the conditions were and what</p> | <p>1 A. That's correct; and the converse of that is 2 true, as well, in that physicians would frequently use 3 these medications, without promotion associated, based 4 upon what they felt was best for patients.</p> <p>5 Q. But they know a lot more about the drugs if 6 people like Dr. Biederman are out there touting the 7 successes and efficacy of antipsychotics. Isn't that 8 right?</p> <p>9 A. No. I think that this is a condition where 10 there's children in need of treatment and where you 11 have parents and physicians looking for ways to try to 12 help resolve a very serious condition.</p> <p>13 And again, as I remember, at this time there 14 was little information regarding the use of drugs that 15 were commonly being used, where parents were at the end 16 of their rope, so there was a real need to better 17 understand how to diagnose and how to treat these 18 patients.</p> <p>19 Q. I want to make sure, though, that I understand 20 your agreement or disagreement, though.</p> <p>21 If Dr. Biederman is out there touting or 22 supporting the use of antipsychotics for the treatment 23 of mental disorders in children and adolescents, don't 24 you think that would more likely affect a physician or</p> |

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| <p>1 a psychiatrist who is thinking about using an 2 antipsychotic rather than not?</p> <p>3 MR. MURPHY: Object to the form of the 4 question, lack of foundation and does call for 5 speculation. You may answer.</p> <p>6 THE WITNESS: I'm not sure I understand 7 the question.</p> <p>8 MR. McCORMICK: Sure.</p> <p>9 BY MR. McCORMICK:</p> <p>10 Q. My question was, if Dr. Biederman comes out -- 11 and we don't have to say Risperdal. If Dr. Biederman 12 shows up at a meeting and says "I think you should use 13 antipsychotics for the treatment of bipolar disorder in 14 pediatrics or child and adolescents," don't you think 15 that is likely to affect those physicians and 16 psychiatrists that are at that conference to more 17 likely prescribe an antipsychotic medication?</p> <p>18 A. I think it requires some speculation, but I 19 would assume at this time physicians who are trying to 20 treat patients who had severe illness were looking for 21 additional data, were looking for additional 22 information on trying to treat them appropriately.</p> <p>23 Q. Dr. Biederman is a key opinion leader, right?</p> <p>24 A. (No response)</p> | <p>1 to a media that frequently questions the validity of 2 childhood disorders, genetic and brain imaging studies 3 are needed to show the validity of these disorders as 4 and brain disorders that respond to medication."</p> <p>5 Did I read that right?</p> <p>6 A. Yes, you did.</p> <p>7 Q. I presume that one of these medications would 8 be Risperdal. Is that correct?</p> <p>9 MR. MURPHY: Is your presumption 10 correct?</p> <p>11 BY MR. McCORMICK:</p> <p>12 Q. Mr. Gorsky, is one of these medications that 13 would be used to treat these childhood disorders 14 Risperdal?</p> <p>15 A. I think it could have been, along with others.</p> <p>16 Q. Okay. And then two sentences down the annual 17 report states that "Without such data, many clinicians 18 question the wisdom of aggressively treating children 19 with medications, especially those like neuroleptics, 20 which expose children to potentially serious adverse 21 events."</p> <p>22 Is that right, or did I read that correctly?</p> <p>23 A. Yes, you read that correctly from the 24 paragraph.</p> |
| <p style="text-align: right;">Page 98</p> <p>1 Q. Or was a key opinion leader at this time.</p> <p>2 A. Yes, Dr. Biederman would have been considered 3 a key opinion leader in this field.</p> <p>4 Q. So, I believe the basis for calling him a key 5 opinion leader is that he has some superior knowledge 6 to others that others tend to listen to regarding that 7 particular treatment or diagnosis or illness. Is that 8 right?</p> <p>9 MR. MURPHY: Objection to the form.</p> <p>10 Are you asking him whether that's his definition 11 of a key opinion leader?</p> <p>12 BY MR. McCORMICK:</p> <p>13 Q. Is that your definition of a key opinion 14 leader -- what's your definition of a key opinion 15 leader, Mr. Gorsky?</p> <p>16 A. My definition of a key opinion leader is 17 someone who has got strong academic and clinical 18 credentials and is very well studied in a particular 19 area and thought highly of by his or her peers.</p> <p>20 Q. And would you -- strike that. Mr. Gorsky, 21 let's turn to the next paragraph in paragraph 861.</p> <p>22 A. Okay.</p> <p>23 Q. The second sentence of this paragraph reads, 24 "Because parents, patients and clinicians are exposed</p> | <p style="text-align: right;">Page 100</p> <p>1 Q. And would one of those neuroleptics that we're 2 talking about there, one of those medications, be 3 Risperdal?</p> <p>4 A. I don't know, because Risperdal was usually 5 referred to as an atypical antipsychotic.</p> <p>6 Q. You never heard atypical antipsychotics 7 referred to as neuroleptics?</p> <p>8 A. I'm saying I have, but usually they were 9 distinct. I wouldn't have seen it in this case very 10 frequently at all.</p> <p>11 Q. Well, would Risperdal be considered an 12 aggressive treatment for children and adolescents?</p> <p>13 MR. MURPHY: By whom?</p> <p>14 MR. McCORMICK: By Mr. Gorsky.</p> <p>15 THE WITNESS: I really can't answer 16 that question.</p> <p>17 MR. McCORMICK: Okay.</p> <p>18 BY MR. McCORMICK:</p> <p>19 Q. This paragraph appears to be setting forth one 20 of the goals is for Johnson & Johnson, through this 21 center, to be able to prove objectively with a test 22 that a child has some sort of brain disorder or mental 23 illness. Is that correct?</p> <p>24 MR. MURPHY: The paragraph that begins</p> |

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| <p style="text-align: right;">Page 101</p> <p>1 "Equally important"?</p> <p>2 MR. McCORMICK: Yes.</p> <p>3 THE WITNESS: My understanding of this</p> <p>4 paragraph, in reading it, is that it was very</p> <p>5 important to, number one, better understand the</p> <p>6 underlying disease.</p> <p>7 And while there are a lot of different</p> <p>8 takes on it, I think that the published data would</p> <p>9 reflect that there was an increasing recognition</p> <p>10 of incidence of these diseases during this period,</p> <p>11 and that it was therefore necessary to better</p> <p>12 understand not only the disease itself and the</p> <p>13 underlying pathology and the etiology, but also</p> <p>14 what treatments should and could be used and how</p> <p>15 they should be tested for the appropriate use in</p> <p>16 those patients.</p> <p>17 BY MR. McCORMICK:</p> <p>18 Q. I think besides the treatment, one of the</p> <p>19 things that -- one of the goals here was to find some</p> <p>20 sort of objective diagnostic test to diagnose these</p> <p>21 mental disorders, right?</p> <p>22 A. Yes, I think it was referred to here several</p> <p>23 times about the importance of improving the diagnostic</p> <p>24 criteria to differentiate these diagnoses and, you</p> | <p style="text-align: right;">Page 103</p> <p>1 Issues"?</p> <p>2 A. Yes, I do.</p> <p>3 Q. The second bullet point underneath the first</p> <p>4 paragraph reads, "Developing and assessing the validity</p> <p>5 of screening tests for complex disorders such as</p> <p>6 comorbid ADHD, psychosis and pediatric bipolar</p> <p>7 disorder," right?</p> <p>8 A. That's correct.</p> <p>9 Q. So, that was one of the specific goals of this</p> <p>10 area regarding diagnostic testing, right?</p> <p>11 A. As outlined in this, yes.</p> <p>12 Q. The second bullet point says, "Implementing</p> <p>13 training programs --</p> <p>14 MR. MURPHY: It's the third.</p> <p>15 MR. McCORMICK: I'm sorry.</p> <p>16 By MR. McCORMICK:</p> <p>17 Q. Mr. Gorsky, let's look at the third bullet:</p> <p>18 point: "Implementing training programs for screening</p> <p>19 tools in continuing medical education programs</p> <p>20 targeting pediatricians and general psychiatrists."</p> <p>21 Do you see that?</p> <p>22 A. I do see that.</p> <p>23 Q. Okay. And then do you see the next bullet</p> <p>24 point? It says, "Analyzing baseline data from Janssen</p> |
| <p style="text-align: right;">Page 102</p> <p>1 know, ultimately to ensure that physicians understood</p> <p>2 what they were treating.</p> <p>3 Q. Right. But besides the actual recognition of</p> <p>4 the disorder, I think what we're looking for, what they</p> <p>5 were looking for here was to see if there was just one</p> <p>6 objective test, one way to figure out whether this</p> <p>7 mental disorder or this illness existed. Is that</p> <p>8 right?</p> <p>9 MR. MURPHY: Is that his understanding</p> <p>10 of a goal?</p> <p>11 MR. McCORMICK: Yes.</p> <p>12 MR. MURPHY: Do you understand the</p> <p>13 question?</p> <p>14 THE WITNESS: That's not my</p> <p>15 understanding. I think usually these diseases are</p> <p>16 very difficult and lie along a continuum. I'm not</p> <p>17 a full expert in the area, but from my exposure it</p> <p>18 was actually a constellation of diseases that had</p> <p>19 a lot of different inter-patient variability.</p> <p>20 MR. McCORMICK: Let's turn to the next</p> <p>21 page, page 862, Mr. Gorsky.</p> <p>22 BY MR. McCORMICK:</p> <p>23 Q. Do you see the heading there halfway down the</p> <p>24 page "Resolving Complex and Controversial Diagnostic</p> | <p style="text-align: right;">Page 104</p> <p>1 funded studies to validate affective disorder sub-type</p> <p>2 in the conduct disorder subpopulation."</p> <p>3 Do you see that?</p> <p>4 A. Yes, I do.</p> <p>5 Q. And it continues on to say, "Further</p> <p>6 validation of this group will alert physicians to the</p> <p>7 existence of a large group of children who might</p> <p>8 benefit from treatment with RISPERDAL." Is that right?</p> <p>9 A. That's what it says, yes.</p> <p>10 Q. So, one of the specific goals of the Center</p> <p>11 For Pediatric Psychopathology at the Massachusetts</p> <p>12 General Hospital was validation of the fact that these</p> <p>13 disorders existed and these children might benefit from</p> <p>14 the treatment of Risperdal, right?</p> <p>15 A. As I interpret this paragraph, yes, I think</p> <p>16 what they were trying to do was to develop better</p> <p>17 diagnostic criteria for patients who are suffering from</p> <p>18 a serious illness so that they could better be treated</p> <p>19 as the physician felt most appropriate.</p> <p>20 Q. Well, it specifically says here they may</p> <p>21 benefit from treatment of Risperdal. Is that correct?</p> <p>22 A. It says "who might benefit from treatment with</p> <p>23 RISPERDAL," yes.</p> <p>24 Q. And it doesn't say anything about Zyprexa or</p> |

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| <p style="text-align: right;">Page 105</p> <p>1 Seroquel there, does it? It just says Risperdal. Is 2 that right?</p> <p>3 A. Not in this particular one paragraph of a 4 multipage document, but it refers to the use of 5 multiple treatments throughout the document.</p> <p>6 Q. Well, do you think if this was called the Eli 7 Lilly Center for Pediatric Psychopathology, it would 8 say Zyprexa and not Risperdal?</p> <p>9 A. I can't speculate on that, but I know that, 10 based upon the comment, there is one other thing: That 11 they had actually tested olanzapine in the disorder. 12 It was in an earlier paragraph.</p> <p>13 Q. All right. Let's look at the -- well, strike 14 that. They may have tested Olanzapine and Zyprexa, but 15 they still only list Risperdal here as one of the 16 possible treatments, right?</p> <p>17 A. In this one particular paragraph of this 18 document, that's correct.</p> <p>19 Q. Well, let's look up at the two bullet points 20 above that. We talked about the validity of screening 21 tests, and it says it "will alert physicians about 22 disorders that exist which Risperdal --</p> <p>23 A. Excuse me, but where are you?</p> <p>24 Q. I'm sorry, the second bullet point, where it</p> | <p style="text-align: right;">Page 107</p> <p>1 document, about another five minutes. Is that 2 okay with you, Mr. Gorsky?</p> <p>3 THE WITNESS: That's okay.</p> <p>4 MR. McCORMICK: All right.</p> <p>5 BY MR. McCORMICK:</p> <p>6 Q. The last bullet point says, "Analyzing 7 databases at MGH to clarify the continuity between 8 childhood and adult disorders."</p> <p>9 Do you see that?</p> <p>10 A. Yes, I do.</p> <p>11 Q. And it says -- and this is interesting -- 12 "Showing how pediatric mania evolves into what some 13 have called mixed or atypical mania in adulthood will 14 provide further support for the chronic use of 15 RISPERDAL from childhood through adulthood."</p> <p>16 Do you see that?</p> <p>17 A. Yes, I do.</p> <p>18 Q. So, one the specific goals of the center is to 19 show that pediatric mania will evolve into mania in 20 adulthood, which will then require the chronic use of 21 Risperdal from childhood to adulthood. Is that right?</p> <p>22 MR. MURPHY: Objection to form of the 23 question, mischaracterizes the document, but you 24 may answer.</p> |
| <p style="text-align: right;">Page 106</p> <p>1 says --</p> <p>2 A. Where it says "Developing. . .</p> <p>3 Q. Yes. And then if you look at the second 4 sentence it says, "Once appropriately validated" -- 5 there is that word, "validated"; I think that's 6 important -- "the use of these screening tests will 7 alert physicians about disorders that exist which 8 RISPERDAL and CONCERTA might treat."</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And Risperdal is a Janssen drug, right?</p> <p>12 A. That is correct.</p> <p>13 Q. And Concerta is manufactured by who?</p> <p>14 A. Concerta was at that time sold by McNeil.</p> <p>15 Q. And McNeil is a Johnson & Johnson company, 16 right?</p> <p>17 A. Yes, it was; yes, it is.</p> <p>18 Q. All right. Let's go down to the last bullet 19 point on page 862 which starts "Analyzing databases."</p> <p>20 MR. MURPHY: Before you go forward, I 21 don't know how much more you have, but it's 12:50.</p> <p>22 MR. McCORMICK: Okay.</p> <p>23 MR. MURPHY: We agreed to 12:45.</p> <p>24 MR. McCORMICK: Let me finish up this</p> | <p style="text-align: right;">Page 108</p> <p>1 THE WITNESS: Again, I'm speculating on 2 the conclusion, but I think that the attempt here 3 was to understand the course of the disease; that 4 there were many in the field who believed that if 5 this disease was left untreated during a child and 6 adolescent stage, it could evolve into a much more 7 serious disease; therefore, better understanding 8 treatments earlier on could have a profound 9 positive effect on them.</p> <p>10 So, I think if that was the goal as 11 outlined, that was a reasonable research 12 objective.</p> <p>13 BY MR. McCORMICK:</p> <p>14 Q. And that may have been the research objective 15 of MGH, but this collaboration also required J&J to 16 have some goals.</p> <p>17 And I would assume J&J's goal would be that, 18 once you get somebody on Risperdal or being treated 19 with Risperdal in childhood, they would continue that 20 through adulthood. Wouldn't that be a goal of Johnson 21 & Johnson?</p> <p>22 MR. MURPHY: Objection to the form of 23 the question. You may answer.</p> <p>24 THE WITNESS: Our goal at Johnson &</p> |

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| <p style="text-align: right;">Page 109</p> <p>1 Johnson is to try to help patients live better, 2 longer and healthier lives. And if they could be 3 treated and their symptoms resolved earlier, 4 that's our absolute goal. 5 And of course, you know, we're a 6 company that also makes money, but our first goal 7 is outlined in the credo that we talked about 8 earlier, was to help patients. 9 BY MR. McCORMICK: 10 Q. And the continuation of Risperdal from 11 childhood to adulthood would be one of those -- 12 remember back in the beginning of this document we saw 13 the word there were commercial goals of Johnson & 14 Johnson, right? 15 A. Yes, I did see that. 16 Q. All right. And the continuation of a 17 Risperdal prescription from a young man or young boy 18 through adulthood would be a commercial goal of 19 Risperdal, right? Or of Johnson & Johnson, I'm sorry. 20 A. Successful treatment of patients, if they were 21 responsive on the medication, for them to stay 22 compliant on the medication would be one of our goals, 23 but only if the drug was working and the patient was 24 living better.</p> | <p style="text-align: right;">Page 111</p> <p>1 clearer end points, clearer diagnostic facts, so that 2 then they could hopefully be treated appropriately and 3 it could interrupt the course of the disease. 4 Q. Johnson & Johnson would not have invested this 5 \$500,000 per year in this center unless they were going 6 to get some kind of deliverable or benefit from it, 7 would they have? 8 A. I think we would expect to get a deliverable 9 in terms of getting better diagnostic criteria, data 10 that could confirm or show that it did not work in a 11 particular population. So that yes, ultimately then we 12 could achieve an indication and realize commercial 13 success. 14 I mean, that's what we do as a pharmaceutical 15 company, to ensure that we can continue to invest in 16 research and development, as we are today for things 17 such as Alzheimer's and cancer and other diseases. 18 It was only to ensure that we could go through 19 and collect the appropriate information so that we 20 could promote it accordingly. 21 Q. But the commercial goals of Johnson & Johnson 22 are way down on the credo, right? The final 23 responsibility is to the stockholders. The first 24 responsibility is to the patients, the "mothers and</p> |
| <p style="text-align: right;">Page 110</p> <p>1 Q. So, the way I interpret this is that Johnson & 2 Johnson and Massachusetts General Hospital and Dr. 3 Biederman are collaborating to validate a lifetime use 4 and treatment with Risperdal. Is that correct? 5 MR. MURPHY: Does he agree with your 6 interpretation? 7 BY MR. McCORMICK: 8 Q. Do you agree with my interpretation? 9 A. No, I do not agree with your interpretation. 10 Q. Okay. And one of the ways that Johnson & 11 Johnson was accomplishing that goal was to validate 12 some sort of objective criteria to conform or confirm 13 if an individual had a mental illness. Is that correct? 14 MR. MURPHY: Again, your 15 interpretation? 16 MR. McCORMICK: I'm asking -- 17 BY MR. McCORMICK: 18 Q. How about your interpretation, Mr. Gorsky? Is 19 that what you believed? 20 A. My interpretation is that we were working with 21 Massachusetts General, experts in the field, to 22 validate a diagnosis that was already being done 23 routinely without validated scales, potentially leading 24 to misdiagnosis; to improving those criteria to get</p> | <p style="text-align: right;">Page 112</p> <p>1 fathers and all others who use our products and 2 services," right? 3 A. Absolutely. And I think it's very consistent 4 with the criteria that we outlined here, was to try to 5 better the disease. 6 Again, these are children where the data, it's 7 my understanding, is fairly represented the increasing 8 need for treatment, and they're seeing an increased 9 number of diagnoses during this period with little to 10 no information available. 11 So, I think that was quite consistent with our 12 credo, to be working with an expert from Massachusetts 13 General Hospital and Harvard, one of the premier 14 institutions in the world, to define the best criteria 15 to help diagnose these patients so that they would end 16 up getting the very best treatment. 17 Q. The goal of the fact that by providing Dr. 18 Biederman with this amount of money he may be able to 19 convince others that bipolar disorder in children, for 20 example, is a real and treatable disease wouldn't have 21 benefited Johnson & Johnson financially because more 22 prescriptions for Risperdal would have been written 23 never came into the -- a factor into paying this \$500, 24 000?</p> |

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| <p style="text-align: right;">Page 113</p> <p>1 MR. MURPHY: Objection to the form of 2 the question. If you understand it, you may 3 answer it.</p> <p>4 THE WITNESS: I can't respond to the 5 question the way that you phrased it.</p> <p>6 MR. McCORMICK: Why don't we take a 7 break? I'll see if I can rephrase it and I'll ask 8 it when we come back.</p> <p>9 THE VIDEOGRAPHER: Going off the record 10 at 12:57 p.m.</p> <p>11 (At 12:57 p.m. there was a luncheon 12 recess taken)</p> | <p style="text-align: right;">Page 115</p> <p>1 the various dysfunctions and the long-term effects of 2 pharmacologic and other interventions."</p> <p>3 Did I read that correctly?</p> <p>4 A. Yes, you did.</p> <p>5 Q. Okay. And then two sentences down from that 6 it says, "It shows clinicians that aggressive treatment 7 is warranted because these disorders lead to 8 substantial disability." That's right? Is that right?</p> <p>9 A. That's what it says, yes.</p> <p>10 Q. Toward the end of that paragraph the very last 11 sentence says, "Specific goals of this area of work 12 include" and then there are a number of bullet points 13 underneath that. Do you see them?</p> <p>14 A. Yes, I do.</p> <p>15 Q. The second bullet point says, "Characterizing 16 the chronic, debilitating course of bipolar disorder to 17 help people understand need for aggressive treatment 18 such as RISPERDAL."</p> <p>19 Did I read that one correctly?</p> <p>20 A. Yes, you did.</p> <p>21 Q. So, that bullet point for the center is 22 specifically advocating for the use of Risperdal for 23 the treatment of bipolar disorder. Is that right?</p> <p>24 A. The way I read it, it says "such as</p> |
| <p style="text-align: right;">Page 114</p> <p>1 (AFTERNOON SESSION)</p> <p>2 -----</p> <p>3</p> <p>4</p> <p>5 THE VIDEOGRAPHER: Stand by, please.</p> <p>6 Back on the record at 1:44 p.m. This is tape four.</p> <p>7 BY MR. McCORMICK:</p> <p>8 Q. Mr. Gorsky, we're back from a lunch break. Do 9 you understand you're still under oath?</p> <p>10 A. Yes, I do.</p> <p>11 Q. And you still have Exhibit 12 in front of you. Is that right?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Can you turn to page 863 of Exhibit 12, 14 please?</p> <p>15 A. Yes.</p> <p>16 Q. In the middle of the page there is a heading 17 that says "Assessing The Severity And Chronicity Of 18 Child Psychopathology."</p> <p>19 Do you see that?</p> <p>20 A. Yes, I do.</p> <p>21 Q. The first sentence in the 2002 annual report 22 says that "We will study the natural course of 23 pediatric psychopathology, the long-term incidence of</p> | <p style="text-align: right;">Page 116</p> <p>1 RISPERDAL."</p> <p>2 Q. Okay. It doesn't mention Zyprexa or Seroquel, 3 though, does it?</p> <p>4 A. No, it did not, but it does say "for 5 aggressive treatment such as RISPERDAL."</p> <p>6 Q. Mr. Gorsky, one of the things that may help us 7 go a little faster this afternoon is, if I ask you a 8 yes or no question, if you could respond yes or no.</p> <p>9 If you have a disclaimer, Mr. Murphy or Mr. 10 Powers can ask you questions at the end, but that 11 question was a simple -- was a yes or no.</p> <p>12 MR. MURPHY: Well, to be fair to the 13 witness, if he needs to expand, then he will 14 expand to respond to your question.</p> <p>15 MR. McCORMICK: Well --</p> <p>16 MR. MURPHY: But fair point.</p> <p>17 MR. McCORMICK: I think so.</p> <p>18 BY MR. McCORMICK:</p> <p>19 Q. Let's move to the end of this page. Do you 20 see the heading at the bottom, "Clarifying The 21 Biological Basis Of Childhood Psychopathology," that 22 heading?</p> <p>23 A. Yes, I do.</p> <p>24 Q. And then underneath there is a paragraph that</p> |

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| <p style="text-align: right;">Page 117</p> <p>1 describes "One of the main obstacles to the medical 2 treatment of childhood disorders is the myth that they 3 simply reflect problems of family and culture rather 4 than dysfunctions of the brain." Is that right? 5 A. Yes, that's correct. 6 Q. And we talked about that theory a little bit 7 this morning. That's one of the things that Johnson & 8 Johnson and Dr. Biederman wanted to debunk, that myth. 9 Is that right? 10 A. I don't agree that it's just Johnson & Johnson 11 and Dr. Biederman. I believe that there are a number 12 of people in the field who had similar opinions. 13 Q. But for purposes of this Johnson & Johnson 14 Center For Pediatric Psychopathology Annual Report, 15 we're talking about Johnson & Johnson and Dr. 16 Biederman, right? 17 A. I'm assuming Dr. Biederman and his physicians 18 who may or may not be affiliated with him at the 19 institution. 20 Q. The next sentence says "We will help dispel 21 these myths using genetic and neuroimaging studies," 22 right? That's what the statement says, right? 23 A. Yes, it does. 24 Q. And we're back to the point of trying to find</p> | <p style="text-align: right;">Page 119</p> <p>1 JJRE 00054013. 2 I'm only going to have one quick question on 3 this document, so please take a quick glance at it, 4 then I'll direct you to that particular page. 5 MR. MURPHY: What page is that? 6 MR. McCORMICK: Page 4014 and 4015. 7 THE WITNESS: Okay. 8 BY MR. McCORMICK: 9 Q. For the record, Mr. Gorsky, this appears to be 10 an annual update of the J&J-MGH Center For Pediatric 11 Psychopathology Research. Do you see that? 12 A. Yes. 13 Q. And it looks like it was the executive summary 14 of a meeting that was held at Janssen in Titusville on 15 January 10th, 2003. Is that correct? 16 A. That's correct. 17 Q. And if we look at page 4014, again we see that 18 there were representatives from Mass General Hospital, 19 Janssen, McNeil Consumer and J&J PRD. Do you see all 20 of those? 21 A. Yes, I do. 22 Q. And that you gave the opening welcome at the 23 meeting, although we don't know how long you were 24 there. You did come and at least welcome everyone to</p> |
| <p style="text-align: right;">Page 118</p> <p>1 some sort of objective study or test that will show 2 mental disorder. Is that correct? 3 MR. MURPHY: Objection to the form of 4 the question. You may answer. 5 THE WITNESS: I'm not sure what 6 conclusion I can draw just from those couple of 7 sentences. 8 BY MR. McCORMICK: 9 Q. "These studies further validate childhood 10 disorders as medical conditions and thereby give 11 physicians more confidence in the use of medical 12 treatments." 13 Did I read that correctly? 14 A. Yes, I did. 15 Q. And Risperdal would be one of these medical 16 treatments. Is that right? 17 A. It's not mentioned here specifically. I'm 18 assuming that may be one of them, yes. 19 Q. You can put that document aside. 20 (Exhibit Gorsky-13 was marked for 21 identification) 22 BY MR. McCORMICK: 23 Q. Mr. Gorsky, I've handed you what's been marked 24 Exhibit 13. It is a multipage document Bates-labeled</p> | <p style="text-align: right;">Page 120</p> <p>1 the meeting, correct? 2 A. Yes. I don't recall it, but it's reflected in 3 the notes here. I'm assuming that's the case. 4 Q. Let's turn to page two, 4015. Do you see 5 there is a heading there that says "Other Areas of Key 6 Interest"?</p> <p>7 A. Yes, I do. 8 Q. And then underneath there is in bold the name 9 Janssen with five bullet points that were the key 10 interests for Janssen. Is that right? 11 A. Yes. 12 Q. And then underneath that do you see "McNeil" 13 and there are several more bullet points that stretch 14 over onto the top of the next page? 15 A. Yes, I do. 16 Q. And would we -- strike that. Would you 17 characterize these bullet points under areas of key 18 interest as the deliverables or objectives of this 19 collaboration that we discussed earlier in the 20 deposition? 21 A. You know, I don't remember. Just from looking 22 at this document, it's hard for me to draw a 23 conclusion. 24 Q. Okay. You can put that document aside, Mr.</p> |

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| <p style="text-align: right;">Page 121</p> <p>1 Gorsky. 2 (Exhibit Gorsky-14 was marked for 3 identification)</p> <p>4 BY MR. McCORMICK: 5 Q. I'm handing you what I've marked as Exhibit 6 14. Exhibit 14 is a March 20th, 2009 letter and 7 attachment from Charles Grassley, the ranking member of 8 the Committee on Finance in the US Senate, to Dr. Drew 9 Faust at Harvard and Dr. Peter Slavin at Mass General. 10 Again, I'm going to have very few questions, 11 but I'd ask that you just glance through the document, 12 then I'll direct you to where we need to go.</p> <p>13 MR. MURPHY: Brian, again, do you want 14 to tell him what page you're going to talk to and 15 then he can focus on that?</p> <p>16 MR. McCORMICK: When we get there, he 17 can take a look at those few pages.</p> <p>18 THE WITNESS: Okay.</p> <p>19 BY MR. McCORMICK: 20 Q. Mr. Gorsky, have you had a chance to review or 21 glance at Exhibit 14?</p> <p>22 A. I just did a quick review of the introductory letter.</p> <p>23 Q. Okay.</p> | <p style="text-align: right;">Page 123</p> <p>1 Q. It talks about the documents that were 2 reviewed by his staff, and it talks about pertaining to 3 matters of Dr. Biederman, Massachusetts General 4 Hospital and then the Johnson & Johnson Center For 5 Pediatric Psychopathology Research that we were just 6 talking about, right?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And then if we turn to the top of the 9 next page, which is page two of Senator Grassley's 10 letter, the first paragraph says, the first full 11 paragraph, "The slides raise potential concerns about, 12 among other matters, Dr. Biederman and the Center. My 13 main concern is whether or not the attached slides 14 suggest a predisposition to specific findings and 15 conclusions prior to the studies being commenced."</p> <p>16 Do you see that I read that right or 17 correctly?</p> <p>18 A. Yes, you did read that correctly.</p> <p>19 Q. The next sentence says, "My other concern is 20 whether or not NIH," the National Institutes of Health, 21 "was aware that Dr. Biederman was performing research 22 sponsored by J&J on psychiatric disorders when it 23 awarded him a grant to collaborate with other doctors 24 to study those same psychiatric disorders."</p> |
| <p style="text-align: right;">Page 122</p> <p>1 A. If you would like me to take more time to go 2 through the rest of the document?</p> <p>3 Q. No, I'll direct you to the attachments. The 4 introductory letter from Senator Grassley discusses 5 various conflicts of interest and related issues that 6 he is investigating into Massachusetts General Hospital 7 and Dr. Joseph Biederman and Harvard University. Is 8 that correct?</p> <p>9 A. That's what I was able to take away from the 10 letter that I just read, yes.</p> <p>11 Q. And if we look at the third paragraph of the 12 first page it says, "Recently, I was provided a number 13 of documents, including slides that became available 14 during ongoing litigation."</p> <p>15 Do you see that?</p> <p>16 A. Yes, I do.</p> <p>17 Q. Okay. And that refers to the litigation in New 18 Jersey regarding certain diabetes cases, or plaintiffs 19 who are alleged to have been injured by suffering from 20 diabetes as a result of taking Risperdal. Do you know 21 that?</p> <p>22 A. No.</p> <p>23 Q. Do you know anything about that litigation?</p> <p>24 A. No, I do not.</p> | <p style="text-align: right;">Page 124</p> <p>1 Did you see that concern of Senator 2 Grassley's?</p> <p>3 A. That's what it says in the paragraph, yes.</p> <p>4 Q. Do you recall any discussions around the time 5 of your first deposition in the Texas litigation, which 6 was January of 2009, on this letter that came out a 7 month or two afterwards from Senator Grassley regarding 8 Dr. Biederman and a potential conflict of interest in 9 his services being rendered to the Johnson & Johnson 10 center at Mass General Hospital?</p> <p>11 A. No, I do not. Based upon my review of a 12 number of these things, a good portion of these were 13 done in the period after I had departed.</p> <p>14 Q. Can we turn to page five of the letter? Do you 15 see where it talks about Attachments G and H?</p> <p>16 A. Yes, I do.</p> <p>17 Q. And it talks about a J&J slide entitled "2003 18 Business Plan." It's right in the middle of that 19 paragraph. It talks about "In one slide J&J notes that 20 it will leverage the MGH Center to raise awareness of 21 bipolar disorder in kids because 'use of psychotropic 22 medications in children and adolescents remains 23 controversial.'"</p> <p>24 Did I read that correctly?</p> |

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| <p style="text-align: right;">Page 125</p> <p>1 A. You did.</p> <p>2 Q. And the slide that they're discussing, which</p> <p>3 we can look at later, which is in the back of the</p> <p>4 attachments, appears to be similar to what I've been</p> <p>5 asking you about, which is J&J's efforts to use Dr.</p> <p>6 Biederman's research to increase awareness and thus</p> <p>7 prescriptions for Risperdal. Is that the way you read</p> <p>8 that?</p> <p>9 MR. MURPHY: Objection to the form of</p> <p>10 the question. You have not shown him the slide,</p> <p>11 but you're asking him --</p> <p>12 MR. McCORMICK: I'm asking him about</p> <p>13 this sentence.</p> <p>14 MR. MURPHY: But you asked him about</p> <p>15 the slide.</p> <p>16 BY MR. McCORMICK:</p> <p>17 Q. Can you answer that question from looking at</p> <p>18 that sentence?</p> <p>19 A. No, I cannot.</p> <p>20 Q. Okay, let's turn back to the slide, then. In</p> <p>21 the back you've got to find Attachment G, like Gorsky.</p> <p>22 A. Okay.</p> <p>23 Q. Mr. Gorsky, we're looking at Attachment G to</p> <p>24 Senator Grassley's letter and it says "Child and</p> | <p style="text-align: right;">Page 127</p> <p>1 Q. I understand.</p> <p>2 A. Because they could be prepared for a sub team</p> <p>3 and then another team later on, so I'm just not sure</p> <p>4 which version I would actually see.</p> <p>5 Q. All right. Let's turn to the next page, which</p> <p>6 is strategic initiatives. If we look down the left</p> <p>7 side, there is a column there that says "Use of</p> <p>8 psychotropic medications in child and adolescents</p> <p>9 remains controversial."</p> <p>10 Do you see that heading?</p> <p>11 A. Yes, I do.</p> <p>12 Q. Then down at the bottom it says, "Leverage</p> <p>13 J&J-MGH Pediatric Psychopathology Center to drive</p> <p>14 awareness."</p> <p>15 Do you see that?</p> <p>16 A. Yes, I do.</p> <p>17 Q. That strategic initiative appears to support</p> <p>18 some of the things we saw in the 2002 annual report,</p> <p>19 that J&J was intending to use the research from the</p> <p>20 Pediatric Psychopathology Center to increase awareness</p> <p>21 of mental disorders or illnesses in children in order</p> <p>22 to drive up Risperdal prescriptions. Is that correct?</p> <p>23 MR. MURPHY: You're asked him whether</p> <p>24 he agrees with what you just said?</p> |
| <p style="text-align: right;">Page 126</p> <p>1 Adolescent & Other New Business, 2003 Business Plan,</p> <p>2 July 29, 2002."</p> <p>3 Do you see that?</p> <p>4 A. I do see that.</p> <p>5 Q. On July 29, 2002 were you still a Janssen</p> <p>6 employee?</p> <p>7 A. Yes, I was.</p> <p>8 Q. And you were the president of Janssen at that</p> <p>9 time, right?</p> <p>10 A. Yes, I was.</p> <p>11 Q. And would a Child and Adolescent & Other New</p> <p>12 Business 2003 Business Plan have been presented at some</p> <p>13 point to you and/or the board of Janssen?</p> <p>14 A. What I can say is that at some point we would</p> <p>15 have had a discussion about the 2003 business plan.</p> <p>16 Whether that was this document or not, I can't confirm.</p> <p>17 Q. If Mr. DeLoria said during the course of his</p> <p>18 deposition that he believes that this business plan was</p> <p>19 presented to the board at one point, would you have</p> <p>20 reason to doubt his recollection since he would have</p> <p>21 been one of the people presenting this?</p> <p>22 A. No. If he remembered it that way, then of</p> <p>23 course -- there can be multiple copies of these</p> <p>24 different documents.</p> | <p style="text-align: right;">Page 128</p> <p>1 MR. McCORMICK: I'm asking him if that</p> <p>2 supports what we saw in the annual report.</p> <p>3 THE WITNESS: No, I don't think it</p> <p>4 supports what it says in the annual report. I</p> <p>5 think, as we talked about earlier, it was</p> <p>6 discussing an area of significant need and an</p> <p>7 awareness that there needed to be an increase in</p> <p>8 the knowledge and awareness of the condition.</p> <p>9 BY MR. McCORMICK:</p> <p>10 Q. Well, that word "leverage" has certain</p> <p>11 meaning, sorts of like "validate" we looked at in the</p> <p>12 annual report.</p> <p>13 You don't think the word "leverage" there</p> <p>14 means J&J is going to use the center for its own</p> <p>15 purposes to drive awareness of psychotropic medicines</p> <p>16 in child and adolescents?</p> <p>17 A. I don't know what the intended use of the word</p> <p>18 "leverage" was in this particular case. But certainly</p> <p>19 driving awareness of the disease and the condition that</p> <p>20 was affecting children at the time seems consistent.</p> <p>21 Q. And if we go back -- if you could keep your</p> <p>22 finger on that page but go back to the original page in</p> <p>23 Senator Grassley's letter, right above that the example</p> <p>24 we just looked at Senator Grassley says, "It seems,</p> |

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| <p style="text-align: right;">Page 129</p> <p>1 based upon a review of the J&J internal communications 2 that the collaboration between the Center and J&J was 3 driven more by business and marketing as opposed to 4 pure science and research."</p> <p>5 Did I read that correctly?</p> <p>6 A. Just a minute. I'm trying to find that 7 sentence.</p> <p>8 Q. I'm sorry.</p> <p>9 A. It's the second sentence.</p> <p>10 Q. Yes, it is.</p> <p>11 A. That's what this sentence says.</p> <p>12 Q. And do you agree with Senator Grassley?</p> <p>13 A. No, I do not.</p> <p>14 Q. You can put that document aside. Thank you, 15 Mr. Gorsky.</p> <p>16 (Exhibit Gorsky-15 was marked for 17 identification)</p> <p>18 BY MR. McCORMICK:</p> <p>19 Q. Mr. Gorsky, I've handed you what's been marked 20 as Exhibit 15, which is a printout from the website of 21 the -- I believe the Harvard Crimson is the Harvard 22 University newspaper. It a copy of a letter from Dr. 23 Biederman and Dr. Spencer and Wilens July 1st of last 24 year.</p> | <p style="text-align: right;">Page 131</p> <p>1 A. That's what it appears to be the case from 2 this letter.</p> <p>3 Q. So, after taking Johnson & Johnson's money to 4 open an institute that was supposed to be unbiased, Dr. 5 Biederman and his colleagues admitted that they made 6 mistakes and that they were in violation of a Harvard's 7 conflict-of-interest policies.</p> <p>8 Do you see that in the letter?</p> <p>9 A. Well, there are a number of things that they 10 state in that letter; that's one of them.</p> <p>11 Q. And they say "We accept responsibility for our 12 actions. . ."? Do you see that in the fourth 13 paragraph?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And do you see in the last line or the last 16 paragraph of their letter Dr. Biederman says, and his 17 colleagues, "We've learned a great deal from this 18 painful experience, and we profoundly hope that our 19 mistakes will benefit our colleagues by bringing 20 clarity and attention to these important issues"?</p> <p>21 Do you see that?</p> <p>22 A. Yes, I do.</p> <p>23 Q. After reading this letter, Mr. Gorsky, do you 24 still believe that Johnson & Johnson's annual</p> |
| <p style="text-align: right;">Page 130</p> <p>1 Can you take a minute to review that letter 2 and let me know when you're finished?</p> <p>3 A. Okay.</p> <p>4 Q. Mr. Gorsky, when I earlier characterized the 5 \$500,000 pavement to Mass General Hospital or the 6 \$200,000 that Janssen paid as a bribe, you disagreed 7 with me and your attorneys got a little upset.</p> <p>8 Am I right about that interpretation?</p> <p>9 MR. MURPHY: Which interpretation, a 10 bribe or the reactions to it?</p> <p>11 MR. McCORMICK: The reactions to it.</p> <p>12 THE WITNESS: I can't comment on the 13 reactions, but I disagree with the statement 14 regarding the bribe.</p> <p>15 BY MR. McCORMICK:</p> <p>16 Q. Have you had a chance to review Exhibit 15, 17 which is what is referred to here as the Doctor's 18 Apology Letter from Dr. Biederman?</p> <p>19 A. Yes, briefly.</p> <p>20 Q. After taking J&J's money and managing the 21 Johnson & Johnson Center For Pediatric Psychopathology 22 at Mass General Hospital, Dr. Biederman and some of his 23 other colleagues issued an apology for that conduct. 24 Is that correct?</p> | <p style="text-align: right;">Page 132</p> <p>1 contribution to the Center For Pediatric 2 Psychopathology at Mass General Hospital was not 3 improper?</p> <p>4 A. Based upon my review of the documents that we 5 just went through and my knowledge of it, yes, I do -- 6 I believe it was proper.</p> <p>7 And what I don't know, even in this letter, in 8 the apology, was Dr. Biederman's statement that "We 9 always believed that we were complying in good faith 10 with the institutional policies and that our mistakes 11 were honest ones. We now recognize that we should have 12 devoted more time and attention to the detailed 13 requirements of these policies and to their underlying 14 objectives."</p> <p>15 So, I'm not sure specifically what the exact 16 nature may have been, but I think, you know, based upon 17 even documents that we reviewed earlier, that we 18 certainly tried to follow in good faith clear 19 guidelines regarding the grants to ensure that they 20 were done appropriately.</p> <p>21 Q. But Senator Grassley and then Dr. Biederman 22 both felt they were not done properly. Is that 23 correct?</p> <p>24 A. I cannot draw that conclusion. I'm not sure</p> |

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1 whatever happened with the rest of the findings and I'm
 2 not -- and again, in this particular letter Dr.
 3 Biederman made a number of different statements.

4 Q. Does Johnson & Johnson continue to contribute
 5 to the Johnson & Johnson Center For Pediatric
 6 Psychopathology at Mass General Hospital?

7 A. I do not know.

8 Q. During the time frame of 2002 to 2003, we've
 9 established that you attended at least two meetings,
 10 including both annual updates of the J&J-MGH Center For
 11 Pediatric Psychopathology Research. Is that correct?

12 A. Yes. Based upon the notes that we saw, I
 13 attended some portion thereof of those two different
 14 meetings.

15 Q. And you approved the original invoice for
 16 \$200,000 or \$500,000, whatever we want to argue it was,
 17 for the first year of this annual contribution. Is
 18 that correct?

19 MR. MURPHY: Objection to the form of
 20 the question, mischaracterizes the evidence, but
 21 you may answer.

22 THE WITNESS: I signed off on the
 23 original request that noted it as being \$200,000
 24 for the Janssen portion for that time period.

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1 (Exhibit Gorsky-16 was marked for
 2 identification)

3 BY MR. McCORMICK:

4 Q. Mr. Gorsky, I've handed you what's been marked
 5 as Exhibit 16. If you would take a minute to review it
 6 and let me know when you're finished.

7 A. Yes. Okay.

8 Q. Mr. Gorsky, have you had a chance to review
 9 Exhibit 16?

10 A. I have.

11 Q. And Exhibit 16 states that it's "Minutes from
 12 Outcomes/Risperdal Brand Strategic Planning meeting" on
 13 October 19, 1998. Is that correct?

14 A. That's correct.

15 Q. And you were present at this meeting?

16 A. Yes, that's what it notes.

17 Q. And --

18 A. I don't recall this meeting, but it notes that
 19 I was present, yes.

20 Q. Do you have any reason to doubt you were
 21 present?

22 A. No.

23 Q. And in October of 1998, that looked like from
 24 your CV it would have been your transition between the

1 vice-president of marketing to the vice-president --
 2 from the vice-president in CNS. Does that sound about
 3 right?

4 A. Somewhere in that range, yes.

5 Q. So, it wouldn't have been unusual for you to
 6 be at a Risperdal brand strategic planning meeting in
 7 October of 1998, would it have been?

8 A. No, it would not have been.

9 Q. Let's look down at the sixth bullet point.
 10 See that? It starts "Prolactin levels."

11 A. Yes.

12 Q. It says "Prolactin levels: need to examine the
 13 effect of hyperprolactinemia on sexual dysfunction,
 14 menstrual disturbances, and long term effects (e.g.,
 15 osteoporosis, cardiovascular effects, fertility).
 16 Lilly has 3 trials investigating the effects of
 17 increased prolactin."

18 Did I read that correctly?

19 A. Yes, you did.

20 Q. So, does that mean to you that this would have
 21 been one of the issues that would have been discussed
 22 at this meeting on October 19, 1998?

23 A. Based upon the way this is pulled together, it
 24 is one of, it looks like, about twelve or thirteen

1 other issues that would have been discussed.

2 Q. Okay. Do you recall prolactin and the effect
 3 of prolactin on a person due to their ingestion of
 4 Risperdal being an issue in October of 1998?

5 A. I remember it being an issue related to
 6 Risperdal, nothing specific to the October 1998 time
 7 frame.

8 Q. Okay.

9 A. It was actually an issue with a number of the
 10 different drugs that were used in this category.

11 Q. And what it says here is that it needs to
 12 examine the effect of hyperprolactinemia, right? On
 13 sexual dysfunction and three or four other things. Do
 14 you see that?

15 A. Yes, I do.

16 Q. Do you know if that was ever done?

17 A. I'm not familiar with the details of all the
 18 research that was done in that area.

19 Q. But as of at least October of 1998 you, along
 20 with several other individuals, including Ramy Mahmoud
 21 and Janet Vergis, attended a meeting where prolactin
 22 and its effect were discussed relating to Risperdal.

23 Is that right?

24 MR. MURPHY: Objection to the form of

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1 the question. You may answer.
2

3 THE WITNESS: Yes. Again, it was
4 discussed in the context of a number of issues
5 that day, according to these minutes.

6 BY MR. McCORMICK:

7 Q. Well, I guess let's ask it this way: As of
8 October 1998, according to these minutes, at a meeting
9 you attended, Janssen knew that it needed to examine
10 the long-term effects of Risperdal on
11 hyperprolactinemia. Is that correct?

12 A. No, I don't conclude that from these remarks.
13 I think what I can conclude is, it says here, among
14 many recommendations, that prolactin levels is an area
15 that needed to be examined and the different effects as
16 you just read in the sentence. But again, it is one
17 among many different issues that were talked about and
18 discussed that day.

19 Q. Right, and one of the issues was that -- let
20 me see if maybe we spoke past each other: That as of
21 October 1998 Janssen knew -- or at least the
22 individuals at this meeting knew -- that as to the
23 issue of prolactin levels, it needed to be examined to
24 effect the -- examine the effect of hyperprolactinemia
on sexual dysfunction, menstrual disturbances, and

1 other long-term effects. Is that correct?

2 A. I think what this would have reflected, the
3 way these documents were usually used, is that you
4 would be taking notes; and then coming out of the
5 meeting you would, you know, then develop the specific
6 plan that you would have to address each one of these
7 issues.

8 So, I'm not -- this appears to me again --
9 they're minutes, they're observations, they're
10 comments, and that's one that's noted. I'm not sure
11 exactly how they were acted on following that.

12 Q. Well, I'm not asking you about whether you
13 actually did the studies or not -- I've talked to other
14 people about that -- and whether you knew or didn't
15 know, maybe we'll talk about later.

16 But all I'm asking you is, according to these
17 minutes from an October 1998 meeting, it says
18 "Prolactin levels: need to examine the effect of
19 hyperprolactinemia on sexual dysfunction, menstrual
20 disturbances, and long term effects," right?

21 A. And I agreed with you on that. I just didn't
22 know what context they were then taken or what was done
23 with them, but that's the comment that appear on here,
24 yes.

1 (Exhibit Gorsky-17 was marked for
2 identification)

3 BY MR. McCORMICK:

4 Q. Mr. Gorsky, I've marked as Exhibit 17 a
5 two-page email. If you could take a minute to review
6 it and let me know when you're finished?

7 A. Okay.

8 Q. Mr. Gorsky, have you had a chance to review
9 Exhibit 17?

10 A. Yes, I have.

11 Q. Do you see the first email in the email chain
12 is from Sally Berry, who was the associate director of
13 CNS medical affairs in December of 2000, to a number of
14 individuals, including yourself?

15 Do you see your name in the "to" list?

16 A. Yes, I do.

17 Q. And then the top email is from Sam Keith at
18 Janssen responding to Dr. Berry's email later that day,
19 and again you're included on the response. Do you see
20 your name in that list?

21 A. Yes, I do.

22 Q. In 2000, December of 2000, would you still
23 have been the vice-president of sales and marketing for
24 Janssen US?

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1 A. I believe so. I don't have my specific CV in
2 front of me, but I think I would have been.

3 Q. Okay. Dr. Berry's email, if we turn to the
4 second page of the document, is about her attendance at
5 a Lilly CME the night before. Do you see that?

6 A. Yes, I do.

7 Q. And then the very last line of the email, of
8 her email, says, "Emphasized in summary to think of
9 efficacy, prolactin and QTc when choosing an
10 antipsychotic."

11 Did I read that correctly?

12 A. Yes, you did.

13 Q. And then we turn back this email from Sam
14 Keith in response, and Sam says, "Sally, very nice
15 report on the Lilly party line. I do think that we
16 need to do more with our own data on prolactin. Ramy
17 has done a nice job here and there is enough material
18 from the endocrine world to help us here."

19 Do you see that?

20 A. Yes, I do.

21 Q. So, in October of 1998 there is a note that
22 Janssen needs to examine prolactin levels, and here we
23 are, almost a year and a half later, and Sam Keith is
24 saying that "we still need to do more with our own data

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1 on prolactin." Do you see that?

2 MR. MURPHY: Objection to the form of
3 the question. It mischaracterizes the document.
4 You may answer.

5 THE WITNESS: I'm not sure exactly what
6 Dr. Keith meant in his statement "I do not think
7 we need to do more -- or "I do think that we need
8 to do more of our own work [sic] on prolactin,"
9 because immediately after that he states that
10 "Ramy has done a nice job here and there is enough
11 material from the endocrine world to help us here.
12 Also has there been any progress on the Harvard
13 Study that we heard last summer on its
14 publication."

15 So, it seems contradictory. I'm not
16 sure what that means.

17 BY MR. McCORMICK:

18 Q. But I think we can agree that Dr. Keith
19 definitely says "we need to do more with our own data
20 on prolactin." Is that right?

21 A. He makes that statement in the sentence,
22 certainly, but the other sentences confuse me somewhat
23 as to exactly what he meant. Are we done --

24 Q. Yes, we're done with that one.

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1 (Exhibit Gorsky-18 was marked for
2 identification)

3 BY MR. McCORMICK:

4 Q. Mr. Gorsky, I've handed you what's been marked
5 as Exhibit 18. It's an email chain from January of
6 2001. Take a minute to review it, let me know when
7 you're finished.

8 A. Okay.

9 Q. Mr. Gorsky, have you had a chance to review
10 Exhibit 18?

11 A. Yes, I have.

12 Q. Do you see that on January 20th, 2001 you sent
13 an email to a number of individuals at Janssen US and
14 Janssen Belgium, including Ivo Caers, Janet Vergis,
15 Ludwig Hantson and Ramy Mahmoud?

16 A. Yes, I did.

17 Q. And the subject line is "Competitive
18 Activity"?

19 A. Yes, it is.

20 Q. And does this email concern Risperdal and
21 competition from other antipsychotics?

22 A. Yes, it covers my thoughts around our clinical
23 developments programs.

24 Q. If we turn to page two of the document, which

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1 is a continuation of your email, looking at the third
2 bullet point where you say "While we cannot respond to
3 each and every competitive jab...we should expect that
4 we will be challenged on a number of fronts due to our
5 market position...therefore we need to be proactive in
6 expanding on our strengths (efficacy long and short
7 term, agitation, weight gain, etc) and defending our
8 weak spots (prolactin, QTc, EPS)" and then an
9 elliptical or ellipsis.

10 Do you see -- did I read that correctly?

11 A. Yes, you did read that correctly.

12 Q. And in here you identify prolactin as one of
13 Risperdal's weak spots, correct?

14 A. Identified it as one of our weak spots
15 relative to our competitors and our positioning in the
16 marketplace at the time.

17 Q. In January of 2001, Mr. Gorsky, you would have
18 still been vice-president of sales and marketing for
19 Janssen US. Is that correct?

20 A. Yes, that's correct.

21 Q. And even then you knew that prolactin was a
22 weak spot for Risperdal. Is that correct?

23 A. I believe what I was referring to at that
24 time, there was a major promotional battle taking place

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1 between the various antipsychotics and their relative
2 positioning, and this was the way that the -- the
3 result of what our competitors were saying and
4 information in the marketplace.

5 So yes, that was generally, I think, an
6 accepted point of view, as I put in the paragraph.

7 Q. And what was a generally accepted point of
8 view?

9 A. Regarding the relative strengths and
10 weaknesses. I don't think it was necessarily based --
11 it was based on perceptions that had been developed
12 over the previous years.

13 Q. Well, Risperdal caused prolactin to be more
14 elevated than other antipsychotics, right?

15 MR. MURPHY: Objection to the form.
16 You may answer.

17 THE WITNESS: While I was working on
18 the brand, I don't remember that ever being
19 concluded with statistically significant data.

20 MR. McCORMICK: Okay. Let me see if you
21 can answer -- can you go back, Lance, to the
22 question I asked before the last answer?

23 (The record was read by the court
24 reporter as requested)

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1 BY MR. McCORMICK:

2 Q. Can you answer that with a yes or no, Mr.
3 Gorsky?

4 A. No.

5 Q. But you called it a weak spot. Is that
6 correct?7 A. I called it a weak spot in the context of
8 competitive positioning, not based upon concrete,
9 significant data at the time.10 Q. Do you know if in this time frame, 2000/2001,
11 Janssen was working toward -- strike that.12 (Exhibit Gorsky-19 was marked for
13 identification)

14 BY MR. McCORMICK:

15 Q. Mr. Gorsky, I'm handing you what's been marked
16 as Exhibit 19. It contains Bates labels JJPHD
17 00008768.18 If you could take a minute to glance through
19 the document, particularly at the pages with Bates
20 labels 8778 and 8779 and the second page and first page
21 of the document, we'll direct you to some questions.

22 A. 778 and 779?

23 Q. Yes, and the second page of the document.

24 A. Just a moment, please.

1 you can find that for me?

2 A. It was noted as 47.8 percent.

3 Q. And what was it for haloperidol?

4 A. 57.8 percent.

5 Q. And then next under that they say there was a
6 statistically significant difference between the
7 treatment groups and the number of patients with
8 prolactin-related adverse events, too. Is that
9 correct?

10 A. That's correct.

11 Q. And what was the percentage of
12 prolactin-related adverse events for Risperdal?

13 A. It says five percent.

14 Q. And what was it for haloperidol?

15 A. 0.4 percent.

16 Q. So, let's turn back to page 8779, please. Do
17 you see in the middle there 3.1.3, it has
18 "Prolactin-related adverse events"?

19 A. Yes, I do.

20 Q. And then it has the same percentages down
21 there in the third or fourth row, the total number of
22 patients with prolactin-related AEs? It has five
23 percent for risperidone and 0.4 for Haloperidol?

24 A. Yes, it does.

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1 Q. Sure.

2 A. So, the first two pages and then did you say
3 8778 and 8779?

4 Q. Exactly.

5 A. Okay.

6 Q. Mr. Gorsky, have you had a chance to review
7 Exhibit 19?8 A. The first two pages and the two pages that you
9 outlined, yes.10 Q. And you see that these are the topline results
11 for the Risperdal trial RIS-INT-35?

12 A. Yes.

13 Q. And the title of that is "Double-blind
14 evaluation of Risperidone versus haloperidol on the
15 long-term morbidity of early psychotic patients."

16 Do you see that.

17 A. Yes.

18 Q. The date is May 17th, 2002 in the top
19 left-hand corner?

20 A. Yes.

21 Q. If we turn to page two at the topline results
22 summary, it has two numbers there I want to talk about.
23 The first one in the second paragraph: What was the
24 rate of EPS-related adverse events and risperidone, if1 Q. And that's fourteen patients out of 278 had
2 prolactin-related adverse events in this clinical
3 trial. Is that right?

4 A. That's correct.

5 (Exhibit Gorsky-20 was marked for
6 identification)

7 BY MR. MURPHY:

8 Q. Mr. Gorsky, I've handed you what we've marked
9 as Exhibit 20, which is an email chain from May of
10 2002. In fact, I think all the emails are from May 1st
11 of 2002.12 Can you take a minute to review that and let
13 me know when you're finished?

14 A. Okay.

15 Q. Mr. Gorsky, have you had a chance to review
16 Exhibit 20?

17 A. Yes, I have.

18 Q. You see there is a May 21st email from
19 somebody at PRD in Belgium forwarding the topline
20 results for RIS-INT-35 to a number of individuals. Is
21 that correct?

22 A. That's correct.

23 Q. And that email, then, is forwarded on to a
24 number of other people, and it's then forwarded on to

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| | |
|--|---|
| <p style="text-align: right;">Page 149</p> <p>1 you from Joe Scodari. Is that right? 2 A. That's correct. 3 Q. And Joe Scodari has a JJCUS email address. 4 What did that mean at the time? 5 A. He was located at corporate -- I think it's 6 Johnson & Johnson corporate US. 7 Q. And Mr. Scodari says "FYI. Doesn't look 8 promising," does it? That's what his email to you 9 says, doesn't it? 10 A. It says "FYI. Doesn't look promising." 11 Q. And that's the topline results we just looked 12 at in Exhibit 19, correct? 13 A. That's correct. 14 Q. And then you forward it on to Janet Vergis and 15 say "Please do not pass along yet...FYI," correct? 16 A. That's correct. 17 Q. So, you've told Ms. Vergis not to forward on 18 the topline results that contain a clinical trial 19 showing that there was a statistically significant 20 difference between the number of prolactin-related 21 adverse events in Risperdal versus haloperidol. Is 22 that correct? 23 A. I did so consistent with the guidance in the 24 original email that says "Please -- just one second.</p> | <p style="text-align: right;">Page 151</p> <p>1 BY MR. McCORMICK: 2 Q. Mr. Gorsky, we're back from a break. You 3 understand you're still under oath? 4 A. Yes, I do. 5 Q. We're looking at Exhibits 19 and 20, which 6 have to do with the clinical trial RIS-INT-35. We were 7 talking about a drug called haloperidol. The common 8 name for that is Haldol. Is that correct? 9 A. Yes, it is. 10 Q. That was a Janssen product or a -- it was a 11 J&J product before Risperdal? 12 A. It was originally discovered by Dr. Paul 13 Janssen and originally promoted by, I believe, McNeil 14 Pharmaceutical. 15 Q. And the study that we looked at, if you could 16 turn to page -- I'm not trying to pull a fast one on 17 you. I know I told you not to look at this page, but 18 turn to page 8770. 19 MR. MERVIS: What exhibit are you on? 20 MR. McCORMICK: Nineteen. 21 MR. MERVIS: And the page, please? 22 MR. McCORMICK: 8770, page three. 23 MR. MERVIS: Thank you. 24 MR. McCORMICK: You're welcome.</p> |
| <p style="text-align: right;">Page 150</p> <p>1 It says, "May we ask you not to distribute these 2 topline results on a large scale at this moment. This 3 study has been performed under the guidance of an 4 advisory board of external experts. Moreover, there is 5 a massive amount of additional data in the database. 6 We therefore would like to review the present data and 7 plan for additional analysis with this advisors before 8 we bring the data in the public domain. We plan this 9 review tentatively end of June."</p> <p>10 Q. And then right above that Ms. Van Hove wrote 11 that "The results contained in this document have been 12 verified by the statisticians and programmers of 13 Biometrics. Nevertheless, these results may differ 14 slightly from what will appear in the final Clinical 15 Study Report," right? 16 A. That's what it says, yes. 17 Q. Okay. 18 MR. McCORMICK: Why don't we take a 19 break? 20 THE VIDEOGRAPHER: Going off the record 21 at 2:45 p.m. This is the end of tape four. 22 (A brief recess was taken) 23 THE VIDEOGRAPHER: Stand by, please. 24 Back on the record at 2:55 p.m. This is tape five.</p> | <p style="text-align: right;">Page 152</p> <p>1 BY MR. McCORMICK: 2 Q. Down at the bottom it has the demographic and 3 baseline characteristics of the study. Do you see 4 that. 5 A. Yes. 6 Q. And the age in years is one of the 7 demographics. Is that right? 8 A. That's correct. 9 Q. And the median age or mean age for this study 10 was what? 11 A. The mean age for the total group was 25.4 12 years and the median age was 24. 13 Q. Are you familiar with the fact that the label 14 for Risperdal now states that Risperdal may affect 15 children more seriously in the elevation of prolactin 16 than it affects adults? 17 MR. MURPHY: Objection to the form of 18 the question. You may answer. 19 THE WITNESS: I'm not sure I understand 20 your question. 21 MR. McCORMICK: Sure. 22 BY MR. McCORMICK: 23 Q. Risperdal elevates prolactin. I think we can 24 all agree on that, right?</p> |

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1 A. I was confused around where it appears in the
2 package insert or when.

3 Q. This study, which says that five percent of
4 the clinical trial participants had prolactin-related
5 adverse events, correct? That's what this trial says?

6 A. And that's what this trial concluded based on
7 the tables we reviewed, yes.

8 Q. And this clinical trial involved primarily
9 adults. The ages are -- median age is 25.4, right?

10 A. That's correct.

11 Q. Okay. Do you know that Risperdal affects
12 children more seriously in the elevation of prolactin
13 than it affects adults?

14 A. I wasn't aware of the statistical data or even
15 the trending data, and I don't remember what our label
16 said.

17 I remember there being language around
18 prolactin clearly in our label when I was working on
19 it, and I also remember there being language, some
20 language -- I don't remember the specific language --
21 around use in children. I don't know if there was a
22 specific call-out in the children area about the side
23 effects.

24 Q. I want to ask you one more question about

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1 Exhibit 20, Mr. Gorsky.

2 A. That's the email?

3 Q. That's the email, I'm sorry, yes.

4 A. Okay.

5 Q. Let me start over. Mr. Gorsky, can you turn
6 to Exhibit 20, which is the email that we were looking
7 at earlier?

8 A. Yes.

9 Q. Mr. Scodari's email to you says "Doesn't look
10 promising." Is that right?

11 A. That's what it says, yes.

12 Q. Do you recall any discussion with Mr. Scodari
13 about why he thought the results didn't look promising?

14 A. No, I don't recall.

15 Q. You can put that document aside. Thank you,
16 sir.

17 (Exhibit Gorsky-21 was marked for
18 identification)

19 BY MR. McCORMICK:

20 Q. Mr. Gorsky, I've handed you a document that's
21 been marked as Exhibit 21. It is a 2001 Risperdal Base
22 Business Plan. Can you take a minute to glance through
23 it? Then I'll direct you to certain pages to ask you
24 questions.

1 A. Okay. I haven't had a chance to review the
2 entire document the. I can certainly take -- if we're
3 going through it in detail, I can. . .

4 Q. No, I'll direct you to certain pages. Mr.
5 Gorsky, can you turn to page 260, which is the
6 executive summary of the base business plan for 2001?

7 A. Yes.

8 Q. And this business plan is Risperdal only.
9 It's not any other drug in the CNS franchise, right?

10 A. I haven't had a chance to look at it entirely.
11 But I'm assuming, based upon the title, that that's the
12 case.

13 Q. In the first paragraph, about the sixth line,
14 it says -- the fifth line: "Overall growth in the
15 schizophrenia segment in the market is flat." Is that
16 correct?

17 A. That's correct.

18 Q. And that would have been a problem for
19 Risperdal in 2001?

20 A. I don't know what you mean by your conclusion
21 that it's a problem.

22 Q. Well, the overall growth in the schizophrenia
23 segment of the market is flat: That means that
24 Risperdal is not going to be selling more prescriptions

1 for schizophrenia, right?

2 MR. MURPHY: Objection to the form of
3 the question. You may answer.

4 THE WITNESS: No, I believe what it was
5 referring to is that the schizophrenia portion of
6 the market tended to be a fairly well-defined
7 segment; therefore, it was not growing as fast as
8 others, but there still would be shifts in share
9 among the various agents that would be used in
10 that category.

11 BY MR. McCORMICK:

12 Q. The next sentence says, "Although the
13 RISPERDAL Base business is rooted in the Schizophrenia
14 marketplace, another fast-growing portion of this
15 market is in children and adolescents. The
16 child/adolescent antipsychotic segment (19 years and
17 under) is growing at a rate of 17% and is currently
18 valued at approximately \$340 million. Use of RISPERDAL
19 in this segment has grown 50% in the past two years,
20 and prescriptions in this category account for 20% of
21 overall RISPERDAL use."

22 Did I read that right?

23 A. Yes, you did.

24 Q. And because of the growth of the child and

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1 adolescent antipsychotic market, did Risperdal begin
 2 to -- did Johnson & Johnson begin to approach this
 3 market in a different way in or around 2001?

4 MR. MURPHY: Objection to the form of
 5 the question, lack of foundation. You may answer.

6 THE WITNESS: Not that I'm aware, other
 7 than we were continuing to pursue the clinical
 8 development program of the product in that area.

9 MR. McCORMICK: Okay.

10 BY MR. McCORMICK:

11 Q. Turn to the top of the next page, please, page
 12 261. See where it says "RISPERDAL use in the
 13 child/adolescent population is exploding"? Is that
 14 correct?

15 A. That's what it says, yes.

16 Q. Then down below it says, "Key Base Business
 17 Goals -- well, strike that. I'm sorry.

18 "RISPERDAL use in the child/adolescent
 19 population is exploding," but in this time frame,
 20 2001/2002, Risperdal is not indicated by the FDA for
 21 any pediatric use, is it?

22 A. Again, we did not have the specific
 23 indication, as we discussed earlier, until 2006. I
 24 don't remember exactly what the labeling said regarding

1 activities regarding the development as well as the
 2 promotion of Risperdal.

3 That being said, all of our actual promotion
 4 to the physicians would follow what was outlined in our
 5 package insert and all of our materials went through a
 6 significant review process, and that's the way our
 7 representatives were trained. And in an area such as
 8 this, this is a marketer versus a sales representative,
 9 their language.

10 And when in fact physicians took it upon
 11 themselves and their patients to prescribe the product,
 12 their statement would in fact be correct: To ensure
 13 that when a physician made that choice, that it was in
 14 fact Risperdal.

15 Q. You were the vice-president of sales and
 16 marketing at this time frame, 2000/2001, correct?

17 A. It depends when this was actually previewed.
 18 I don't know if there's a date on here or not, but I
 19 think that's the case, yes.

20 Q. You became the vice-president of sales and
 21 marketing in December of 1999, correct?

22 A. My statement related to -- I believe I became
 23 president of Janssen in late 2001.

24 Q. Okay. Even if a doctor can prescribe

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1 use in children, but as I discussed earlier, there was
 2 a significant -- there appeared to be a significant
 3 increase in the recognition of this condition in
 4 children and adolescents during this time, which was
 5 substantiated by data and its occurrence.

6 And physicians have an opportunity to use a
 7 treatment that they perceive to be appropriate and
 8 effective in a particular patient population, and
 9 that's clearly what we were seeing happening in this
 10 area.

11 Q. Look down at the heading that says "Key Base
 12 Business Goals and Objectives." Do you see that?

13 A. Yes.

14 Q. And the fifth of the Key Base Business Goals
 15 says "Grow and protect share in child/adolescents." Is
 16 that right?

17 A. Yes, that's correct.

18 Q. My question is, how can Johnson & Johnson grow
 19 a share in a child and adolescent market when the drug
 20 isn't even indicated for use in the child and
 21 adolescent market?

22 A. Well, my interpretation of that is, this is in
 23 fact a marketing plan, not a selling plan. As a
 24 marketing plan, its intent is to cover a wide range of

1 Risperdal for an off-label use and create a market
 2 share, you still cannot or Janssen still cannot market
 3 the drug to that doctor, a pediatric doctor, for use,
 4 can you?

5 A. To the best of my knowledge, we did not
 6 promote the use of Risperdal in that patient vis-a-vis
 7 direct promotional programs.

8 Q. Okay. Even though it says grow the share in
 9 child and adolescents on this bullet point as a key
 10 base business goal, right?

11 A. Yes -- again, this was a marketing document,
 12 not a sales-direction guideline.

13 Q. Well, it's a marketing document, but it's
 14 still an internal Janssen document. You don't think
 15 the people in marketing knew that Janssen didn't have
 16 -- or Risperdal didn't have an indication for a
 17 pediatric use?

18 MR. MURPHY: Objection to the form of
 19 the question, argumentative. You may answer
 20 again.

21 THE WITNESS: I'm certain they realized
 22 that. And they realize, also, that all of the
 23 promotional materials would go through a review
 24 process to ensure that they were consistent with

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1 our labeling.

2 This, the marketing plan, would include
3 programs now, but also for the future, associated
4 with ongoing development of the compound.

5 BY MR. McCORMICK:

6 Q. Let's look down at the key base business core
7 strategies right underneath there. And here in the
8 2001 Risperdal base business plan, it says, number two,
9 "Protect and Expand Reach/Partnership with Key Customer
10 Base," right?

11 A. Why.

12 Q. Listed underneath there, what's the third
13 bullet point listed underneath there?

14 A. It says child and adolescents.

15 Q. So, this is another place where Janssen is
16 attempting to protect what it already has, but also
17 expand its reach into this key customer base, right?

18 A. That's what the document says.

19 Q. Okay. Was the indirect marketing through Dr.
20 Biederman and Massachusetts General Hospital part of
21 this business strategy or business goal?22 MR. MURPHY: Objection to the form and
23 lack of foundation. You may answer.

24 THE WITNESS: I think the activities

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1 treat a very difficult condition among children and
2 adolescents; where, to the best of my knowledge, none
3 of the antipsychotics were approved and yet there were
4 little to no other options for physicians to use in a
5 particular population; hence, they were making a
6 decision, based upon their knowledge and understanding
7 of the different data, to treat these patients in what
8 they considered to be the best possible way, which is
9 different than promoting the product in a particular
10 area under an indication.11 Our marketing plans frequently covered a
12 significant period of time. It would be updated
13 annually. But many of the ongoing activities in here,
14 particularly as it related to clinical development
15 programs, could span a two- or three-year period, hence
16 some of the language and some of the other activities
17 that are mentioned in here.18 Q. So, you're saying that because it says "Grow
19 and protect share in child/adolescents," what this
20 marketing plan is doing is looking down the road
21 several years? It's not talking about right then in
22 2001/2002?23 A. I don't know because I don't remember the
24 specifics, but it would not be unusual for it to be

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1 with Dr. Biederman were done vis-a-vis a grant and
2 a CME program. They were not in direct marketing.

3 BY MR. McCORMICK:

4 Q. Can you turn to the top of page 262? It's the
5 next page, please. The bottom paragraph, the fourth
6 line there talks about the child and adolescent
7 antipsychotic market, which is nineteen years and
8 under, and it says Risperdal currently has over a 54%
9 share of that market.

10 Do you see that?

11 A. Yes, I do.

12 Q. And even when the drug is not -- strike that.
13 Even though Risperdal doesn't have an indication by the
14 FDA for child and adolescent at this time frame, when
15 Risperdal has fifty-four percent of the market, does
16 the credo still apply? Does the protection for
17 Janssen's patients and mothers and fathers still apply?18 A. Absolutely our credo still applies. I think
19 in this case there are a couple of important facts that
20 are relevant to that statement.21 I mean, first of all, there is the issue of
22 how that particular market is defined, and I believe
23 they're defining it as on that particular portion of
24 the market, again, where physicians are attempting to

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1 construed in that way.

2 Q. Turn to page 267, please. Do you see the
3 heading in the middle of the page that says "2000
4 Lessons Learned for 2001"?

5 A. Yes, I do.

6 Q. And the second-to-last bullet point there
7 says, "Short-term opportunities in pediatrics and the
8 acute setting exist." Is that right?

9 A. Yes, I do see that.

10 Q. So, the short-term opportunities in pediatrics
11 doesn't sound like a long-term goal of getting an
12 approval or an indication for a child and adolescent
13 use, does it?14 MR. MURPHY: Objection to the form of
15 the question. Your question is does he agree with
16 your statement?17 MR. McCORMICK: I'm asking him if he can
18 interpret it that way.19 MR. MURPHY: That's something
20 different. It's your question.21 THE WITNESS: I don't know how to
22 interpret that. If he was referring to the
23 business; if he was referring to educating
24 physicians, providing them different diagnostic

41 (Pages 161 to 164)

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1 guidelines, I'm not sure.
 2 BY MR. McCORMICK:

3 Q. When you say "he," who do you think wrote this
 4 in 2000/2001?

5 A. I meant that in a non-gender-specific manner.
 6 I'm not sure who would have written it.

7 Q. You didn't write this, did you?

8 A. No.

9 Q. Would you have reviewed it?

10 A. I don't recall.

11 Q. I didn't ask you if you remembered reviewing
 12 it. Would you have reviewed it in your position?

13 A. I don't know. There were numerous documents.
 14 At this time I believe, again, I was head of marketing
 15 for all of our brands, and so I'm not sure if this was
 16 the specific final version, if I would have reviewed
 17 it. I can't sit here today and say that conclusively.

18 Q. Okay. You were in marketing for a long time,
 19 Mr. Gorsky. When you see the word "short-term," does
 20 that mean to you a goal within a year or does that mean
 21 a longer-term goal of a couple years?

22 A. I don't know what they intended when they said
 23 "short-term" in the construct that they have in
 24 opportunities.

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1 Q. Turn to page 269, please. At the bottom there
 2 is a heading there that says "One-year Marketing
 3 Objectives." Do you see that?

4 A. I do see that.

5 Q. And then do you see the fourth bullet point
 6 says, "Grow and protect share in child/adolescents via
 7 medical education initiatives and effective
 8 rep-targeting with a year-end exit share of 70%"?

9 Do you see that?

10 A. I do see that.

11 Q. So, the one-year goal here is to grow the
 12 child and adolescent market from fifty-three percent or
 13 fifty-four percent up to seventy percent. Is that
 14 right?

15 A. I would not interpret it that way.

16 Q. Okay.

17 A. I think what it says is grow and protect share
 18 in the market, which again to me could mean the
 19 existing market, as physicians have deemed to prescribe
 20 it within that market, not necessarily growing the
 21 market.

22 Q. I'm not talking about growing the market. I'm
 23 even talking about, if you have a fifty-four percent
 24 share and they want to get to a seventy percent share,

1 that's the way you're interpreting it, right?

2 A. That's the best that I can interpret it
 3 sitting here today.

4 Q. Okay -- well, how else are you going to get
 5 from fifty-four to seventy percent if you're not out
 6 there promoting the drug?

7 MR. MURPHY: Objection to the form of
 8 the question. It's argumentative. You may
 9 answer.

10 THE WITNESS: Again, as I said earlier,
 11 I think that this is a marketing plan separate
 12 from a sales-direction plan. And I know that
 13 based upon the guideline reviews that we did
 14 earlier, that our direction going to our sales
 15 force was very consistent with our labeling.

16 At the same time we were generating
 17 data -- and appropriately so, I believe -- because
 18 of the need for additional data in this patient
 19 population. And frankly, we felt that we had the
 20 very best alternative for those patients and I
 21 know that we had the most data at that time in
 22 that particular population.

23 So, as physicians became aware of that
 24 data and made their own decision to treat patients

1 within that category, I'm sure that we felt that
 2 we had the best option.

3 It wasn't a matter of promoting. These
 4 were decisions that physicians were making in the
 5 best interests of their patients.

6 So, this marketing plan is very
 7 different from a sales direction. All of our sales
 8 direction would have to go through, again,
 9 significant review, and I'm not sure when and how
 10 this would have made its way to that audience.

11 BY MR. McCORMICK:

12 Q. Mr. Gorsky, even if this is a marketing plan
 13 instead of a sales plan, I can't get by the fact that
 14 it says here one-year marketing objectives: Grow the
 15 share in children and adolescents via medical
 16 initiatives and effective rep-targeting with a year-end
 17 exit share of seventy percent.

18 This is for a time -- strike that. Strike all
 19 that. Let's go through this again.

20 Once again, Mr. Gorsky, was Risperdal approved
 21 in 2001 for any pediatric or child and adolescent use?

22 MR. MURPHY: Objection, asked and
 23 answered a number of times. Don't answer it
 24 again.

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1 BY MR. McCORMICK:

2 Q. Mr. Gorsky, would you agree with me that
3 Risperdal was not indicated for a child and adolescent
4 use in 2001?5 A. I would agree, based upon our discussions
6 earlier today and the knowledge of the insert changes
7 even after I left, that the specific indication for
8 child and adolescent was provided, I believe, in 2006,
9 as per your earlier comment.10 What I don't remember are the specific
11 guidelines around its use prior to that point in time
12 in the child and adolescent population.

13 Q. Okay.

14 A. As you know, package inserts have a number of
15 different areas that may characterize use in different
16 areas without specifically recommending or
17 contraindicating the use of a drug in a particular
18 patient population. That's really the choice of the
19 physician based upon the patients as they present.20 MR. McCORMICK: Lance, would you repeat
21 the question and see if we can get a yes or no?22 (The record was read by the court
23 reporter as requested)

24 MR. McCORMICK: You can answer, Mr.

1 MR. McCORMICK: It's answered with a
2 three-paragraph qualifier. I just want a yes or a
3 no.4 THE WITNESS: I tried to answer the
5 best of my ability to make sure that my full
6 intent was communicated.

7 MR. McCORMICK: Okay.

8 BY MR. McCORMICK:

9 Q. Mr. Gorsky, who would have prepared this base
10 business plan, if not you, in that market -- in that
11 division, if you recall?12 A. At this time I believe we agreed earlier that
13 I was the head of sales and marketing for Janssen,
14 which meant I was likely responsible for ten different
15 brands, so it certainly would not have been me.16 And it would have been several of the
17 different product managers and/or directors on the
18 Risperdal brand team that would likely have worked
19 together to produce this document.20 Q. Looking at this one-year marketing objective
21 that we just looked at and went over a couple of
22 times --

23 A. What page are you referring to?

24 Q. Page 269. I believe you're still there?

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1 Gorsky.

2 THE WITNESS: I answered that in the
3 first part of my last question.

4 BY MR. McCORMICK:

5 Q. The answer was it was not indicated, right?

6 A. It did not have the specific indication as
7 awarded in 2006. However, I don't know the specific
8 language that it had regarding recommendations for use
9 in a younger population prior to 2006.10 Again, a package insert has a number of
11 different areas and comments around various patient
12 populations that physicians will use as one source of
13 information when prescribing.14 Q. And I understand that's a great explanation of
15 what a package insert says. I'm just asking the simple
16 question whether the FDA had approved Risperdal for a
17 child and adolescent or pediatric use, whatever you
18 want to do, in 2001.19 It has nothing to do with whatever other
20 safety standards or language is in the package insert.
21 I'm just asking that simple question.22 MR. MURPHY: And I'm going to object to
23 the question, if that's the question that's on the
24 table, as asked and answered.

1 A. Yes.

2 Q. It was the fourth bullet point underneath
3 "One-Year Marketing Objectives" on page 269.4 Would you agree with me that a goal to
5 increase market share in a population with no
6 indication is off-label marketing?7 A. I can't answer that question the way you've
8 phrased it.

9 Q. Why not?

10 A. Because in this context, again, I don't know
11 what time frame we're talking about, nor do I
12 understand the full intent of the statement in a
13 marketing-plan context different from being a selling
14 context.15 Q. Let me just ask you generally, then: Would
16 you agree with me that a goal to increase market share
17 in a population with no indication, having nothing to
18 do with Risperdal, is off-label marketing?19 A. If that was the sales direction to our sales
20 representative, then that would be inconsistent with
21 our policy.22 Q. Inconsistent with your policy because it would
23 be off-label marketing, correct?

24 A. It would be off-label promotion.

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| <p style="text-align: right;">Page 173</p> <p>1 Q. Off-label promotion, okay. You can put that 2 aside.</p> <p>3 Mr. Gorsky, do you have any contact with Dave 4 Mallegol any more?</p> <p>5 A. I may get a holiday email from him once a year 6 wishing me a happy holiday season. That's about it.</p> <p>7 Q. Does he still work for Janssen or Johnson & 8 Johnson, or is he retired?</p> <p>9 A. He's retired from Johnson & Johnson.</p> <p>10 Q. Do you know that Mr. Mallegol had his 11 deposition taken in the Texas litigation, the same case 12 where you had your deposition taken?</p> <p>13 A. No, I was not aware of that.</p> <p>14 Q. And did you know that Mr. Mallegol, during a 15 break in one of the depositions, was talking to a US 16 Attorney who was present at the deposition, during a 17 break like we take during these depositions, and said 18 to that US Attorney or Assistant US Attorney that he 19 had a very challenging job when he took over healthcare 20 compliance at Janssen?</p> <p>21 Did anyone ever tell you that?</p> <p>22 A. No, I was never told about that comment, 23 although that comment -- it was a significant endeavor 24 across the industry at that time because of the number</p> | <p style="text-align: right;">Page 175</p> <p>1 MR. MURPHY: Same objection. You may 2 answer the question.</p> <p>3 THE WITNESS: I can't speculate on the 4 full context of his discussion.</p> <p>5 MR. McCORMICK: Well --</p> <p>6 THE WITNESS: I think it was a challenge 7 across the industry, given some of the changes 8 that were put into play. So, without additional 9 perspective on his comment, I really can't -- it 10 appears to be a sidebar conversation.</p> <p>11 BY MR. McCORMICK:</p> <p>12 Q. It was a sidebar conversation. The reason I 13 was curious is because you sort of explained his first 14 comment about it being challenging as to the whole 15 industry, but then Mr. Mallegol did follow it up with a 16 comment that he had to change the culture at Janssen. 17 And I wanted to know what you thought about 18 that, whether you thought at the time that you put him 19 into that position whether you thought a change in the 20 culture would have made that type of job challenging.</p> <p>21 A. Again, I don't understand the full context of 22 Dave's sidebar conversation. I just know we worked 23 together very collaboratively and he made a lot of 24 contributions during his time.</p> |
| <p style="text-align: right;">Page 174</p> <p>1 of changes that were instituted, and we did try to set 2 a very high standard in adapting the American Medical 3 Association, the trade organization PhRMA guidelines at 4 the time.</p> <p>5 And Dave was not only at Janssen, took the 6 leadership role, but also became involved in the 7 industry in helping to develop, establish, set up and 8 enforce those standards.</p> <p>9 Q. And did you know that Mr. Mallegol, after 10 saying it was a very challenging job, said it was a 11 challenge, in part, because there had to be a change in 12 the culture at Janssen?</p> <p>13 MR. MURPHY: Does he know that he said 14 that?</p> <p>15 MR. McCORMICK: That Mr. Mallegol told 16 that to an Assistant US Attorney.</p> <p>17 MR. MURPHY: Objection to the form of 18 the question and lack of foundation, but you may 19 answer.</p> <p>20 THE WITNESS: No, I'm unaware of that.</p> <p>21 BY MR. McCORMICK:</p> <p>22 Q. Would it surprise you that Mr. Mallegol said 23 that his job was changing because of the change in the 24 culture that was required at Janssen at that time?</p> | <p style="text-align: right;">Page 176</p> <p>1 (Exhibit Gorsky-22 was marked for 2 identification)</p> <p>3 BY MR. McCORMICK:</p> <p>4 Q. Mr. Gorsky, let me hand you another document. 5 It's been marked as Exhibit 22.</p> <p>6 A. I can't quite read all of the slides, just 7 because of the way they're printed, with my glasses.</p> <p>8 Q. We'll work with that. Mr. Gorsky, can you 9 turn back to -- do you see the slide on the first 10 page -- the tab "2001 Tactical Plan (Risperdal)"?</p> <p>11 A. Yes.</p> <p>12 Q. Is that your handwriting?</p> <p>13 A. No, that's not.</p> <p>14 Q. Okay. Let's turn to page 9385. Do you see 15 that third slide at the bottom, "Child & Adolescent 16 Market Summary"?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Mr. Gorsky, I'm going to have to go back. 19 Let's go back to page 9383, which is the front slide. 20 Do you see the cover slide of this presentation, 21 "Risperdal Base 2001 Tactical Plan"?</p> <p>22 A. Yes.</p> <p>23 Q. RBD meeting of January 2001?</p> <p>24 A. Yes, I do.</p> |

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| <p style="text-align: right;">Page 177</p> <p>1 Q. What does RBD stand for? 2 A. I believe that would have meant our regional 3 business directors. So that in the field you have 4 representatives, a group of representatives that report 5 to a district manager, then a district manager would 6 report to -- so, it would be basically your second-line 7 managers, your senior-most sales managers.</p> <p>8 Q. Would this have been the type of meeting that 9 you would have participated in in this time frame? 10 A. Not usually, no.</p> <p>11 Q. Okay, let's turn to page 9385. If we look at 12 the third slide, "Child & Adolescent Market Summary," 13 right?</p> <p>14 A. Yes.</p> <p>15 Q. Customers are prescribing Risperdal in the 16 child and adolescent market, correct?</p> <p>17 A. Correct.</p> <p>18 Q. So, at the time Janssen -- Johnson & 19 Johnson -- knew that customers were prescribing 20 Risperdal in this market, even though it didn't have an 21 FDA indication for a child and adolescent use, correct?</p> <p>22 A. Yes. There is a significant amount of other 23 information, but I'll hold my response.</p> <p>24 Q. Let's turn to page 9386, please, "2001 Base</p> | <p style="text-align: right;">Page 179</p> <p>1 BY MR. McCORMICK: 2 Q. Well, let me ask you this question, Mr. 3 Gorsky: I think you already told us that this is a 4 presentation that would be made to the regional 5 business directors, right? 6 A. That's what was outlined on the front page, 7 yes. 8 Q. And somebody, whoever presented this on behalf 9 of Janssen to the regional business directors, is 10 telling them to protect and expand partnerships with 11 key customers, including child and adolescent market, 12 right? 13 A. I would need to go back and read what they're 14 explaining to them because it's being very selective in 15 what you're specifying versus what's actually in these 16 slides. 17 Q. Well, this is the -- if you turn to the 18 previous page, this is the start of a . . . 19 A. To answer your question completely, I would 20 need to go to page 385, on the bottom slide, where it 21 talks about child and adolescent market summary, and it 22 states "Customers Rxing RISPERDAL in child/adolescent 23 market. Presentation should increase field awareness," 24 this presentation.</p> |
| <p style="text-align: right;">Page 178</p> <p>1 Business Goals," the middle slide? 2 A. Yes? 3 Q. It says "Grow awareness of RISPERDAL use in 4 child/adolescent market via medical education." 5 Do you see that? 6 A. Yes, I do. 7 Q. That's a little bit different than the way we 8 saw it phrased in the 2001 base business plan, right? 9 This one says "Grow awareness of RISPERDAL use," right? 10 A. That's what it says. I don't recall what it 11 said in the previous one, but . . . 12 Q. Now let's turn to page 9387. Go to the top 13 slide. The top slide lists some base business key 14 strategies. 15 The second large bullet point says "Protect 16 and expand partnerships with key customers," and then 17 underneath there it says "Child and Adolescents" is the 18 second bullet point. Can you read that one? 19 A. Yes, I can. 20 Q. And that's similar to what we saw in the 2001 21 base business plan, which was expanding partnerships 22 with a different number of groups of markets, right? 23 MR. MURPHY: Object to the form of the 24 question. You may answer.</p> | <p style="text-align: right;">Page 180</p> <p>1 "Take-away is NOT to begin discussing 2 children/adolescents with customers.... Instead.. 3 Implement CME with customers expressing interest in 4 this area...And..Understand customers needs when Rxing 5 antipsychotics in this area." 6 Q. So, the idea is, get the customers in, the 7 doctors, into a CME and present them with information 8 about Risperdal so that they go out and prescribe 9 Risperdal, right? 10 MR. MURPHY: Objection to the form of 11 the question. You may answer. 12 THE WITNESS: No, that's not my 13 understanding. 14 BY MR. McCORMICK: 15 Q. Well, that's what it says, "Implement CMEs 16 with customers expressing interest in this area." 17 MR. MURPHY: That wasn't your question. 18 MR. McCORMICK: Okay. 19 BY MR. McCORMICK: 20 Q. Let's turn to page 392. Do you see that 21 second bullet point, "Metrics and Milestones Analysis 22 of CME Programs"? 23 MR. MURPHY: Second slide. 24 MR. McCORMICK: Second slide.</p> |

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| 1 THE WITNESS: Yes, but I can't 2 read... 3 BY MR. McCORMICK: 4 Q. I can't read the bottom, either. I'm just 5 going to ask you a broad question: Did Janssen track 6 metrics and milestones that would have resulted from 7 CME programs? 8 MR. MURPHY: Objection to the form of 9 the question, lack of foundation. You may answer. 10 THE WITNESS: Not that I'm aware of. 11 BY MR. McCORMICK: 12 Q. Can you turn to the next page, 393? Do you see 13 it has "Base Business Key Strategy #2" for Risperdal? 14 A. Yes, I see that. 15 Q. And then it has that same heading we looked at 16 before, "Protect and expand reach/partnerships with key 17 customers" and this time it lists pediatrics underneath 18 there. Do you see that? 19 A. Yes, under "expand reach/partnerships with key 20 customers." 21 Q. Right. And at this time Risperdal doesn't 22 have an indication for any pediatric use, does it? 23 MR. MURPHY: What time would that be, 24 counsel? | 1 following topics per Region: schizophrenia, affective, 2 and child & adolescent." Is that correct? 3 A. That's correct. 4 Q. Okay. Then we're looking at the bottom slide, 5 the child and adolescent plan slide on this page. The 6 objective is to reach psychiatrists who treat child and 7 adolescent mental disorders with CME education, 8 correct? 9 A. Correct. 10 Q. And the field involvement is for the sales 11 reps. That's what they're supposed to do, correct? 12 A. I can't tell from this particular slide if -- 13 usually the representatives would not be directly 14 involved with the CME education programs. 15 I don't remember the specific parameters on 16 what exactly they could and could not do, but they were 17 part of our overall healthcare compliance training. 18 Q. It says "identify these customers in your 19 database; invite to attend programs!" Who else would 20 have identified customers? 21 A. It could have been members of the marketing 22 team or medical affairs team that worked with, you 23 know, physicians that actually work with them in the 24 field. |
| Page 182 | Page 184 |
| 1 MR. McCORMICK: Excuse me? 2 MR. MURPHY: What time would that be? 3 MR. McCORMICK: 2001 tactical plan. 4 THE WITNESS: No, it does not. 5 MR. McCORMICK: Okay. 6 BY MR. McCORMICK: 7 Q. Let's turn to page 394. See the top slide 8 says "Protect & Expand Reach Key/Partnerships Key 9 Customer Base"? 10 A. Yes, I do. 11 Q. Then it has underneath there "Home Office 12 Advisory Forum." That would be one of the ways that 13 Janssen would protect and expand the partnerships with 14 the key customer base, correct? 15 A. I'm not -- are you referring to HOV? 16 Q. Top slide, I'm sorry. 17 A. Okay. 18 Q. 394, page 394. 19 A. I see. Yes, okay. 20 Q. And then in the bottom -- it's tough to read; 21 I'm hoping you can get it. It says description -- has 22 a description of the different programs, eighteen 23 programs, three per region, "streamline and targeted at 24 specific disease states. Will include each of the | 1 Q. But somebody would have identified customers 2 or potential customers, put them into the Janssen 3 database to make sure they got invited to these CME 4 programs. Is that correct? 5 MR. MURPHY: Objection to the form of 6 the question. You may answer. 7 THE WITNESS: As I recall, there are a 8 number of the different ways that those lists 9 could be developed: Based upon people who had 10 signed up for them at previous medical-education 11 events, knowledge of people treating in the field. 12 I don't remember the exact construction of those 13 lists. 14 BY MR. McCORMICK: 15 Q. This plan that was developed and presented to 16 the regional business directors in January of 2001, a 17 large portion of it, or at least a portion of it that 18 you and I just reviewed and went over, was directed at 19 the child and adolescent market. Is that correct? 20 A. I would not agree with your characterization. 21 There were a few slides out of this entire program. 22 I'm not sure if it was -- I forgot the exact words that 23 you used. 24 Q. I withdrew the "large." I just said a portion |

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| <p style="text-align: right;">Page 185</p> <p>1 of it.</p> <p>2 A. Oh, a portion of it, okay.</p> <p>3 Q. And education programs, home office visits,</p> <p>4 other scientific presentations did not just come forth</p> <p>5 from and by scientists presenting the informational</p> <p>6 data for education, did it?</p> <p>7 MR. MURPHY: Objection to the form of</p> <p>8 the question, lack of foundation, but you may</p> <p>9 answer.</p> <p>10 THE WITNESS: I can't speculate on that</p> <p>11 question.</p> <p>12 BY MR. McCORMICK:</p> <p>13 Q. I think what we saw here instead was really</p> <p>14 Johnson & Johnson using education, in context with</p> <p>15 prescribing physicians specifically, to expand their</p> <p>16 market of Risperdal to children and adolescents. Is</p> <p>17 that correct?</p> <p>18 A. No, I disagree. I think in this case -- I</p> <p>19 mean, based upon my review, it was an attempt,</p> <p>20 consistent with the guidelines that were discussed</p> <p>21 earlier, it was to better understand the disease</p> <p>22 category in an area of significant unmet need, to look</p> <p>23 at the different treatment options that were already</p> <p>24 being used, and it was done in the appropriate CME</p> | <p style="text-align: right;">Page 187</p> <p>1 A. As I had mentioned earlier, and I think some</p> <p>2 of the language in here is clearly -- these are sales</p> <p>3 and marketers, so there's going to be some of that</p> <p>4 language in here. But I think on other slides it</p> <p>5 clearly says this is not to be used in a selling</p> <p>6 situation, such as back on page 385, where that was</p> <p>7 clearly discussed.</p> <p>8 It was also highlighted, as you can see on</p> <p>9 slides such as 388, where it says field involvement or</p> <p>10 no rep involvement; on page 389, no rep involvement;</p> <p>11 then it actually has the sales representative message</p> <p>12 where it clarifies what would be part of the sales</p> <p>13 message, as well as on page 390 and on 391.</p> <p>14 So these were -- they were, I believe, in</p> <p>15 their best-faith effort trying to provide them both an</p> <p>16 overall view of the marketing plan as well as what the</p> <p>17 selling plan was and what should and should not be used</p> <p>18 in the field.</p> <p>19 Q. And for example, page 388, that diabetes</p> <p>20 reprint, it says "No rep involvement." What does that</p> <p>21 mean?</p> <p>22 A. It says that that's not sales-promotional</p> <p>23 material that should be used. That was allowed, I</p> <p>24 believe, at that time under CME to perhaps be mailed or</p> |
| <p style="text-align: right;">Page 186</p> <p>1 context.</p> <p>2 In this particular document, these were our</p> <p>3 senior-most sales leaders who may also have some input</p> <p>4 into the marketing plan, and this particular discussion</p> <p>5 is not translated into sales direction, as noted on</p> <p>6 several of these different slides that we went through</p> <p>7 that I mentioned that you had passed over about what</p> <p>8 should and should not be used in the promotion, but</p> <p>9 rather provided for them to have a broader</p> <p>10 understanding of the field and what to expect over the</p> <p>11 next several years.</p> <p>12 Q. Let's turn to page 387. Do you see the bottom</p> <p>13 slide there, "Differentiate RISPERDAL From the</p> <p>14 Competition"?</p> <p>15 A. Yes, I do.</p> <p>16 Q. And it says this is a "Ziprasidone Destruction</p> <p>17 Plan," right?</p> <p>18 A. Yes.</p> <p>19 Q. Ziprasidone is Geodon, right?</p> <p>20 A. I believe so.</p> <p>21 Q. Okay. Is this part of a medical education</p> <p>22 presentation to be made to better educate your regional</p> <p>23 business directors, a destruction plan of how to get</p> <p>24 rid of Geodon?</p> | <p style="text-align: right;">Page 188</p> <p>1 distributed to a physician vis-a-vis another means</p> <p>2 within all the appropriate regulatory and legal</p> <p>3 guidelines, but did not have direct representative</p> <p>4 involvement.</p> <p>5 So, my point in this is that this was a</p> <p>6 discussion among our senior-most sales leaders. Some</p> <p>7 of it's strategic and marketing in nature and some of</p> <p>8 it more specific selling and directional in nature, and</p> <p>9 that's why we're using different material.</p> <p>10 But I would also assume that any of the</p> <p>11 materials that was used coming out of this that would</p> <p>12 be provided to our representatives would go through the</p> <p>13 our own rigorous legal, regulatory and compliance</p> <p>14 review process that ultimately were all submitted to</p> <p>15 the FDA.</p> <p>16 Q. And do you really believe that, if sales reps</p> <p>17 were given handouts or reprints or whatever and told</p> <p>18 not to distribute them to doctors, that that actually</p> <p>19 never happened?</p> <p>20 A. Based upon the guidelines at that time -- and</p> <p>21 I would have to refresh my memory of the specifics -- I</p> <p>22 believe that they were allowed, under FDAMA, which was</p> <p>23 tested in court and was approved under the guidelines,</p> <p>24 to distribute reprints that were enclosed in a</p> |

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| <p style="text-align: right;">Page 189</p> <p>1 container, not to discuss them. 2 And yes, as we also saw earlier, there were 3 clear guidelines with the representatives that if they 4 did use those such materials, it could be considered, I 5 believe, a Class 1 offense that could lead to them 6 being terminated from the job. 7 Q. And at that time do you recall any sales 8 representatives being terminated for that type of 9 off-label marketing?</p> <p>10 MR. MURPHY: At any point during his 11 tenure or at a year in particular?</p> <p>12 MR. McCORMICK: During his tenure.</p> <p>13 THE WITNESS: Yes, I do remember sales 14 representatives being terminated for violation of 15 our policies. I don't remember the specific names 16 or each instance, but I do remember that there 17 were sales representatives terminated.</p> <p>18 BY MR. McCORMICK: 19 Q. Have you seen news reports about a possible 20 settlement of a federal Qui Tam action regarding the 21 off-label promotion and marketing of Risperdal? 22 A. Yes, I have through the years seen different 23 news reports. 24 Q. And I'm sure you've seen more than news</p> | <p style="text-align: right;">Page 191</p> <p>1 break. 2 THE VIDEOGRAPHER: Going off the record 3 at 3:55 p.m. This is the end of tape five. 4 (A brief recess was taken) 5 THE VIDEOGRAPHER: Stand by, please. 6 Back on the record at 4:08 p.m. This is tape six. 7 MR. McCORMICK: Mr. Gorsky, we're back 8 from a break, you understand you're still under 9 oath? 10 THE WITNESS: Yes, I do. 11 (Exhibit Gorsky-23 was marked for 12 identification) 13 BY MR. McCORMICK: 14 Q. Mr. Gorsky, I'm going to hand you what's been 15 marked as Exhibit 23. In the interests of time, Mr. 16 Gorsky, I ask that you review the cover email, glance 17 at the attachment, and then I'll direct you to certain 18 pages and give you time when we get there. 19 A. Okay. 20 Q. Mr. Gorsky, have you had a chance to review 21 Exhibit 23? 22 A. Just the introductory slides. 23 Q. Okay. Do you see that you are copied on the 24 cover email from John Jacoppi on June 21st, 2001?</p> |
| <p style="text-align: right;">Page 190</p> <p>1 reports in your position, but that settlement appears 2 to be aimed at exactly what you're saying never 3 happened but must have happened at some point, correct? 4 MR. MURPHY: Objection to the form of 5 the question, lack of foundation and wholly 6 irrelevant. You may answer. 7 MR. McCORMICK: You can answer. 8 THE WITNESS: I can't answer that 9 question. 10 BY MR. McCORMICK: 11 Q. You're saying that -- well, you . . . 12 A. You're asking me to speculate on a 13 supposition, and I can't do that. 14 Q. That's all right, I don't want to argue with 15 you, Mr. Gorsky. Suffice it to say that the 2001 16 tactical plan at the regional business directors 17 meeting included certain slides that discussed the 18 child and adolescent market. Is that correct? 19 MR. MURPHY: Objection, asked and 20 answered. You may answer it again. 21 THE WITNESS: Yes, it did, with, I 22 believe, the appropriate notation about how they 23 should be utilized. 24 MR. McCORMICK: Let's take a five-minute</p> | <p style="text-align: right;">Page 192</p> <p>1 A. Yes, I do. 2 Q. And you received a copy of the Risperdal 3 Tracking Study Presentation, correct? 4 A. It was attached to this email. 5 Q. And this annual tracking study, for the use of 6 perception of atypical antipsychotics, was performed 7 in-house by the marketing research team. Is that 8 correct? 9 A. I can't ascertain from this, but it was not 10 uncommon at that time that our marketing research 11 department might outsource this to another market 12 research organization to actually conduct the trial or 13 the information gathering. 14 Q. Turn to page 712, please. 15 A. 7 . . . 16 Q. 12. 17 A. I see. Sorry. 18 Q. This describes the methodology, correct? 19 A. Yes, it does. 20 Q. And this data was not bought from a vendor. 21 It was either Janssen or a third-party vendor, as you 22 say, going out and doing these in-office interviews, 23 correct? 24 A. Again, I don't know. There are a multitude of</p> |

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| <p>1 different ways this information could be collected. 2 Sometimes it's part of a broad study. Sometimes it's 3 specifically designed. So, I couldn't tell from the 4 cursory review what the specific methodology was. 5 Q. Okay. Turn to page 714, please. The heading 6 on this page is "Current Antipsychotic Prescribing 7 Practices KEY FINDINGS," correct? 8 A. That's correct. 9 Q. And the first bullet point talks about "Top 10 symptoms treated with antipsychotics," correct? 11 A. That's correct. 12 Q. And then the bullet point underneath there 13 talks about "Top symptoms addressed with antipsychotics 14 in children/adolescents." Is that right? 15 A. Yes, it does. 16 Q. So, that would have been one of the questions 17 that would have been asked by either Janssen or, more 18 likely, a third-party vendor they would have been 19 asking about children and adolescent research. Is that 20 correct? 21 MR. MURPHY: Objection to form of the 22 question. You may answer. 23 THE WITNESS: I don't know how it was 24 collected. It looks like they were collecting</p> | <p>1 the way it's broken out, are child psychiatrists. It's 2 the second from the right. Do you see that? 3 A. Yes, I do. 4 Q. So, part of the survey was to speak with child 5 psychiatrists about Risperdal usage, correct? 6 A. Correct. 7 Q. Okay. Page 721 is "Top Children and 8 Adolescent Symptoms Addressed with Antipsychotics." Is 9 that the heading of this slide? 10 A. Yes, it is. 11 Q. And according to this slide, "Hallucinations 12 and Aggressions are the leading symptoms treated in 13 child and adolescent patients." Do you see that? 14 A. Yes, I do. 15 Q. Turn to page 728, please. The title of this 16 slide is "Attribute importance for Antipsychotic 17 Prescribing." Is that correct? 18 A. Just a minute. I'm getting there. 19 Q. Sure. 20 A. Was it "Attribute Importance For Antipsychotic 21 Prescribing"?</p> |
| | <p>22 Q. Right. 23 A. On 28? 24 Q. 728, exactly.</p> |
| Page 194 | Page 196 |
| <p>1 information across a broad range of different 2 patient types. 3 BY MR. McCORMICK: 4 Q. But one of the patient types was children and 5 adolescents, right? 6 A. Based upon the comments here, they did collect 7 information on the use in that population, yes. 8 Q. And in the next point it talks about children 9 and adolescents again, right? The other -- the bigger 10 bullet point, "Risperdal is the most often prescribed"?</p> | <p>1 A. Okay. 2 Q. And then one of the columns there is child and 3 adolescent disorders. Do you see that? 4 A. Yes, I do. 5 Q. It also talks about adult schizophrenia and 6 adult bipolar disorders, right? 7 A. Yes. 8 Q. You can put that document aside. 9 (Exhibit Gorsky-24 was marked for 10 identification) 11 BY MR. McCORMICK: 12 Q. Mr. Gorsky, I'm handing you what's been marked 13 Exhibit 24. It's a one-page email. Take a minute to 14 review it and let me know when you're finished. 15 A. Okay. 16 Q. Mr. Gorsky, have you had a chance to review 17 Exhibit 24? 18 A. Yes, I have. 19 Q. And do you recognize the name Sally Berry and 20 Ramy Mahmoud? 21 A. I recognize Ramy's name. I'm not as familiar 22 with Sally Berry. 23 Q. And Ramy Mahmoud was a group director in 24 medical affairs and had some responsibility for</p> |

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1 Risperdal, correct?

2 A. I'm not sure what his position was at that
3 time. Along the way Ramy had various roles on the
4 team; I just don't know what it was at the time.5 Q. But he had responsibility for Risperdal either
6 way. Is that correct?7 A. In some ways, yes; for actually several, I
8 think, of our neuroscience or central nervous system
9 compounds.10 Q. I want you to look at Dr. Berry's email to
11 Ramy, the third line, the sentence that starts out "I
12 attempted to include only positive data so that the
13 data cannot be used against us. My hope is to
14 communicate that PRL is not correlated with side
15 effects and that the 'special properties' of Risperdal
16 that cause high prolactin probably also render
17 risperdal superior to olanzapine in other domains."

18 Do you see that sentence?

19 A. Yes, I do.

20 Q. And do you see the title of the subject line
21 of the email is "PRL Poster"?

22 A. Yes, I do.

23 Q. Would you say that attempting to include only
24 positive data in a poster presentation is meeting1 Q. Okay. Mr. Gorsky, do you think a scientific
2 presentation that would include only positive data and
3 not data from bad patients is of high quality?4 MR. MURPHY: Objection to the form of
5 the question. It lacks a foundation. You've got
6 terms in there that you haven't defined.

7 BY MR. McCORMICK:

8 Q. Can you answer the question?

9 A. Not the way that you framed it.

10 Q. Okay.

11 A. Again, what I would say is, I don't know what
12 they mean when they say "bad data." I mean, is that
13 bad data because it was not sourced properly or because
14 it had a negative outcome? I don't know the way that
15 it's phrased.16 Q. Well, do you see Dr. Berry's sentence that
17 says, "My hope is to communicate that PRL," meaning
18 prolactin, "is not correlated with side effects . . .?"19 It appears to me that she's trying to hide
20 data or include only positive data that would say the
21 opposite. Is that the way you read it?22 A. No, I can't draw that same conclusion. And
23 while I don't know Dr. Berry as well, I've worked with
24 Ramy for many years and I've always found him to be

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1 Janssen's responsibilities to doctors and nurses?

2 MR. MURPHY: Objection to the form of
3 the question, lack of foundation, but you may
4 answer.5 THE WITNESS: I can't tell that from
6 this email. We would want to reflect all the data
7 in a balanced and appropriate manner in the
8 posters that we were generating. I'm not sure
9 what was meant by this email. I've never seen it
10 before, that I can recall.

11 BY MR. McCORMICK:

12 Q. Do you think people that use -- do you think
13 people are competent managers that would attempt to
14 include only positive data in a poster that's being
15 presented to doctors?16 A. What I don't know from this is if the poster
17 was intended to be presented to doctors, if it was an
18 internal poster, an external poster, and what exactly
19 "bad data" was in this.20 Did "bad data" mean that it was erroneous in
21 the way that it was collected -- by that I mean it
22 wasn't the correct sampling -- or was it bad based upon
23 a negative perception of the product? I can't tell from
24 this single email.1 very experienced and truthful in my dealings with him.
2 (Exhibit Gorsky-25 was marked for
3 identification)

4 BY MR. McCORMICK:

5 Q. Mr. Gorsky, I marked as Exhibit 25 an email
6 chain, including two emails from you and then a
7 response. Can you take a minute to review that and let
8 me know when you're finished?

9 A. Certainly. Okay.

10 Q. Mr. Gorsky, have you had a chance to review
11 Exhibit 25?

12 A. Yes.

13 Q. And do you see that it's an email from you to
14 a number of individuals on January 21st, 2001 and then
15 a response from you later on the next day?

16 A. Yes.

17 Q. And the email you've sent out to Janet Vergis,
18 Ludwig Hantson, Ramy --

19 A. Excuse me, I respond on Monday.

20 Q. I'm sorry, what did I say?

21 MR. MURPHY: So, it's the 20th and then
22 the 22nd.

23 MR. McCORMICK: Okay.

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1 BY MR. McCORMICK:

2 Q. Mr. Gorsky, do you see that you sent two
3 emails in this email chain and that somewhere in
4 between Ramy Mahmoud sent you an email?

5 A. Yes, I do.

6 Q. And do you see that your email goes to Janet
7 Vergis, Ludwig Hantson and a couple of other
8 individuals, including Ramy Mahmoud?

9 A. Yes.

10 Q. And Ramy Mahmoud responds to your email and
11 says, "We have 'spread the word' on the DKA death on
12 olanzapine in the Abbott trial in a number of
13 one-to-one OL contacts, and I have discussed with Alex
14 Danyluk how to handle in Med Services."

15 Do you see that?

16 A. Yes.

17 Q. And when you received the email from Ramy
18 Mahmoud saying "We have to 'spread the word' on the DKA
19 death on olanzapine in the Abbott trial," did you ask
20 him what he meant by that?21 A. I don't know what contact we had in between
22 the two.23 Q. Do you know now what he meant by that,
24 "spread the word" on the DKA death"?

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1 A. No, I don't.

2 Q. Do you know what he's referring to there, the
3 "DKA death on olanzapine in the Abbott trial"?

4 A. I don't recall.

5 Q. And then you see your response --

6 A. You know, just seeing "DKA death," I believe
7 it was a diabetic ketoacidosis death that occurred on
8 an olanzapine patient, but I just remember that from
9 the DKA.10 Q. So, your assumption is -- and I think you're
11 right -- is that during a trial involving olanzapine or
12 Zyprexa, one of the clinical trial patients died from
13 diabetic ketoacidosis, correct?14 A. Right. I'm just not sure how Ramy was
15 bringing it up in the context of my message, but -- so,
16 I'm not any more familiar with it.17 Q. And that's what I'm going to ask you. I mean,
18 is it typical or ethical of a Janssen employee to go
19 out there and spread the word on something as important
20 as a death in a clinical trial, even though it is a
21 competing drug?22 MR. MURPHY: Objection to the form of
23 the question, lack of foundation. You may answer.

24 THE WITNESS: I don't know what Ramy

1 meant by "spread the word," but it appears here he
2 may have spoken to a couple other opinion leaders
3 and then he said he was going to talk to our
4 medical affairs department to make sure it was
5 going to be handled in the right way.

6 BY MR. McCORMICK:

7 Q. Well, he doesn't say "how to handle in the
8 right way." It just says "how to handle," right?

9 A. "How to handle."

10 Q. And then your response is "Good...it sounds
11 like we have taken the right steps." Is that right?12 A. Well, I'm assuming that he would take it
13 through the appropriate steps of our medical services
14 group and follow all the appropriate guidelines.15 Q. Is that something that Dr. Mahmoud should be
16 proud of under the credo, that he's out spreading the
17 word on the death of a patient in the trial, even
18 though they're taking Zyprexa?19 MR. MURPHY: Objection to the form of
20 the question, lack of foundation. Once again, you
21 may answer the question.22 THE WITNESS: I can't speculate on Dr.
23 Mahmoud. I've known Dr. Mahmoud for quite some
24 time. He served in our armed services I believe1 for over twelve years and at one time led the
2 epidemiology group for the United States Armed
3 Services before joining Janssen and has enjoyed a
4 strong reputation, and I have full faith and
5 confidence that he would follow all the right
6 guidelines.7 How that was manifested in a single
8 email, I can't make a conclusion from that.

9 BY MR. McCORMICK:

10 Q. "Spread the word" is in quotation marks,
11 right?12 A. Yes; that's what I mean: I'm not sure what he
13 was meaning by that single comment.

14 Q. Okay.

15 A. But Ramy's somebody who has been involved
16 throughout our creation and dissemination and
17 development and testing of all of our compliance
18 materials.

19 Q. Is that good or bad?

20 A. I think Ramy is a professional. Again, I
21 can't take this one particular comment and expand
22 beyond that given his track record.23 Q. And do you think that it's within your credo
24 that Ramy would take this type of information and

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1 spread it out to your Janssen advisors, about the death
 2 of a patient in a clinical trial?

3 MR. MURPHY: Objection. Again, lack of
 4 foundation. You may answer the question.

5 THE WITNESS: I think it states in here
 6 that he spoke with a couple of opinion leader
 7 contacts and that he was going to handle it with
 8 medical services, which I would assume, coming
 9 from somebody of Ramy's background, to be done in
 10 the appropriate and regulatory and legally correct
 11 manner.

12 MR. McCORMICK: MR. Gorsky, you can put
 13 that aside. Let me hand you what I'll mark as
 14 Exhibit 26.

15 (Exhibit Gorsky-26 was marked for
 16 identification)

17 THE WITNESS: Okay.

18 BY MR. McCORMICK:

19 Q. Mr. Gorsky, have you had a chance to review
 20 Exhibit 26?

21 A. Yes, I have.

22 Q. And do you see that you were the recipient of
 23 an email and then the sender of an email in January of
 24 2002?

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1 A. Yes, I am.

2 Q. And let's turn to Ramy Mahmoud's email to you
 3 and a number of other individuals on January 16th, with
 4 the subject line "Another big win on the horizon..."
 5 Do you see that?

6 A. Yes.

7 Q. He says, "Just wanted to give you a
 8 confidential heads up that it looks very likely that
 9 we'll be seeing a second Risperdal New England Journal
 10 of Medicine paper in 2002. We have seen review and
 11 editorial comments (with the usual sworn secrecy) on
 12 the RUPP trial, and the comments were extremely benign.
 13 This is great news and is probably something that
 14 deserves some preparation..."

15 "We promised to share only with 'senior
 16 management', and we could truly jeopardize the paper
 17 (not to mention really anger the authors...) if we
 18 'leaked' and made the news about the NEJM public. . ."

19 Do you see that?

20 A. Yes.

21 Q. Okay. Do you recall receiving this email from
 22 Ramy Mahmoud in January 2002?

23 A. No, I do not.

24 Q. Do you see he mentions a confidential heads-up

1 in his email.

2 A. Yes, he does mention that.

3 Q. And then he talks about the usual sworn
 4 secrecy. Do you see that?

5 A. Yes, I do.

6 Q. And do you think he got a copy of this RUPP
 7 article before he was supposed to?

8 A. No, that wouldn't be my memory. If I remember
 9 correctly at that time, it was not usual for a
 10 publication to share a publication to ensure that all
 11 the facts, the data sets and other things, were correct
 12 at times prior to publication without releasing the
 13 data.

14 So, I don't think it was an uncommon practice
 15 by a journal such as the New England Journal of
 16 Medicine, American Journal, all the major published
 17 datas, not to make any changes in the conclusions that
 18 were drawn, but to ensure that some of the data sets
 19 and actual points were correct.

20 Q. And that may be correct if it was a Janssen
 21 study, but this is a RUPP study that was being done by
 22 the National Institute of Mental Health.

23 So, what would Janssen be checking in what was
 24 supposed to be an unbiased study?

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1 A. I don't know what involvement they may have
 2 had along the way or, if any, participation.

3 Q. So somehow, some way, Ramy Mahmoud is involved
 4 in obtaining a copy of the NIMH RUPP study and the
 5 editorial comments before it was even published in the
 6 Journal in 2002. Is that how you read this?

7 A. All I can read is what he put in this email.

8 Q. Well, you got the email in January 2002.

9 A. Exactly, and that's why I said all I can do is
 10 understand it as he wrote it.

11 Q. And did you call him and say, "Man, how did we
 12 get this?" or "Was this leaked to you somehow?" I mean,
 13 he uses the word "leaked," right?

14 A. As I said earlier, I'm assuming Ramy was going
 15 to follow all the appropriate guidelines when
 16 interacting with that kind of an agency.

17 Q. Then we see there is an email -- the next
 18 email in the chain is from Gahan Pandina and then one
 19 from Christine -- Dr. Christine Cote. Do you see those
 20 two emails?

21 A. Yes.

22 Q. And they are suggesting and discussing the
 23 possibility of replicating the RUPP study in Europe and
 24 using that to get a pediatric approval in Europe. Is

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1 that right?

2 MR. MURPHY: You mean each of them,
3 each of the two emails you're talking about?4 MR. McCORMICK: Right -- well, try to
5 group them together, but we can separate them out.

6 BY MR. McCORMICK:

7 Q. Do you see Pandina's email on Friday, January
8 18th? It's the top of page two.9 A. I do -- I don't remember the specifics of this
10 discussion.

11 Q. Okay.

12 A. What I just don't know is, if it's a he or a
13 she had recommended in Europe and then Christine -- I'm
14 not sure if she was recommending that to be done in the
15 Europe or the United States. I just can't tell.16 Q. What she says is "...the replicate trial needs
17 to be run very carefully so we really do end up with a
18 second positive [sic] result...therefore I recommend
19 that our team are involved in reviewing the design of
20 the study and the data handling must be done to REG
21 standards."

22 Do you see that?

23 A. Yes, it do.

24 Q. Didn't we look at, when we looked at the

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1 guidelines earlier, that involvement in the design of a
2 study was improper?3 A. No, I take this in a completely different way.
4 I believe the nature and the intent of Christina --
5 Christina at that time, Christina Cote, was responsible
6 for the medical affairs team in the United States that
7 usually conducted trials after a product was launched,
8 but would also be involved at times with the conduct of
9 trials for submission to the FDA for additional
10 indications.11 And my understanding of her letter is that
12 there is -- and again, I'm not sure what our
13 involvement may have been with the RUPP trial because I
14 believe the underlying assumption here was that the
15 RUPP trial, combined with another trial -- you need two
16 double-blind, placebo-controlled trials, and that's why
17 I would have to check with the rep. There may have
18 been some involvement with our team.19 You would then need to have a second,
20 confirmatory trial. And to conduct that trial, as
21 recommended in the first email, in Europe, the
22 regulatory standards in Europe can be different than
23 the regulatory standards in the United States at times
24 regarding the clinical end points, the expectations for1 the clinical trial sites and some of the standards,
2 particularly back in 2001.3 What we were attempting to do was to ensure
4 that we could coordinate and align our global clinical
5 development plan so that, with this other trial, it
6 would have to have the highest science done, all the
7 correct US and European standards, in an attempt to
8 have a second, confirmatory trial to help achieve an
9 indication in this area. That would be my take on the
10 letter.11 Q. Well, I mean, my take is a little bit simpler
12 just from her sentence: It just says, "...the replica
13 trial needs to be run very carefully so we really do
14 end up with a second positive [sic] result."15 It looks to me like she's going to design the
16 study to make sure that you got a good result, but you
17 don't understand it that way.18 A. Not at all. This is a very difficult patient
19 population with different end points, and again
20 ensuring that it's to the standard that the FDA would
21 accept was, I believe, Christine and Dr. Cote's
22 intention.23 Q. And then you respond to the email and it says,
24 "I think it would be very helpful to have a discussion1 at the BDUM on our strategy with RISP and children,"
2 and I assume RISP means Risperdal?

3 A. Yes.

4 Q. And what's BDUM?

5 A. I forget all the acronyms. It's something
6 Business Development Update Meeting. I don't remember
7 exactly.8 Q. And your strategy with Risperdal in children
9 at this time, in January 2002, I think we've
10 established that Risperdal isn't approved by the FDA
11 for any use in children, is it?12 A. Again, predicated upon our earlier discussion,
13 I don't believe we had the specific indication.
14 However, I also don't know what the precise language in
15 our label said at the time. I don't believe it was
16 contraindicated. I think there was some language about
17 use in children in the label.18 We were clearly doing our best, I feel, to be
19 the first antipsychotic that I'm aware of at that time
20 to generate substantial data for use in this
21 difficult-to-treat population and to work with the FDA
22 toward an official indication.23 Q. You've talked in the last couple minutes about
24 a difficult-to-treat population or a difficult

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1 population for this drug.

2 Do you think that this difficult-to-treat
 3 population or population with mental illness required
 4 more protection because of their condition than a
 5 normal patient or customer?

6 MR. MURPHY: Objection to the form of
 7 the question. You may answer.

8 THE WITNESS: I think all, both adult
 9 and children and others, all of them required very
 10 careful treatment, and that's why we were so
 11 committed to working with opinion leaders and
 12 regulators in this condition to treat -- to
 13 conduct the trials in the right way, to gather all
 14 their appropriate information so they could be
 15 treated accordingly.

16 Again, these were, as I think you
 17 probably saw from the last chart that we went
 18 through, suffering from hallucination, aggressive
 19 symptoms, and with little to no treatment options
 20 and little to no clinical data done in a
 21 controlled setting.

22 And back to Dr. Cote's email, it was
 23 important to try to generate that data.

24

1 while.

2 What I can tell you is, at that time it was
 3 very important to try to gather information. And
 4 frankly, that's where I had to rely on the
 5 psychiatrists and the clinicians who were using the
 6 DSM-4 to fully understand and characterize its use the
 7 right way. That really wasn't my decision.

8 Q. What I'm asking you is that Risperdal and most
 9 of the atypical antipsychotics are indicated for very
 10 serious mental disorders. I think you would agree with
 11 that, right?

12 A. I don't know what the specific independent
 13 indication is at this point in time. I haven't been
 14 directly associated with the drugs for many years.

15 Q. Even back then -- well, let's say 2002, then.
 16 It was indicated for schizophrenia. I don't know if it
 17 had gotten the indication for bipolar disorder, but --

18 A. If I can, at that time the indication was for
 19 the manifestation of psychotic disorders, and there was
 20 an ongoing debate at that point in time, but at that
 21 time it still had the label for the manifestations of
 22 psychotic disorders.

23 Q. I think we're just going to keep going back
 24 and forth, so let's just move on.

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1 BY MR. McCORMICK:

2 Q. Do you think, though, that treating a
 3 hallucination or -- what did you say? I think the other
 4 one was. . .

5 A. Aggression.

6 Q. (Continuing) -- aggression with Risperdal or
 7 an atypical antipsychotic is the right treatment?

8 I mean, these are pretty serious drugs.
 9 They're only indicated for very specific reasons:
 10 Schizophrenia, bipolar disorder, you know, serious
 11 mental illnesses, not your day-to-day
 12 hallucination/aggression/depression. I mean, that's
 13 why, right?

14 MR. MURPHY: What is your question?

15 MR. McCORMICK: Whether he thinks that,
 16 really, hallucinations and aggression are the
 17 types of -- I mean, strike all that.

18 BY MR. McCORMICK:

19 Q. Risperdal still isn't indicated for
 20 hallucinations or aggression, is it?

21 A. I don't know the specific language. I believe
 22 it's received a broader indication for use in children
 23 and adolescents, so I'm not familiar with the language
 24 because I haven't been associated with the drug for a

1 A. Want me to read this document?

2 Q. No.

3 (Exhibit Gorsky-27 was marked for
 4 identification)

5 BY MR. McCORMICK:

6 Q. I've marked as Exhibit 27 a multipage
 7 document. I'm going to direct you just to one page in
 8 particular, but I'm going to ask you about the top. It
 9 says it's a Risperdal Regional Advisory Forum up in the
 10 top left?

11 A. Yes, I do.

12 Q. April 13th, 2003 down the bottom left. Do you
 13 see that?

14 A. Yes.

15 Q. Do you recognize any of the names on the top
 16 of the page: Andrew Greenspan or Mark Lehman or Kurt
 17 Barry?

18 A. Kurt Barry I recognize, but this was after --
 19 I believe I was actually in Europe at this time.

20 Q. Let's turn to page eight. It's Bates-labeled
 21 575.

22 A. Okay.

23 Q. And at this time I think you said you don't
 24 recognize the name Andrew Greenspan, correct?

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| | |
|---|--|
| <p style="text-align: right;">Page 217</p> <p>1 A. No, I do not.</p> <p>2 Q. At the time he was an assistant director of</p> <p>3 clinical development and worked in the medical affairs</p> <p>4 department. And April 2003 would have been after you</p> <p>5 installed Dave Mallegol into that compliance position</p> <p>6 sometime earlier than that, correct?</p> <p>7 A. I don't remember the exact date, but I think</p> <p>8 it was, yes, several years earlier.</p> <p>9 Q. On page eight of the document, if you go down</p> <p>10 six headings, do you see the word "Randy"?</p> <p>11 A. Yes.</p> <p>12 Q. It says, "I do a fair amount of CME programs,</p> <p>13 and I signed this letter that says I can only talk</p> <p>14 about indications. However, I always plant a shill</p> <p>15 because if I get asked a question from the audience, I</p> <p>16 can then speak off label. So you never like go to a</p> <p>17 CME meeting without knowing ahead of time that somebody</p> <p>18 is going to ask you what about dementia. And that way</p> <p>19 you haven't broken your contract."</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes, you did.</p> <p>22 Q. And then you see that Dr. Greenspan, a Janssen</p> <p>23 employee, actually assistant director of medical</p> <p>24 affairs, says "That's good practical advice." Do you</p> | <p style="text-align: right;">Page 219</p> <p>1 A. Yes.</p> <p>2 Q. This is a Risperdal Reimbursement PME Request</p> <p>3 Form. Do you see that?</p> <p>4 A. Yes, I do.</p> <p>5 Q. Is that your name at the bottom and your</p> <p>6 initials next to it approving it?</p> <p>7 A. Yes, it is.</p> <p>8 Q. Up in the top right, is that a note from you?</p> <p>9 A. Yes, that's my handwriting.</p> <p>10 Q. What is this approval for?</p> <p>11 A. I don't remember specifically. But based upon</p> <p>12 this, it says "Public Sector Meetings." I don't have</p> <p>13 the rest of the attachment. Usually these would have</p> <p>14 some other, further explanation.</p> <p>15 Q. Who is the vendor?</p> <p>16 A. Excerpta Medica.</p> <p>17 Q. Do you know, before you would get or approve a</p> <p>18 reimbursement for \$450,000, would you have asked what</p> <p>19 was the money going to or what was the amount for?</p> <p>20 A. Yes. Usually attached to this there would be</p> <p>21 a full description of the event. I believe we actually</p> <p>22 had a form that they had to fill out that would itemize</p> <p>23 the objective, everything else. And as you had can see</p> <p>24 in the upper right-hand corner I asked if legal had</p> |
| <p style="text-align: right;">Page 218</p> <p>1 see that?</p> <p>2 A. Yes.</p> <p>3 Q. Do you think that this was good advice, as Dr.</p> <p>4 Greenspan agrees, advocating for Janssen advisors to</p> <p>5 bring up off-label marketing during CMEs by planting a</p> <p>6 shill out in the audience?</p> <p>7 MR. MURPHY: Objection to the form of</p> <p>8 the question, lack of foundation, but you may</p> <p>9 answer.</p> <p>10 THE WITNESS: I don't know Randy. I</p> <p>11 don't know Dr. Greenspan. I can't comment on</p> <p>12 that, what they meant by that.</p> <p>13 MR. McCORMICK: Okay.</p> <p>14 BY MR. McCORMICK:</p> <p>15 Q. Well, do you think planting a shill -- that's</p> <p>16 a pretty simple concept. Do you think that's a concept</p> <p>17 that fits within the credo of Johnson & Johnson?</p> <p>18 A. That would not be consistent with what we do.</p> <p>19 Q. Okay.</p> <p>20 (Exhibit Gorsky-28 was marked for</p> <p>21 identification)</p> <p>22 BY MR. McCORMICK:</p> <p>23 Q. Mr. Gorsky, I've handed you what's been marked</p> <p>24 as Exhibit 28.</p> | <p style="text-align: right;">Page 220</p> <p>1 reviewed this to make sure that it was consistent with</p> <p>2 our policies and guidelines.</p> <p>3 Q. And then do you see down below at the very</p> <p>4 bottom, underneath your signature, it says "Alex,</p> <p>5 please sign contract also"?</p> <p>6 A. Yes, that would have been my intention. I</p> <p>7 think that contract would have been attached to it with</p> <p>8 the broader description.</p> <p>9 And I'd asked the question of Sid -- a person</p> <p>10 by the name of Sid Frank was responsible for this</p> <p>11 particular department, and I'm just assuming, based</p> <p>12 upon the dates, that I probably asked for that on July</p> <p>13 31st and he responded, and that's when I signed.</p> <p>14 MR. McCORMICK: Mr. Gorsky, I hate to</p> <p>15 do this, but I've got to take a personal break.</p> <p>16 Let's go off the record for five minutes.</p> <p>17 THE VIDEOGRAPHER: Going off the record</p> <p>18 at 4:53 p.m.</p> <p>19 (A brief recess was taken)</p> <p>20 THE VIDEOGRAPHER: Stand by, please.</p> <p>21 Back on the record at 5:01 p.m. This is tape</p> <p>22 seven.</p> <p>23 MR. McCORMICK: Mr. Gorsky. Ken.</p> <p>24 MR. MURPHY: You've got an extra.</p> |

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1 (Exhibit Gorsky-29 was marked for
 2 identification)

3 BY MR. McCORMICK:

4 Q. Mr. Gorsky, I've handed you what's been marked
 5 as Exhibit 29. Can you take a minute to review it, let
 6 me know when you're finished?

7 A. Okay.

8 Q. Mr. Gorsky, have you had a chance to review
 9 Exhibit 29?

10 A. Yes, I have.

11 Q. And do you see this email chain begins with an
 12 email from Magali Reyes-Harde in May of 2003?

13 A. Yes.

14 Q. And you worked with Dr. Reyes-Harde, right?

15 A. Just for a short period of time. By the time
 16 of this email I had left this role.

17 Q. And you were with Novartis in 2003?

18 A. I was in Europe at the time.

19 Q. But Dr. Reyes-Harde worked in CNS marketing as
 20 a product director, correct?

21 A. At noted on this email. I forget what her
 22 exact role is, but that's what it said, yes.

23 Q. And do you see she's providing the update on a
 24 meeting with a Dr. Klibanski, who is the chairwoman of

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1 point number one says, "Our standpoint is that
 2 prolactin related side effects is a non-issue. Our
 3 tactics should be supportive of that, I'm not sure if
 4 an academic helpline is in line with this; let's
 5 discuss tactics within the team."

6 Do you see that?

7 A. I do see that.

8 Q. And do you believe competent management, under
 9 the Johnson & Johnson credo, would allow someone in
 10 marketing to determine Johnson & Johnson's standpoint
 11 on safety issues as to a pharmaceutical?

12 MR. MURPHY: Objection to the form of
 13 the question, lack of foundation. You may answer.

14 THE WITNESS: I don't think anybody in
 15 marketing would have the final say on how we
 16 should or should not handle a side effect of a
 17 drug.

18 It may have been his opining on this
 19 particular email, but it wouldn't have been my
 20 experience that he would have made any type of
 21 final decision on something like that.

22 MR. McCORMICK: Okay.

23 BY MR. McCORMICK:

24 Q. Would it fit within your credo that somebody

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1 the Department of Endocrinology at Mass General
 2 Hospital in Boston?

3 A. Yes.

4 Q. And that the purpose of the meeting was to
 5 initiate a collaboration between her group and Janssen
 6 to help address the many needs related to prolactin.
 7 Do you see that?

8 A. Yes, I do.

9 Q. And one of the ideas that is being considered
 10 is, number one, establishment of an MGH-run
 11 neuropsychiatry clinical information service. Is that
 12 correct?

13 A. These what the email says, yes.

14 Q. And then you see there is a response from
 15 Ronald Kalmeijer, who was the director of marketing at
 16 CNS at the time. Do you see that?

17 A. Yes.

18 Q. And did you work with Mr. Kalmeijer when you
 19 were working in the CNS department, division?

20 A. I worked with him in a role that he played
 21 both in the CNS division as well as our oncology and
 22 pain area as well as in a business-development
 23 position.

24 Q. And underneath Mr. Kalmeijer's email bullet

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1 in the marketing department would even be able to
 2 participate in a discussion on that and offer his
 3 opinion?

4 A. I think it's entirely consistent with our
 5 credo to encourage open debate and discussion among a
 6 number of people from different backgrounds to
 7 ultimately get to the best decision.

8 But in a case dealing directly with patient
 9 safety, our physicians in any cases that I've been
 10 involved with have always had the final say.

11 Q. Are you concerned, Mr. Gorsky, that even
 12 though Mr. Kalmeijer is in the marketing department, he
 13 would even suggest that the tactics for pharmaceutical
 14 marketing should support a standpoint rather than the
 15 science issue?

16 MR. MURPHY: Objection to the form of
 17 the question. It mischaracterizes the document,
 18 but you may answer.

19 THE WITNESS: I don't draw that full
 20 conclusion. I think he's stating his opinion
 21 here. I really can't comment on the context of
 22 that. I'm saying that if our professionals felt
 23 that that was in order, that they would move ahead
 24 with it. Again, we would be relying on

56 (Pages 221 to 224)

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| <p style="text-align: right;">Page 225</p> <p>1 physicians. Dr. Kalmeijer was a physician 2 himself.</p> <p>3 MR. McCORMICK: You can put that aside, 4 Mr. Gorsky. Let me hand you what's been marked 5 exhibit 30. It's an email chain from May of 2003. 6 Can you take a minute to review it?</p> <p>7 (Exhibit Gorsky-30 was marked for 8 identification)</p> <p>9 THE WITNESS: Okay.</p> <p>10 BY MR. McCORMICK:</p> <p>11 Q. Mr. Gorsky, have you had a chance to review 12 Exhibit 30?</p> <p>13 A. Yes, I have.</p> <p>14 Q. And do you see that the subject line of this 15 email chain is "prolactin"?</p> <p>16 A. Yes.</p> <p>17 Q. And do you see that Dr. Kalmeijer sent an 18 email on May 16th, 2003 to a number of individuals, 19 including John Jacoppi and Georges Gharabawi, saying 20 "My understanding is that when prolactin increases our 21 recommendation is bromocriptin [sic]."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And then we turn to the next page and Georges</p> | <p style="text-align: right;">Page 227</p> <p>1 could serve to create a sense that Ris is 'difficult,'" 2 and "difficult" is in quotation marks.</p> <p>3 Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. The first email from Ronald Kalmeijer, he's 6 asking for guidance on what to tell sales 7 representatives regarding prolactin. Is that correct?</p> <p>8 MR. MURPHY: Objections to the form. 9 You may answer.</p> <p>10 THE WITNESS: I can't draw that 11 conclusion. He says "to the field." The field 12 could be our field medical affairs specialists. 13 I'm not sure what he means by that.</p> <p>14 BY MR. McCORMICK:</p> <p>15 Q. But he's asking for a recommendation to give 16 advice or direction to somebody in the Janssen company 17 about what to do when prolactin increases. Is that 18 right?</p> <p>19 A. I have no other context for this email other 20 than a conversation taking place on an email between 21 some various product managers and directors.</p> <p>22 Q. And then do you see Ramy Mahmoud says don't 23 give the advice about how to treat prolactin?</p> <p>24 MR. MURPHY: Where is that, counsel?</p> |
| <p style="text-align: right;">Page 226</p> <p>1 Gharabawi responds to Ronald Kalmeijer, the same 2 individuals, which includes Ramy Mahmoud, and gives the 3 recommendation or explains the recommendation that he 4 had given before.</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. And then we see Ramy Mahmoud's email back to 8 everyone: It says, "Back up a minute" and then he 9 gives the steps. The last line of his email says, "Why 10 and how would we want to send guidance to the field 11 sales force on this?"</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. He's talking about the recommendation about 15 what to do if there's elevated prolactin from 16 Risperdal. Is that correct?</p> <p>17 A. That's correct.</p> <p>18 Q. And then John Jacoppi responds and says, 19 "Agreed that we need to be careful here. As we moved 20 toward higher functioning schizophrenic patients and 21 eventually bipolar (when indication hits), we need to 22 be" very "careful to ensure physicians perceive 23 Risperdal to be 'easy' to use," with "easy" in quotes. 24 "I think field recommendations to clinicians</p> | <p style="text-align: right;">Page 228</p> <p>1 MR. McCORMICK: Where he says "Why and 2 how would we want to send guidance to the field 3 sales force on this?"</p> <p>4 MR. MURPHY: So, your question is?</p> <p>5 BY MR. McCORMICK:</p> <p>6 Q. My question is: Do you agree -- well, strike 7 that. My question, Mr. Gorsky, is: Do you think it 8 fits within the credo that Ramy Mahmoud would tell 9 other individuals at Janssen not to give out practical 10 advice on questions that they have about how to treat 11 prolactin increases from Risperdal?</p> <p>12 MR. MURPHY: Objection to the form of 13 the question. It wholly mischaracterizes the 14 document and there is no foundation that you've 15 laid for the question, but you may answer it 16 again.</p> <p>17 THE WITNESS: I read Ramy's response in 18 a very different way. I think, given the previous 19 conversation that's taking place on email -- 20 that's how people communicate -- Ramy's comment 21 about "Back up a minute. The first step in 22 treating a patient with elevated prolactin would 23 rarely or never be to simply add one of these 24 drugs. A proper evaluation would have to be first</p> |

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| Page 229 | Page 231 |
| <p>1 (no clinical symptoms, perhaps no treatment). 2 Depending on the level, a proper work-up may be 3 necessary (not simply assuming it is the RIS). 4 Dose reduction may be a next step (since many 5 patients may have equal efficacy at a bit lower 6 doses)" and "It would be late in the process that 7 you would go to an agonist - in which case 8 cabergolide [sic] would be preferred by most 9 people I would think..." 10 I think Ramy was trying to basically 11 clarify the situation. When he said not to send 12 anything to the field, he was saying no other 13 guidance should go out on this because we need to 14 understand the issue, clarify the right guideline 15 before taking any action, and that was my 16 interpretation of this statement.</p> <p>17 BY MR. McCORMICK:</p> <p>18 Q. And then do you see -- but John Jacoppi has a 19 different interpretation. I mean, his interpretation 20 is that any field recommendation to clinicians is going 21 to create a sense that Risperdal is difficult rather 22 than being easy to use. Do you see that?</p> <p>23 A. Well, just as a conversation would evolve 24 around a table, each of these people are representing</p> | <p>1 THE WITNESS: I'll leave it there. 2 (Exhibit Gorsky-31 was marked for 3 identification)</p> <p>4 BY MR. McCORMICK:</p> <p>5 Q. Mr. Gorsky, I've handed you a document which 6 has been marked as exhibit 31. Take a minute to review 7 it and let me know when you're finished.</p> <p>8 A. Okay.</p> <p>9 Q. Mr. Gorsky, have you had a chance to review 10 Exhibit 31?</p> <p>11 A. Yes, I have.</p> <p>12 Q. Okay. And do you see that the third or the 13 fourth page of this document, which is Bates-labeled 14 632, is a form letter going out from you dated February 15 25th, 1998?</p> <p>16 A. Yes.</p> <p>17 Q. And the letter talks about reaching -- 18 Risperdal reaching -- it's a fourth anniversary, 19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. It's the number one prescribed antipsychotic 22 in the United States?</p> <p>23 A. Yes.</p> <p>24 Q. More than Haldol, more than Zyprexa, more than</p> |
| Page 230 | Page 232 |
| <p>1 different discussion points. 2 So, for example, the conversation from Ronald 3 is on the marketing team, Ramy's providing a medical 4 perspective, and John is providing a medical or a 5 marketing-research perspective. 6 But going back to the earlier comment, any 7 final guideline on a medical or clinical matter would 8 be subject to final review by the medical department. 9 Q. But doesn't it concern you that somebody in 10 sales, I guess, which is John Jacoppi, would put the -- 11 A. John Jacoppi was not in sales. 12 Q. Well, doesn't it concern you that John 13 Jacoppi, as a senior product director in CNS, would put 14 the idea whether Risperdal was easy to use or difficult 15 to use for clinicians ahead of whether the safety was 16 important?</p> <p>17 MR. MURPHY: Objection to the form the 18 question, lack of foundation. Also, the question 19 is improper, as there has been a ruling by the 20 discovery master that questions posed "doesn't it 21 concern you" are inappropriate.</p> <p>22 MR. McCORMICK: You can answer the 23 questions.</p> <p>24 MR. MURPHY: If you can.</p> | <p>1 Seroquel, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And on the second page it talks about common 4 adverse events. Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. And do you see any mention of prolactin or 7 hyperprolactinemia in there?</p> <p>8 A. Not on this page. I think it would have been 9 on the next page with the package insert.</p> <p>10 Q. Which is in about three-point font.</p> <p>11 A. I'm assuming the package insert would have 12 been attached to this and that this was a minimized 13 copy of the package insert. The ones that -- the 14 regular package insert is very legible.</p> <p>15 Q. But getting back to my question: On page 633, 16 which is the common adverse events attached as an 17 outside-the-package insert listed right there, do you 18 see prolactin or hyperprolactinemia?</p> <p>19 A. No, I do not.</p> <p>20 Q. Okay.</p> <p>21 A. This document would have been reviewed 22 significantly -- first of all, I'm not sure if this was 23 actually sent out since this was a sample version; 24 secondly, in 1998 the side effects that would be</p> |
| Page 229 | Page 231 |
| <p>1 different discussion points. 2 So, for example, the conversation from Ronald 3 is on the marketing team, Ramy's providing a medical 4 perspective, and John is providing a medical or a 5 marketing-research perspective. 6 But going back to the earlier comment, any 7 final guideline on a medical or clinical matter would 8 be subject to final review by the medical department. 9 Q. But doesn't it concern you that somebody in 10 sales, I guess, which is John Jacoppi, would put the -- 11 A. John Jacoppi was not in sales. 12 Q. Well, doesn't it concern you that John 13 Jacoppi, as a senior product director in CNS, would put 14 the idea whether Risperdal was easy to use or difficult 15 to use for clinicians ahead of whether the safety was 16 important?</p> <p>17 MR. MURPHY: Objection to the form the 18 question, lack of foundation. Also, the question 19 is improper, as there has been a ruling by the 20 discovery master that questions posed "doesn't it 21 concern you" are inappropriate.</p> <p>22 MR. McCORMICK: You can answer the 23 questions.</p> <p>24 MR. MURPHY: If you can.</p> | <p>1 Seroquel, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And on the second page it talks about common 4 adverse events. Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. And do you see any mention of prolactin or 7 hyperprolactinemia in there?</p> <p>8 A. Not on this page. I think it would have been 9 on the next page with the package insert.</p> <p>10 Q. Which is in about three-point font.</p> <p>11 A. I'm assuming the package insert would have 12 been attached to this and that this was a minimized 13 copy of the package insert. The ones that -- the 14 regular package insert is very legible.</p> <p>15 Q. But getting back to my question: On page 633, 16 which is the common adverse events attached as an 17 outside-the-package insert listed right there, do you 18 see prolactin or hyperprolactinemia?</p> <p>19 A. No, I do not.</p> <p>20 Q. Okay.</p> <p>21 A. This document would have been reviewed 22 significantly -- first of all, I'm not sure if this was 23 actually sent out since this was a sample version; 24 secondly, in 1998 the side effects that would be</p> |

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| <p style="text-align: right;">Page 233</p> <p>1 required to be called out by our regulatory and our 2 legal department were usually the most common, and I'm 3 not sure where prolactin rated; and third, they would 4 certainly have reviewed this prior to distribution to 5 ensure we were compliant with the appropriate 6 guidelines at that time.</p> <p>7 Q. Mr. Gorsky, I have a printout here that says 8 your salary as the chief executive officer is 9 \$6,836,860. Is that correct?</p> <p>10 A. I believe that's my total compensation as 11 noted in our proxy last year, yes. Approximately. I 12 don't know the exact number.</p> <p>13 Q. And do you own shares of stock in Johnson & 14 Johnson?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Do you own stock options in Johnson & Johnson?</p> <p>17 A. Yes, I do.</p> <p>18 Q. Do you have a 401K with Johnson & Johnson?</p> <p>19 A. Yes, I do.</p> <p>20 Q. And does that 401K include Johnson & Johnson 21 stock?</p> <p>22 A. I believe it does contain some Johnson & 23 Johnson -- a portion thereof. I'm not absolutely 24 certain of that.</p> | <p style="text-align: right;">Page 235</p> <p>1 MR. McCORMICK: The issue is if we're 2 going to subpoena Mr. Gorsky to appear at trial, I 3 want to know --</p> <p>4 MR. MURPHY: You can direct the 5 subpoena to me.</p> <p>6 MR. McCORMICK: And you'll accept 7 service?</p> <p>8 MR. MURPHY: You can send it to me and 9 I'll deal with it.</p> <p>10 MR. McCORMICK: Well, say you're going 11 to accept service or not.</p> <p>12 MR. MURPHY: Send it to me and I'll 13 deal with it.</p> <p>14 BY MR. McCORMICK:</p> <p>15 Q. Again, Mr. Gorsky, I'm going to ask you for 16 your home address. Are you still in Doylestown?</p> <p>17 THE WITNESS: Am I required to provide 18 my home address?</p> <p>19 MR. MURPHY: No. We can take that up 20 later.</p> <p>21 MR. McCORMICK: Okay.</p> <p>22 BY MR. McCORMICK:</p> <p>23 Q. Mr. Gorsky, are you an endocrinologist --</p> <p>24 A. I'm sure you can -- I'm sorry. The reason I'm</p> |
| <p style="text-align: right;">Page 234</p> <p>1 Q. And when you say that your salary of \$6.8 2 million includes all your compensation -- and you're 3 right, it says "total calculated compensation" -- what 4 does that include?</p> <p>5 A. There are several difficult components: There 6 is an ongoing salary that I receive biweekly, there is 7 an annual bonus, and then there are certain long-term 8 compensation elements as well. I believe also in that 9 figure are any other benefits at all that I receive 10 from the company.</p> <p>11 Q. Any other what? I'm sorry.</p> <p>12 A. Any other benefits that I receive from the 13 company.</p> <p>14 Q. Mr. Gorsky, I should have asked you in the 15 beginning: Do you still live in Doylestown?</p> <p>16 A. Yes, I do.</p> <p>17 Q. And I believe the most recent version of your 18 CV says that you live at 252 Barrett Drive. Is that 19 still your current address?</p> <p>20 A. No, that is not.</p> <p>21 Q. What is your correct address?</p> <p>22 THE WITNESS: Does this need to be a 23 matter of public record?</p> <p>24 MR. MURPHY: What's the issue, Brian?</p> | <p style="text-align: right;">Page 236</p> <p>1 saying that is mostly because of safety reasons and a 2 matter of public record.</p> <p>3 Q. It would have been a lot simpler -- that's 4 fine.</p> <p>5 A. If counsel deems it's necessary later, I will 6 absolutely comply with your request.</p> <p>7 Q. No big deal.</p> <p>8 A. Okay. I just want to make sure I go on record 9 such that I'm not being difficult.</p> <p>10 Q. Your attorney's being difficult, but that's 11 fine. Thank you, Mr. Gorsky: It's unusual to have a 12 witness that's easier than the attorney, but I'll go 13 with it.</p> <p>14 Q. Are you an endocrinologist?</p> <p>15 A. No, I'm not.</p> <p>16 Q. Are you a doctor?</p> <p>17 A. No, I'm not.</p> <p>18 Q. Are you a lawyer?</p> <p>19 A. No, I'm not.</p> <p>20 Q. Okay. You know the difference between right 21 and wrong. Is that correct, Mr. Gorsky -- am I correct, 22 Mr. Gorsky?</p> <p>23 A. It's a difficult question to answer because 24 I'm not sure in what context. But in my definition of</p> |

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1 right and wrong, yes, I do.

2 Q. And if it's shown that Johnson & Johnson
3 marketed Risperdal to the children and adolescent
4 market when Risperdal was not approved by the FDA for
5 any children and adolescent use, would that be right or
6 wrong?

7 MR. MURPHY: Objection to the form of
8 the question, lack of foundation, and indeed calls
9 for speculation, but you may answer.

10 THE WITNESS: I can't answer that
11 question without significant speculation.

12 BY MR. McCORMICK:

13 Q. Well, if Johnson & Johnson marketed Risperdal
14 to the children and adolescent market when Risperdal
15 was not approved for a pediatric use by the FDA, would
16 that be illegal?

17 MR. MURPHY: Same objection.

18 THE WITNESS: Based on my knowledge and
19 my review of the information, I don't believe that
20 we -- that is, Johnson & Johnson or Janssen --
21 marketed the product in an inappropriate manner,
22 or promoted.

23 BY MR. McCORMICK:

24 Q. If Johnson & Johnson promoted Risperdal to the

1 BY MR. McCORMICK:

2 Q. Mr. Gorsky, do you know that back in March of
3 2012 Johnson & Johnson/State of Texas settled a case
4 where Texas alleged that Johnson & Johnson fraudulently
5 marketed its Risperdal antipsychotic drug for \$158
6 million?

7 MR. MURPHY: Objection to the form of
8 the question, lack of relevance. You may answer
9 if you can.

10 THE WITNESS: Yes, I'm aware of that.

11 BY MR. McCORMICK:

12 Q. Did you have to sign off on that settlement,
13 Mr. Gorsky?

14 A. No.

15 Q. Were you at all involved in any decisions
16 having to do with that settlement?

17 A. I participated in some of the discussions, but
18 I don't believe the final decision, no.

19 Q. Mr. Gorsky, do you know that a judge in
20 Arkansas recently ordered Johnson & Johnson to pay more
21 than \$1.2 billion in fines a day after a jury found
22 that the company had minimized or concealed the dangers
23 associated with Risperdal?

24 MR. MURPHY: Is that your question?

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1 children and adolescent market when it was not approved
2 for any pediatric use by the FDA, would you consider
3 that a breach of the Johnson & Johnson Credo?

4 A. I would consider inappropriate promotion of
5 our products not consistent with the Johnson & Johnson
6 Credo.

7 But I'm not aware, other than very unique or
8 specific situations that can occur in a large
9 organization, I'm not aware of any concerted effort on
10 the part of Janssen or Johnson & Johnson to promote the
11 drug inappropriately.

12 But again, from time to time, as I mentioned
13 earlier, when informed that somebody stepped outside of
14 those guidelines, we would try to take appropriate
15 action -- appropriate disciplinary action.

16 Q. Mr. Gorsky, did Janssen or Johnson & Johnson
17 market or promote Risperdal to the child and adolescent
18 market before Risperdal was approved or indicated by
19 the FDA for pediatric use?

20 MR. MURPHY: Objection, asked and
21 answered. You may answer it again.

22 THE WITNESS: Based upon my
23 recollection and the documents I've seen, we
24 promoted it in an appropriate manner.

1 MR. McCORMICK: Yes, that's my question.
2 MR. MURPHY: Objection, lack of
3 foundation. You may answer.

4 THE WITNESS: Yes, I am, and I know
5 that we're asking for a retrial and appealing that
6 decision.

7 MR. McCORMICK: All right, Mr. Gorsky.
8 Why don't we take a two-minute break, let me look
9 and see if I've got everything done, and then I'll
10 turn you over to Mr. Murphy.

11 THE VIDEOGRAPHER: Going off the record
12 at 5:29 p.m.

13 (A brief recess was taken)

14 THE VIDEOGRAPHER: Stand by, please.
15 Back on the record at 5:32.

16 MR. McCORMICK: Mr. Gorsky, I appreciate
17 your time today. I have no further questions.

18 THE WITNESS: Thank you.

19 MR. McCORMICK: Thank you.

20 MR. MURPHY: Briefly.

21 (Exhibit Gorsky-32 was marked for
22 identification)

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| <p>1 (EXAMINATION)</p> <p>2 BY MR. MURPHY:</p> <p>3 Q. Mr. Gorsky, I've just handed you what's been</p> <p>4 marked as Exhibit 32. Do you recognize this document?</p> <p>5 A. Yes, I do.</p> <p>6 Q. Am I correct that that is a copy of a CV that</p> <p>7 was used during your deposition in the Texas</p> <p>8 litigation?</p> <p>9 A. I don't recall specifically if it was that,</p> <p>10 but based upon the file I would assume that's correct.</p> <p>11 Q. But this is a copy of a CV that you had in use</p> <p>12 at one time. Is that correct?</p> <p>13 A. Yes, it is.</p> <p>14 Q. If you look at the CV to refresh your</p> <p>15 recollection, can you tell us when you began your</p> <p>16 professional career at Janssen?</p> <p>17 A. I started at Janssen in 1988.</p> <p>18 Q. And what was the job title that you had at</p> <p>19 that time?</p> <p>20 A. I was a sales representative.</p> <p>21 Q. At some point during your tenure at Janssen</p> <p>22 did you become group director for psychiatry,</p> <p>23 neurology, allergy, analgesics and oncology?</p> <p>24 A. Yes, I did.</p> | <p>1 operations group for forecasting, marketing research,</p> <p>2 and a number of other activities, where the selling</p> <p>3 group was really focused on directly, especially the</p> <p>4 field sales force, which sells to the representatives,</p> <p>5 were focused on the promotion of our products</p> <p>6 specifically in the field, and they were two very</p> <p>7 distinct functions.</p> <p>8 So, for example, marketing plans, some of</p> <p>9 which we reviewed today, might include aspirational</p> <p>10 elements. They might include programs that could</p> <p>11 stretch over a period of several years and were really</p> <p>12 focused on aligning the resources internally to ensure</p> <p>13 the longer-term development of the product, where in</p> <p>14 the field there were very specific promotional</p> <p>15 guidelines that had to be followed consistent with the</p> <p>16 product labeling.</p> <p>17 Q. During your tenure at Janssen -- and I'm</p> <p>18 speaking from the time that you became a sales rep</p> <p>19 through the time that you ultimately became</p> <p>20 president -- did you ever become familiar with the term</p> <p>21 or the concept of pharmacovigilance?</p> <p>22 A. Yes, I did.</p> <p>23 Q. Did you ever have any direct responsibility in</p> <p>24 the area of pharmacovigilance?</p> |
| <p>1 Page 242</p> <p>2 Q. And during that period of time was Risperdal</p> <p>3 the only Janssen product for which you had some major</p> <p>4 responsibility?</p> <p>5 A. No, there were multiple drugs at that time</p> <p>6 that I had a responsibility for, of which Risperdal was</p> <p>7 one. There was a drug, Reminyl, for Alzheimer's</p> <p>8 Disease that was eventually approved. We had a drug</p> <p>9 called Lubeluzole for stroke that did not make it to</p> <p>10 market.</p> <p>11 There were several other drugs in the</p> <p>12 analgesia category, other drugs in the allergy</p> <p>13 category, and I believe at that time we had two</p> <p>14 emerging drugs in our oncology portfolio.</p> <p>15 Q. During the course of the deposition Mr.</p> <p>16 McCormick has used "marketing" and "sales," those</p> <p>17 terms, with you. Can you explain whether there is a</p> <p>18 difference between marketing and sales?</p> <p>19 A. There is a very distinct demarcation between</p> <p>20 the two functions: Marketing would involve a number of</p> <p>21 activities ranging from coordination and alignment with</p> <p>22 our clinical development programs to ensure that the</p> <p>23 products were being developed in the appropriate areas</p> <p>24 with the right information to get regulatory approval.</p> <p>Marketing might also coordinate with our</p> | <p>1 Page 244</p> <p>2 A. No, I did not.</p> <p>3 Q. Did you ever become aware or familiar with the</p> <p>4 term outcomes research?</p> <p>5 A. Yes, I did.</p> <p>6 Q. Did you ever have any direct responsibility</p> <p>7 related to outcomes research?</p> <p>8 A. No, not direct responsibility. One caveat I</p> <p>9 should put on that: Ultimately when I was president,</p> <p>10 all the different functions would report in to me, but</p> <p>11 within our construct, even in that our medical affairs</p> <p>12 group had a very strong functional tie-in to our</p> <p>13 overall medical department versus a company alignment.</p> <p>14 Q. It's almost 5:45. We started at ten. I've</p> <p>15 shown you one document; Mr. McCormick has shown you a</p> <p>16 total of thirty-one, I believe.</p> <p>17 My question is this: In the documents that</p> <p>18 Mr. McCormick showed you there were a number of</p> <p>19 business plans. Do you recall that?</p> <p>20 A. Yes.</p> <p>21 Q. Were any of those business plans, to your</p> <p>22 knowledge, ever shared or disseminated to any</p> <p>23 physician?</p> <p>24 A. Not that I'm aware.</p> <p>Q. When sales representatives called upon or</p> |

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| <p style="text-align: right;">Page 245</p> <p>1 detailed doctors with regard to Risperdal, what did 2 they use?</p> <p>3 A. They're instructed to utilize the sales 4 brochures that were provided to them after review of 5 our regulatory and legal and compliance teams and 6 submitted to the FDA.</p> <p>7 Q. During the course of this deposition were you 8 confronted or shown any sales aids used by sales 9 representatives detailing Risperdal?</p> <p>10 A. Not that I can remember.</p> <p>11 Q. At some point in 2003 you left Janssen and 12 took on responsibilities at Johnson & Johnson in 13 Europe. Is that correct?</p> <p>14 A. Yes.</p> <p>15 Q. Thereafter, you left Johnson & Johnson and 16 became employed by Novartis. Is that correct?</p> <p>17 A. That's correct.</p> <p>18 Q. And how long did you work at Novartis?</p> <p>19 A. For approximately four years.</p> <p>20 Q. You left Novartis and you came back to Johnson 21 & Johnson. Is that correct?</p> <p>22 A. Yes.</p> <p>23 Q. Why?</p> <p>24 MR. McCORMICK: Objection, relevance.</p> | <p style="text-align: right;">Page 247</p> <p>1 District of Massachusetts, correct? It's a Qui Tam, a 2 whistleblower case?</p> <p>3 A. Yes, we are.</p> <p>4 Q. And we've seen reports in the newspaper about 5 a federal whistleblower case that Johnson & Johnson or 6 Janssen has some involvement in because of Risperdal. 7 Is that correct?</p> <p>8 MR. MURPHY: Objection to form. You've 9 seen it, or are you asking whether he's seen it?</p> <p>10 BY MR. McCORMICK:</p> <p>11 Q. I'm asking have you seen it. I'm sure we've 12 all seen it.</p> <p>13 A. I'm not familiar with it specifically.</p> <p>14 Q. Have you seen the fact -- do you know -- 15 strike that. Johnson & Johnson is a defendant in a 16 group of personal-injury cases involving the drug 17 Levaquin. Do you know that?</p> <p>18 MR. MURPHY: Objection, lack of 19 relevance. You may answer.</p> <p>20 THE WITNESS: I'm not aware of the 21 exact status of our involvement with Levaquin.</p> <p>22 BY MR. McCORMICK:</p> <p>23 Q. Do you know there are a number of 24 personal-injury cases out there regarding the DePuy</p> |
| <p style="text-align: right;">Page 246</p> <p>1 You can answer.</p> <p>2 THE WITNESS: Because it's a company 3 that I feel strongly about. I think what we do -- 4 with our credo for patients; for our employees in 5 the career opportunities; and the livelihood that 6 we provide the communities as well as our 7 shareholders -- does the right thing.</p> <p>8 MR. MURPHY: I thank you for your time 9 and I have no further questions.</p> <p>10 MR. McCORMICK: I just have three quick 11 questions, Mr. Gorsky.</p> <p>12 (EXAMINATION)</p> <p>13 BY MR. McCORMICK:</p> <p>14 Q. You're proud of Johnson & Johnson, correct?</p> <p>15 A. Yes, I am very proud of Johnson & Johnson.</p> <p>16 Q. Johnson & Johnson currently is the defendant 17 in several cases involving the marketing and promotion 18 of Risperdal across the country. Do you know that?</p> <p>19 A. Yes, I'm aware that we're in court in a number 20 of cases, as are, I believe, most of the companies that 21 were involved in one way or another in this particular 22 category.</p> <p>23 Q. And I think Johnson & Johnson is a defendant 24 in the Omnicare case that we looked at earlier in the</p> | <p style="text-align: right;">Page 248</p> <p>1 hip-replacement medical devices? Do you know that?</p> <p>2 MR. MURPHY: Same objection. You may 3 answer.</p> <p>4 THE WITNESS: Yes, I'm aware.</p> <p>5 BY MR. McCORMICK:</p> <p>6 Q. Johnson & Johnson appears to be a defendant in 7 any number of lawsuits right now. I'm sure that's just 8 a small number. Is the credo working, is my question.</p> <p>9 MR. MURPHY: Objection to the form, 10 argumentative. You may answer.</p> <p>11 THE WITNESS: In my opinion, yes, the 12 credo is working, and I think all of those cases 13 have their own unique circumstances.</p> <p>14 I really can't comment on the details 15 other than what I'm aware of is that we've tried 16 to do what's best for patients, for physicians, as 17 well as our other credo constituents. That's our 18 goal and that's our mission.</p> <p>19 BY MR. McCORMICK:</p> <p>20 Q. How about the problems with the plants in Fort 21 Washington, Pennsylvania?</p> <p>22 MR. MURPHY: Objection -- I'm sorry.</p> <p>23 Q. That another problem, right, for Johnson & 24 Johnson?</p> |

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| <p style="text-align: right;">Page 249</p> <p>1 MR. MURPHY: Objection to the form, 2 lack of relevance. You may answer.</p> <p>3 THE WITNESS: I don't know what 4 relevance that has to this.</p> <p>5 BY MR. McCORMICK: 6 Q. Well, it has relevance because Mr. Murphy 7 asked you what a great company Johnson & Johnson was, 8 and you got to give a little speech about how great it 9 is. And that's fine, that's your belief.</p> <p>10 MR. MURPHY: That's not what I asked. 11 him.</p> <p>12 BY MR. McCORMICK: 13 Q. I'm asking you if there are certain aspects of 14 Johnson & Johnson that the jury should also know that 15 are not that great and that may color their opinion in 16 response to your remarks about Johnson & Johnson.</p> <p>17 So, not that I have to explain the relevance, 18 but have there been problems with the -- I think 19 they're McNeil plants in Fort Washington, aren't they, 20 regarding the manufacture of baby Tylenol and baby 21 Motrin and things like that? Is that right?</p> <p>22 MR. MURPHY: Objection to the form the 23 question. You may answer if you can.</p> <p>24 THE WITNESS: Yes, there is a plant in</p> | <p style="text-align: right;">Page 251</p> <p>1 plant in Puerto Rico fairly recently, too, weren't 2 there? They were involved in another federal 3 whistleblower lawsuit? Is that correct?</p> <p>4 MR. MURPHY: Objection to the form of 5 the question. Which is your question, counsel?</p> <p>6 BY MR. McCORMICK: 7 Q. My question is, was there a problem with a 8 manufacturing plant in Puerto Rico recently?</p> <p>9 A. I'm not aware of the second part of your 10 question. One of the plants in Puerto Rico, in Las 11 Piedras, was cited in the consent decree, and we're 12 currently remediating that and working on it with the 13 FDA as we speak.</p> <p>14 Q. My last question is: If you know, and you may 15 not recall at this point, in the 2001 to 2000 -- well, 16 let's say 2000 to 2002 time frame, before you left 17 Janssen to go to Johnson & Johnson in Europe, do you 18 recall what percent of gross sales yearly Risperdal was 19 related to the other products at Janssen?</p> <p>20 A. No, I do not.</p> <p>21 BY MR. McCORMICK: Okay. Thank you, Mr. 22 Gorsky.</p> <p>23 THE WITNESS: Thank you.</p> <p>24 MR. MURPHY: I have no further</p> |
| <p style="text-align: right;">Page 250</p> <p>1 Fort Washington that had gone through issues 2 regarding the manufacturing processes, and we're 3 currently making significant investments, working 4 closely with the FDA to ensure that we get product 5 back out to our customers as soon as we can in a 6 very effective and safe manner.</p> <p>7 BY MR. McCORMICK: 8 Q. You had to recall a vast amount of baby 9 Tylenol and baby Motrin and whatever else, I think, 10 they were manufacturing at that plant. Is that 11 correct?</p> <p>12 A. We proactively took action in working with the 13 FDA to pull those back. And I think if you look at our 14 overall track record throughout our history, we've 15 always tried to act in a very responsible and 16 credo-consistent manner.</p> <p>17 Q. That plant remains closed, doesn't it, in Fort 18 Washington?</p> <p>19 A. The plant is currently being significantly 20 upgraded and redesigned, and according to public 21 record, we anticipate working with the FDA through the 22 latter part of 2013 and 2014 to bring it back online at 23 that time.</p> <p>24 Q. I think there were problems at a manufacturing</p> | <p style="text-align: right;">Page 252</p> <p>1 questions.</p> <p>2 MR. MERVIS: Nothing from me.</p> <p>3 THE VIDEOGRAPHER: Stand by, please.</p> <p>4 We're going off the record at 5:46 p.m. This is 5 the end of tape seven and concludes the deposition 6 of Alex Gorsky.</p> <p>7 (The deposition was concluded at 5:46 8 p.m.)</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> |

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4
5 I hereby certify that the testimony and
6 the proceedings in the foregoing matter are contained
7 fully and accurately in the stenographic notes taken by
8 me and that the copy is a true and correct transcript
9 of the same.
10
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